



FEDERAL REGISTER

Vol. 83

Thursday,

No. 134

July 12, 2018

Pages 32191–32562

OFFICE OF THE FEDERAL REGISTER



The **FEDERAL REGISTER** (ISSN 0097-6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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How To Cite This Publication: Use the volume number and the page number. Example: 83 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 890, 892, and 894

RIN 3206-AN34

Federal Employees Health Benefits Program and Federal Employees Dental and Vision Insurance Program: Expiration of Coverage of Children of Same-Sex Domestic Partners; Federal Flexible Benefits Plan: Pre-Tax Payment of Health Benefits Premiums: Conforming Amendments

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: On October 30, 2013, OPM published final regulations in the *Federal Register* to expand coverage for children of same-sex domestic partners under the Federal Employees Health Benefits (FEHB) Program and the Federal Employees Dental and Vision Insurance Program (FEDVIP). The regulation allowed children of same-sex domestic partners living in states that did not allow same-sex couples to marry to be covered family members under the FEHB and the FEDVIP. Due to a subsequent Supreme Court decision legalizing same-sex marriage in all states, OPM published an interim final regulation on December 2, 2016, that created a regulatory exception that only allowed children of same-sex domestic partners living overseas to maintain their FEHB and FEDVIP coverage until September 30, 2018. OPM recognized that there were additional requirements placed on overseas federal employees that did not apply to other civilian employees with duty stations in the United States making it difficult to travel to the United States to marry their same-sex partners. Understanding that we have provided agencies with additional time for compliance given that overseas federal employees may not have been able to marry immediately following the Supreme Court decision,

OPM is issuing a final rule removing references to domestic partners and domestic partnerships from the regulations. Based on the Supreme Court decision and the two additional year's lead time for domestic partners overseas to marry, the current language in the CFR is not needed and may be somewhat confusing. There is no change in coverage for children whose same-sex partners are married.

DATES: This rule is effective on September 30, 2018.

FOR FURTHER INFORMATION CONTACT: Michael W. Kaszynski, Senior Policy Analyst, at Michael.Kaszynski@opm.gov or (202) 606-0004.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The Federal Employees Health Benefits (FEHB) Program is administered by the Office of Personnel Management (OPM) in accordance with Title 5, Chapter 89 United States Code and our implementing regulations (title 5, parts 890, 892, 894 and title 48, chapter 16). The statute establishes the basic rules for benefits, enrollment, and participation in the Federal insurance programs.

Background

The Federal Employees Health Benefits (FEHB) Program provides health insurance to about 8.2 million Federal employees, retirees, and their dependents each year. It is the largest employer-sponsored health insurance program in the country providing more than \$53 billion in health care benefits annually. Coverage options available to eligible individuals include self only, self plus one or self and family coverage in an approved health benefits plan. Eligible family members include the spouse of an employee or annuitant and a child under 26 years of age, including adopted children, stepchildren or foster children or a child regardless of age who is incapable of self-support because of mental or physical disability which existed before age 26.

Effective January 1, 2014, the Office of Personnel Management (OPM) published the "Federal Employees Health Benefits Program and Federal Employees Dental and Vision Insurance Program: Expanding Coverage of Children; Federal Flexible Benefits Plan: Pre-Tax Payment of Health Benefits Premiums: Conforming Amendments"

final rule (78 FR 64873) to extend FEHB and FEDVIP coverage to children of same-sex domestic partners of Federal employees and annuitants who would marry their partners but live in states that did not allow same-sex couples to marry. As the result of the June 26, 2015, Supreme Court *Obergefell v. Hodges* decision, all U.S. states now allow same-sex couples to marry. Accordingly, as of January 2016, coverage of an enrollee's stepchild(ren) is only allowed if the couple is married. OPM also published an interim final regulation (81 FR 86905) on December 2, 2016. The rule amended §§ 890.302 and 894.101 of title 5, Code of Federal Regulations. The amendments allow an employing agency to request, and for OPM to grant, a continued coverage exception for children of an employee's same-sex domestic partner living outside the United States. Any coverage under such an exception will not extend beyond September 30, 2018. The OPM recognized there were additional requirements placed on overseas employees (as compared to civilian employees with duty stations in the United States) making it difficult to travel to the United States to marry same-sex partners. Therefore, OPM created the authority to allow an exception for children of Federal employees in a domestic partnership and living outside of the United States. If requested by an enrollee's agency, coverage of children of same-sex domestic partners can be continued under self and family or self plus one enrollment in the FEHB and FEDVIP Programs. This regulation removes this continued coverage exception which expires for overseas employees on September 30, 2018.

Comments Received on the Interim Rule

We received five comments on the Interim rule. All commenters were in support of the rule. No commenters recommended changes to the rule. Therefore, no changes have been made to this Final rule based on the comments received.

Expected Impact of Changes

This rule eliminates all regulatory language in FEHB, FEDVIP and FedFlex that authorizes coverage for children of same-sex domestic partners, effective September 30, 2018. This rule amends

the regulations to remove the language that authorizes coverage of children of same-sex domestic partners since all enrollees now have the right to marry in the United States. The regulatory language that authorized coverage for children of same-sex domestic partners overseas is also being removed from the regulation effective September 30, 2018. There is no change to the population of children who have access to coverage based on this rule.

Executive Order 13563 and 12866 Requirements

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a not significant regulatory action under Executive Order 12866.

Paperwork Reduction Act Requirements

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. With this rule there is no change to an existing OMB approved collection of information subject to the PRA—OMB No. 3206–0160, Health Benefits Election Form. The system of record notice for this collection is OPM/Central 1 Civil Service Retirement and Insurance Records, available at <https://www.opm.gov/information-management/privacy-policy/sorn/opm-sorn-central-1-civil-service-retirement-and-insurance-records.pdf>.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities.

Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

List of Subjects

5 CFR Part 890

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5 CFR Part 892

Administrative practice and procedure, Government employees' health insurance, Pre-tax payment of health benefits premiums, Taxes, Wages.

5 CFR Part 894

Administrative practice and procedure, Government employees, Health insurance, Taxes, Wages. U.S. Office of Personnel Management.

Jeff T.H. Pon,
Director.

Accordingly, OPM is amending title 5, Code of Federal Regulations as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.301 also issued under sec. 311 of Pub. L. 111–03, 123 Stat. 64; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104–106, 110 Stat. 521; Sec. 890.112 also issued under section 1 of Pub. L. 110–279, 122 Stat. 2604; 5 U.S.C. 8913; Sec. 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended; Sec. 890.102 also issued under sections 11202(f), 11232(e), 11246 (b) and (c) of Pub. L. 105–33, 111 Stat. 251; and section 721 of Pub. L. 105–261, 112 Stat. 2061; Pub. L. 111–148, as amended by Pub. L. 111–152.

■ 2. In § 890.302, revise paragraphs (a)(2)(iii) and (b)(2) and remove paragraphs (b)(3) through (7) to read as follows:

§ 890.302 Coverage of family members.

(a) * * *

(2) * * *

(iii) Children are entitled to receive benefits under only one enrollment regardless of whether the children qualify as family members under the enrollment of both parents or of a parent and a stepparent and regardless of whether the parents are married, unmarried, divorced, or legally separated. To ensure that no person receives benefits under more than one enrollment, each enrollee must promptly notify the insurance carrier as to which family members will be covered under his or her enrollment. These individuals are not covered under the other enrollment.

(b) * * *

(2) For purposes of this part, the term “stepchild” refers to the child of an enrollee’s spouse and shall continue to refer to such child after the enrollee’s divorce from the spouse or death of the spouse, so long as the child continues to live with the enrollee in a regular parent-child relationship.

* * * * *

PART 892—FEDERAL FLEXIBLE BENEFITS PLAN: PRE-TAX PAYMENT OF HEALTH BENEFITS PREMIUMS

■ 3. The authority citation for part 892 continues to read as follows:

Authority: 5 U.S.C. 8913; 5 U.S.C. 1103(a)(7); 26 U.S.C. 125.

■ 4. In § 892.101, the definition of a “Qualifying life event” is amended by revising the introductory text to read as follows:

§ 892.101 Definitions.

* * * * *

Qualifying life (QLE) event means an event that may permit changes to your FEHB enrollment as well as changes to your premium conversion election as described in Treasury regulations at 26 CFR 1.125–4. Such events include the following:

* * * * *

■ 5. Section 892.102 is revised to read as follows:

§ 892.102 What is premium conversion and how does it work?

Premium conversion is a method of reducing your taxable income by the amount of your contribution to your FEHB insurance premium. If you are a participant in the premium conversion plan, Section 125 of the Internal

Revenue Code allows you to reduce your salary (through an employer allotment) and provide that portion of your salary back to your employer. Instead of being paid to you as taxable income, this allotted amount is used to purchase your FEHB insurance for you. The effect is that your taxable income is reduced. Because taxable income is reduced, the amount of tax you pay is reduced. You save on Federal income tax, Social Security and Medicare tax and in most States and localities, State and local income taxes.

PART 894—FEDERAL EMPLOYEES DENTAL AND VISION INSURANCE PROGRAM

■ 6. The authority citation for part 894 continues to read as follows:

Authority: 5 U.S.C. 8962; 5 U.S.C. 8992; Subpart C also issued under section 1 of Pub. L. 110–279, 122 Stat. 2604.

■ 7. In § 894.101, the definitions for “Domestic partner” and “Domestic partnership” are removed and the definition for “Stepchild” is revised to read as follows:

§ 894.101 Definitions.

* * * * *

Stepchild means your spouse’s child born within or outside marriage or his or her adopted child. The child of your spouse shall continue to be considered your stepchild after your divorce from your spouse or the death of your spouse so long as the child continues to live with you in a regular parent-child relationship.

* * * * *

■ 8. In § 894.403, paragraph (a) is revised to read as follows:

§ 894.403 Are FEDVIP premiums paid on a pre-tax basis?

(a) Your FEDVIP premiums are paid on a pre-tax basis (called premium conversion) if you are an active employee, your salary is sufficient to make the premium allotments, and your agency will be able to make pre-tax allotments.

* * * * *

[FR Doc. 2018–14938 Filed 7–11–18; 8:45 am]

BILLING CODE 6325–63–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 929

[Doc. No. AMS–SC–17–0066; SC17–929–3 FR]

Cranberries Grown in States of Massachusetts, et al.; Establishment of Handler Diversion and Reporting Requirements and New Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation to establish handler diversion and reporting requirements under the marketing order for cranberries grown in the production area (Order). This action establishes the procedures handlers use to divert fruit through disposal or into noncompetitive outlets. The reporting requirements support the diversion procedures by providing the necessary documentation to help ensure compliance when a volume regulation is established.

DATES: Effective August 13, 2018.

FOR FURTHER INFORMATION CONTACT:

Doris Jamieson, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: Doris.Jamieson@ams.usda.gov or Christian.Nissen@ams.usda.gov.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Richard.Lower@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This final rule, pursuant to 5 U.S.C. 553, amends regulations used to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under Marketing Agreement and Order No. 929, as amended (7 CFR part 929), regulating the handling of cranberries grown in the states of Massachusetts, Rhode Island, Connecticut, New Jersey, Wisconsin, Michigan, Minnesota, Oregon, Washington, and Long Island in the State of New York. Part 929 (referred to as the “Order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674),

hereinafter referred to as the “Act.” The Committee locally administers the Order and is comprised of growers of cranberries operating within the production area, and a public member.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule establishes handler diversion and reporting requirements under the Order. This rule establishes procedures handlers use to divert fruit through disposal or into noncompetitive outlets. The reporting requirements support the diversion procedures by providing the necessary documentation to help ensure compliance when a volume regulation is established. This action was recommended by the Committee at its August 31, 2017, September 15, 2017, and October 13, 2017, meetings.

The Order provides for the use of volume regulation to stabilize prices and improve grower returns during periods of oversupply. Section 929.51(a)(2) specifies that a handler withholding program must be

recommended by the Committee no later than August 31 and that such recommendation shall include the free and restricted percentages for the crop year. On August 31, 2017, the Committee met and recommended free and restricted percentages of 85 percent free and 15 percent restricted. Handler diversion is one method that handlers can utilize to meet restricted percentage requirements.

Section 929.54 provides, in part, that whenever the Secretary of Agriculture (Secretary) has fixed the free and restricted percentages for any fiscal period, each handler shall withhold from handling a portion of the cranberries acquired during such period. This section also provides the authority for the Committee to establish, with the approval of the Secretary, rules and regulations necessary to administer this section. Section 929.56 provides special provisions relating to withheld (restricted) cranberries, and § 929.57 provides authority for the Committee to establish, with the approval of the Secretary, outlets for withheld cranberries which are noncompetitive with outlets for unrestricted (free percentage) cranberries.

Section 929.62 provides, in part, authority to require handlers to submit reports of cranberries acquired, held in inventory, quantity handled, total cranberries withheld from handling, the portion of such withheld cranberries on hand, and the quantity and manner of disposition of any such withheld cranberries diverted. Section 929.62(f) further provides authority for the Committee, with the approval of the Secretary, to collect other reports and information from handlers needed to perform its duties.

This final rule uses these authorities to establish new §§ 929.157 and 929.162. Section 929.157 establishes the procedures to be used for handler diversion when free and restricted percentages are instituted. Section 929.162 requires handlers of cranberries, during years when free and restricted percentages are applied, to report to the Committee diversion plans and year-end reports, information on cranberries diverted and cranberries shipped to noncompetitive outlets, and other information to verify compliance with the program, using six specific Committee forms.

The Committee recommended establishing free and restricted percentages under a handler withholding volume regulation for the 2017–18 season in response to historically high inventory levels for cranberries. As this is the first time the Committee has used this volume

regulation provision under the Order, it recognized the need to establish procedures outlining the diversion requirements for restricted fruit.

Free percentage cranberries can be used to supply any available market, including juice, sweetened dried cranberries, sauce, and frozen cranberries. Restricted percentage cranberries can be diverted through disposal or utilized in markets that are noncompetitive with free cranberries. Possible outlets for restricted cranberries include, in part, for fresh export, except to Canada; charity; research and development projects; and any nonhuman food use. Handlers also have the option to divert processed products in lieu of fresh fruit to meet up to 50 percent of their restricted obligation.

At the 2017 meetings in August, September, and October, the Committee discussed the handler diversion procedures and the associated reporting requirements necessary to help ensure compliance with a free and restricted percentage volume regulation. As a result, the Committee developed and approved six specific forms and related procedures to be used during seasons when free and restricted percentages are established for volume regulation.

Committee members discussed the need for Committee staff to know how handlers plan to meet their restricted percentage obligation and if, at the end of the season, they met their diversion requirement. As a result, the Committee developed two specific forms to be added to the reporting requirements under the Order.

With the first form, the Handler Withholding Report (CMC–JUN), handlers provide information on how they plan to meet their restricted percentage obligation. The form will be submitted to the Committee by June 1 during years with established free and restricted percentages and requires the following information: The name and address of the handler, the amount of cranberries to be acquired, the amount of cranberries to be diverted by disposal, the amount of cranberries to be diverted to noncompetitive outlets, and the types of cranberry products to be withheld. The Committee will use this information to estimate the amount of fruit that will be taken off the market, the proposed disposition of the fruit, and as a starting point for tracking handler compliance.

The second form, the Final Handler Withholding Report (CMC–AUG), will be submitted by the end of the crop year. The report requires the same information as the Handler Withholding Report but provides the Committee with

the actual year-end seasonal totals. This form is due by August 31. The final report will be used to verify that handlers met their restricted percentage obligation.

Handlers have several diversion options available to meet their restricted percentage obligation. One method of diversion available to handlers is the disposal of fresh cranberries or cranberry products. In its discussions, Committee members expressed concern regarding verifying the accuracy of the amount of fruit or processed product diverted using this method. The Committee recommended that all disposals take place under the supervision of a non-industry-related third party who will review the handler's disposal documentation, witness the disposal whenever possible, and certify as to the completion of the disposal process. The Committee initially agreed to hire two inspectors to supervise and verify handler compliance. However, due to the size of the production area, the Committee hired four inspectors, one from each of the primary growing regions, who will perform these tasks. The inspection and verification costs will be paid by the handler.

To facilitate this process, the Committee recommended establishing another form. This form, the Handler Disposal Certification (CMC–DISP), will be the primary form used to initiate, track, and certify this method of diversion during years in which a free and restricted percentage volume regulation has been established. The form will be used to notify the Committee of the handler's intent to dispose of cranberries or cranberry products. Information required on the form include the handler's name and address; the amount of fruit to be diverted; the type of cranberry product to be diverted; the amount of processed fruit diverted, if any; and the lot identification information.

Upon receipt of the form, the Committee office will notify the inspector in the handler's growing region. The inspector will contact the handler to schedule a date for the disposal to take place, usually within a week of receipt of the notification. The inspector will meet with the handler on that date to verify the documentation provided and, when possible, witness the disposal.

The Committee recognized that, due to scheduling conflicts, the inspector may not be available to visually witness each disposal of restricted cranberries. Therefore, the Committee agreed that, should the inspector not be available to witness the diversion within seven

days, the handler may proceed with the disposal. The inspector will then verify and complete the certification upon the inspector's next visit to the handler's facility. If the cranberries or cranberry product were disposed of at a landfill, through composting, incineration, at a wastewater treatment facility, or any other site, the inspector may request receipts, visual proof, or any other additional information needed to support the disposal as reported on the form. Once the verification process is completed, the inspector will sign the certification section of the form, and return it to the Committee.

Another method of diversion available is to divert cranberries or cranberry products to noncompetitive outlets. Section 929.57 specifies that cranberries withheld from handling may be disposed of only through diversion to such outlets as the Committee, with the approval of the Secretary, finds are noncompetitive to outlets for unrestricted (free percentage) cranberries. The Committee discussed various outlets and recommended the following: Foreign countries, except Canada; charitable institutions; any nonhuman food use; and research and development projects approved by the Committee dealing with the development of foreign and domestic markets, including but not limited to dehydration, radiation, freeze drying, or freezing of cranberries. The Committee further recommended that cranberries may not be converted into canned, frozen, or dehydrated cranberries or other cranberry products by any commercial process when being diverted to foreign countries. The specific outlets are being considered under a separate rulemaking action.

The Agricultural Marketing Service (AMS) submitted and received OMB's approval on the five initial forms. Handlers complete the forms and submit them to the Committee for purposes of tracking compliance with the handler withholding requirement. OMB approved the forms on October 16, 2017, and assigned them OMB No. 0581-0304. Upon full completion of the forms-approval process, AMS will seek to merge the five forms into the OMB-approved 0581-0189 Fruit Crops containing other forms related to the Federal marketing order for cranberries.

Two specific reporting requirements relating to the diversion of fruit to noncompetitive outlets are added to part 929: A Handler Application for Outlets for Withheld Fruit (CMC-OUT) and a Third-Party Confirmation of Receipt of Withheld Fruit (CMC-CONF). Should a handler elect to divert cranberries or cranberry products to noncompetitive

outlets, the handler must first request Committee approval of the outlet or research project using the Handler Application for Outlets for Withheld Fruit prior to each disposal activity of this type. Information requested on the form includes, among other things, the handler's name and address, information identifying the noncompetitive outlet, the amount and type of cranberry products to be diverted, and how the cranberries will be utilized. The Committee will review the information and approve or disapprove the diversion request.

If the request is approved and the product is delivered, the receiving outlet needs to acknowledge receipt of the product by completing the Third-Party Confirmation of Receipt of Withheld Fruit form, and the handler then returns the completed form to the Committee.

The two above-described reporting requirements help track the disposition of withheld cranberries in noncompetitive outlets and facilitates the compliance process under the recommended handler withholding.

The last form approved by the Committee provides handlers a method for appealing any decision made by the Committee relating to the diversion process. Should a handler disagree with a Committee decision, such as denying the request for approval of a noncompetitive outlet, or a determination that diversion could not be verified, the handler can appeal the decision by submitting a Handler Withholding Appeal form (CMC-APPL). The handler making the appeal is required to submit the form within 30 days of receiving the determination from the Committee. This form includes information about why the handler is making the appeal and provides additional information to support the appeal. The appeal request is reviewed by an Appeals Subcommittee (Subcommittee) for re-consideration. The Subcommittee consists of two independent growers, two members from the major cooperative, and one public member. The handler will be notified of the Subcommittee's determination within 30 days. If the appeal is denied by the Subcommittee, the handler has the option of appealing the decision to the Secretary within 15 days after the notification of the Subcommittee's findings.

In order to enable the Committee to inform the industry of the information needed for handlers to manage their inventories in a way that complies with the industry-supported handler withholding program, the five initial forms were previously submitted to

OMB for approval. These five forms (CMC-JUN, CMC-DISP, CMC-OUT, CMC-CONF and CMC-APPL) were approved by OMB on October 16, 2017, for use for a six-month period, beginning the date of approval. This final rule is necessary for the industry to use the forms beyond the six-month period.

Establishing these handler diversion and reporting requirements facilitates the implementation of, and ensures compliance with, free and restricted percentages when recommended by the Committee.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 1,100 cranberry growers in the regulated area and approximately 65 cranberry handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$7,500,000 (13 CFR 121.201).

According to industry and Committee data, the average grower price for cranberries during the 2016-17 crop year was \$23.50 per barrel, and total sales were around 9.5 million barrels. The value for cranberries that crop year totaled \$223,250,000 (\$23.50 per barrel multiplied by 9.5 million barrels). Taking the total value of production for cranberries and dividing it by the total number of cranberry growers (1,100) provides an average return per grower of \$202,955. Based on USDA's Market News reports, the average free on board (f.o.b.) price for cranberries was around \$30.00 per barrel. Multiplying the f.o.b. price by total utilization of 9.5 million barrels results in an estimated handler-level cranberry value of \$285 million. Dividing this figure by the number of handlers (65) yields an estimated average annual handler receipt of \$4.3

million, which is below the SBA threshold for small agricultural service firms. Therefore, the majority of growers and handlers of cranberries may be classified as small entities.

This final rule establishes handler diversion and reporting requirements under the Order. This final rule establishes procedures handlers will use to divert fruit through disposal or into noncompetitive outlets. The reporting requirements support the diversion procedures by providing the necessary documentation to help ensure compliance when a volume regulation is established. This rule establishes new §§ 929.157 and 929.162. The authority for this action is provided in §§ 929.54, 929.56, 929.57, and 929.62.

These actions could result in some additional costs to the industry. Specifically, handlers could incur some additional costs as a result of inspector verification and certification of the diversion process. In addition, requiring reports of cranberries acquired, handled, and withheld imposes an increase in the reporting burden on all cranberry handlers. However, the benefits are expected to outweigh the costs and increase in reporting burden. The provisions considered in this action will help facilitate the implementation of any recommended handler withholding volume regulation and help ensure compliance with the recommended regulation. Consequently, these changes will help provide important guidance during times when market conditions support the need for establishing volume regulation.

The impact of this rule will be beneficial to growers and handlers. Establishing diversion procedures benefits the entire industry by ensuring handler diversion is conducted consistently and accurately by all handlers, which also helps ensure compliance with the handler withholding program. Authorizing various diversion outlets means handlers are not required to divert cranberries only through destruction. Instead, fruit can be utilized in noncompetitive outlets, such as for charitable purposes. The benefits of this rule are expected to be equally available to all cranberry growers and handlers, regardless of their size, and are greater than any associated costs.

The Committee discussed other alternatives to this action, including using different methods of ensuring accurate diversion of restricted fruit. One method considered was allowing handlers to self-report their diversion of restricted fruit without a formal verification process. However, the Committee deemed this insufficient

verification to ensure compliance with the program. Members were concerned that fruit could be re-routed to a different handling facility for processing, and without established verification procedures, the industry would not have confidence that restricted fruit was being properly diverted. The Committee also considered the value and importance of each of the forms and whether all were required. However, the Committee agreed each of the recommended forms provide important information for the industry and for administering the Order. Therefore, these alternatives were rejected.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this collection has been submitted to OMB for approval. The five currently approved forms in 0581-0304 and one additional form will be merged with forms currently approved under OMB No. 0581-0189, Fruit Crops. This final rule establishes the use of six new reporting requirements and six new Committee forms, which impose a total annual burden increase of 38.4 hours. The forms, "Handler Withholding Report," "Handler Disposal Certification," "Handler Application for Outlets for Withheld Fruit," "Third-Party Confirmation of Receipt of Withheld Fruit," "Handler Withholding Appeal," and "Final Handler Withholding Report," require the minimum information necessary to effectively carry out the requirements of the Order. The information will enable the Committee to ensure compliance when a volume regulation is established.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule. Further, the public comment received concerning the proposal did not address the initial regulatory flexibility analysis.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Further, the Committee's meetings were widely publicized throughout the cranberry industry, and all interested persons were invited to attend the meetings and participate in Committee

deliberations on all issues. Additionally, the Committee's meetings held August 31, September 15, and October 13, 2017, were public meetings, and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on February 15, 2018 (83 FR 6800). Copies of the proposed rule were sent via email to Committee members and cranberry handlers. Finally, the proposed rule was made available through the internet by USDA and the Office of the Federal Register. A 60-day comment period ending April 16, 2018, was provided to allow interested persons to respond to the proposal.

Two comments were received which did not address the merits of the proposed rule. Accordingly, no changes will be made to the rule as proposed based on the comments received.

The proposed rule contained administrative revisions to the Order's subpart headings to bring the language into conformance with the Office of Federal Register requirements. These revisions are not included in this rule as they were included in a final rule published in the **Federal Register** on April 4, 2018 (83 FR 14350).

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/rules-regulations/moa/small-businesses>. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant matter presented, including the information and recommendation of the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 929

Cranberries, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 929 is amended as follows:

PART 929—CRANBERRIES GROWN IN STATES OF MASSACHUSETTS, RHODE ISLAND, CONNECTICUT, NEW JERSEY, WISCONSIN, MICHIGAN, MINNESOTA, OREGON, WASHINGTON, AND LONG ISLAND IN THE STATE OF NEW YORK

■ 1. The authority citation for part 929 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Add § 929.157 to read as follows:

§ 929.157 Handler diversion.

(a) *Methods of diversion.* Handlers may divert cranberries by disposing of cranberries or cranberry products. Diversion by disposal may take place prior to placing the cranberries into the processing line or after processing. Handlers may also divert cranberries or cranberry products to approved, noncompetitive outlets for withheld fruit. Whole berries or processed products diverted must come from the current crop year. Any information collected of a confidential and/or proprietary nature would be held in confidence pursuant to § 929.65.

(1) *Diversion through disposal.* This type of diversion is to be carried out under the supervision of the Committee, and the cost of such supervision is to be paid by the handler. Handlers shall notify the Committee of their intent to dispose of cranberries or cranberry products using Form CMC–DISP as specified in § 929.162(c). Following notification, a Committee inspector will meet with the handler to verify the documentation provided and, when possible, witness the destruction. The Committee inspector may request receipts, visual proof, or any other information needed to support the disposal as reported. Once the verification process has been completed, the Committee inspector will sign the certification section of Form CMC–DISP and return it to the Committee.

(2) *Diversion through noncompetitive outlets.* To divert cranberries or cranberry products to a noncompetitive outlet, handlers must apply to the Committee using Form CMC–OUT as specified in § 929.162(d) prior to each disposal activity of this type. The Committee will review the information and approve or disapprove the diversion request. Once the cranberries or cranberry products are delivered to the approved noncompetitive outlets, the Committee must receive satisfactory documentation of the transaction using Form CMC–CONF as specified in § 929.162(e).

(b) *Committee notification and handler plan.* Any handler intending to divert cranberries or cranberry products pursuant to § 929.54 must notify the Committee of such intent and provide a plan by June 1 that shows how the handler intends to meet the restricted percentage obligation. The handler shall submit this plan using Form CMC–JUNE as specified in the reporting requirements under § 929.162(a). The handler will have until August 31 to fulfill the plan, by which time the

handler shall submit a final report detailing how the restricted percentage obligation was met using Form CMC–AUG as specified in § 929.162(b).

(c) *Request for review.* (1) If a handler is dissatisfied with a determination made by the Committee which affects such handler, the handler may submit to the Committee within 30 days after receipt of the Committee's determination, a request for a review by an appeals subcommittee composed of two independent growers and two cooperative representatives, as well as a public member. The appeals subcommittee shall be appointed by the Committee chairperson. The handler may forward with the request any pertinent materials for consideration of the appeal.

(2) The subcommittee shall review the information submitted by the handler and render a decision within 30 days of receipt of such appeal. The subcommittee shall notify the handler of its decision, accompanied by the reasons for its conclusions and findings.

(3) The handler may further appeal to the Secretary, within 15 days after notification of the subcommittee's findings, if such handler is not satisfied with the appeals subcommittee's decision. The Committee shall forward a file to the Secretary with all pertinent information related to the handler's appeal. The Secretary shall inform the handler and all interested parties of the Secretary's decision. All decisions by the Secretary are final.

■ 3. Add § 929.162 to read as follows:

§ 929.162 Handler diversion reports.

(a) *Handler withholding report.* Handlers shall submit to the Committee, by June 1, a handler withholding report. The report shall be submitted using Form CMC–JUN and contain the following information:

- (1) The name and address of the handler;
- (2) The amount of cranberries acquired;
- (3) The amount of cranberries withheld by disposal;
- (4) The amount of cranberries diverted to noncompetitive outlets;
- (5) The form of cranberry products withheld; and
- (6) The total withholding obligation.

(b) *Handler Withholding Final Report.* Handlers shall submit to the Committee, by August 31, a final handler withholding report. The final report shall be submitted using Form CMC–AUG and contain the following information:

- (1) The name and address of the handler;

(2) The seasonal total of cranberries acquired;

(3) The seasonal total of cranberries withheld by disposal;

(4) The seasonal total of cranberries diverted to noncompetitive outlets;

(5) The form of cranberry products withheld during the season; and

(6) The total withholding obligation.

(c) *Handler disposal certification.* Handlers shall submit to the Committee Form CMC–DISP for each lot of cranberries or cranberry products to be diverted through disposal. The form shall contain the following information:

- (1) Name and address of the handler;
- (2) Marketable cranberries in whole fruit or processed cranberries converted to whole fruit equivalent disposed of in this lot;
- (3) Form of cranberries;
- (4) Volume if in processed form;
- (5) Lot details;
- (6) Disposal site and method; and
- (7) Inspector certification of the completion of the disposal.

(d) *Handler application for outlets for withheld fruit.* Handlers shall submit to the Committee Form CMC–OUT for approval for each lot of cranberries or cranberry products to be diverted to noncompetitive outlets in accordance with § 929.57. The form shall contain the following information:

- (1) Name and address of the handler;
- (2) Project type;
- (3) Product form;
- (4) Quantity of cranberries in whole fruit or processed cranberries converted to whole fruit equivalent diverted;
- (5) A description of the project and how the cranberries will be used.

(e) *Third-party confirmation of receipt of withheld fruit.* Handlers shall submit to the Committee Form CMC–CONF for each diversion to a noncompetitive outlet to verify the receipt of the cranberries or cranberry product by the approved outlet. The form shall contain the following information:

- (1) Name and address of the handler;
- (2) Project type;
- (3) Product form;
- (4) Quantity of cranberries in whole fruit or processed cranberries converted to whole fruit equivalent utilized; and
- (5) Confirmation or documentation of receipt from the receiving outlet.

(f) *Handler withholding appeal.* Handlers may appeal a determination made by the Committee relating to a handler withholding regulation using the appeals process outlined in § 929.157(c) and Form CMC–APPL, which shall contain the following information:

- (1) Name and address of the handler;
- (2) Reason for appeal; and
- (3) Information in support of appeal.

Dated: July 9, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2018-14939 Filed 7-11-18; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0588; Product Identifier 2017-NM-105-AD; Amendment 39-19328; AD 2018-14-08]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 777-200LR series airplanes. This AD requires revising certain documents to provide revised operating limitations. For certain airplanes, modification of the water and fuel scavenge systems in the fuel tanks, electrical changes in the main equipment center, and installation of new electrical load management system (ELMS2) software is an acceptable alternative to the documents revision. This AD was prompted by reports of unreliable performance of the water and fuel scavenge systems. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 27, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 27, 2018.

We must receive comments on this AD by August 27, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; internet <https://www.myboeingfleet.com>. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0588.

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0588; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Kevin Nguyen, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3555; email: Kevin.Nguyen@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

Operators have reported unreliable performance of the water and fuel scavenge systems. During flight, any water in the fuel can sink to the bottom of the fuel tank. This water can enter the fuel scavenge inlets and can then freeze as it travels from the body center fuel tank into the colder fuel scavenge tubes in the left and right cheek center fuel tanks (outboard of the side of body ribs). The frozen water can restrict the flow of scavenge fuel from the center fuel tank to the main fuel tanks, causing the fuel flow to decrease or stop. When this occurs, as much as 700 pounds of fuel can remain unavailable during flight. If the flightcrew is not aware that this fuel is unavailable and the fuel quantity decreases to the quantity of the unavailable fuel, then fuel exhaustion will occur, which could lead to subsequent power loss of all engines due to loss of capability to scavenge fuel in the center fuel tank.

Related Rulemaking

We issued AD 2016-11-03, Amendment 39-18530 (81 FR 34867, June 1, 2016) (“AD 2016-11-03”), that applied to certain Boeing Model 777-200LR series airplanes equipped with or without auxiliary fuel tanks. For airplanes with auxiliary fuel tanks, variable numbers WD049-WD053 inclusive only, AD 2016-11-03 requires modification of the water and fuel scavenge systems after removal of the auxiliary fuel tanks. This AD requires incorporation of revised operating limitations for those airplanes, which terminates the associated requirements of AD 2016-11-03. This AD also provides the option of modifying the water and fuel scavenge systems in the fuel tanks, making electrical changes in the main equipment center, and installing new ELMS2 software after removal of the auxiliary fuel tanks. Either compliance method terminates the requirements of paragraphs (g), (h), and (i) of AD 2016-11-03 for those airplanes.

Additionally, paragraph (g) of this AD requires a revision to certain documents to provide revised operating limitations for airplane variable numbers WD011 through WD015 inclusive and WD016 through WD018 inclusive. These airplanes are not affected by AD 2016-11-03, which refers to Boeing Special Attention Service Bulletin 777-28-0078, Revision 1, dated April 27, 2015, for the applicability.

Airplane variable numbers WD011 through WD015 inclusive are included in the effectivity of Boeing Special Attention Service Bulletin 777-28-0078, Revision 3, dated December 19, 2017; therefore, this AD provides a modification of the water and fuel scavenge systems in the fuel tanks, electrical changes in the main equipment center, and installation of new ELMS2 software as an acceptable alternative to the documents revision. However, there is no approved service information for airplane variable numbers WD016 through WD018 inclusive for the modification of the water and fuel scavenge systems in the fuel tanks, electrical changes in the main equipment center, and installation of new ELMS2 software; therefore, there is no alternative to the documents revision specified in this AD for these airplanes.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Special Attention Service Bulletin 777-28-0078, Revision 3, dated December 19, 2017. The service information describes

procedures for the removal of the auxiliary fuel tanks and modification of the water and fuel scavenge systems in the fuel tanks, electrical changes in the main equipment center, and installation of new ELMS2 software. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA’s Determination

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires revising certain documents to provide revised operating limitations. For certain airplanes, this AD provides for the optional

accomplishment of the actions specified in the service information described previously, as an acceptable alternative to the documents revision.

FAA’s Justification and Determination of the Effective Date

There are currently no domestic operators of this product. Therefore, we find that notice and opportunity for prior public comment are unnecessary and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number

FAA–2018–0588 and Product Identifier 2017–NM–105–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. We will consider all comments received by the closing date and may amend this final rule because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this final rule.

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, we provide the following cost estimates to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product
Revise operating limitations	1 work-hour × \$85 per hour = \$85	\$0	\$85

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Action	Labor cost	Parts cost	Cost per product
Modification	Up to 253 work-hours × \$85 per hour = up to \$21,505.	\$66,960	Up to \$88,465.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service,

as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,

- (2) Is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

- (3) Will not affect intrastate aviation in Alaska, and

- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2018–14–08 The Boeing Company:

Amendment 39–19328; Docket No. FAA–2018–0588; Product Identifier 2017–NM–105–AD.

(a) Effective Date

This AD is effective July 27, 2018.

(b) Affected ADs

This new AD affects AD 2016–11–03, Amendment 39–18530 (81 FR 34867, June 1, 2016) (“AD 2016–11–03”).

(c) Applicability

This AD applies to The Boeing Company Model 777–200LR series airplanes, certificated in any category, variable numbers (V/Ns) WD011 through WD015 inclusive, WD016 through WD018 inclusive, and WD049 through WD053 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by reports of unreliable performance of the water and fuel scavenge systems. We are issuing this AD to prevent fuel exhaustion and subsequent

power loss of all engines due to loss of access to fuel in the center fuel tank.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Revision to Operating Limitations

Except as provided by paragraph (h) of this AD: Within 36 months after the effective date of this AD, revise the applicable section of the documents specified in paragraphs (g)(1) and (g)(2) of this AD to include the information specified in figure 1 to the introductory text of paragraph (g) of this AD.

Figure 1 to the introductory text of paragraph (g) of this AD:
Operating limitation for carrying additional reserve fuel

(Required by AD 2018-14-08)

When center tank fuel is required for the mission, an additional 700 lbs. (320 kg) of reserve fuel must be added to the center tank fuel load.

(1) Insert the information specified in figure 1 to the introductory text of paragraph (g) of this AD into the “Fuel-System—Loading” section of the “Certificate Limitations” section of the FAA-approved Boeing Model 777 Airplane Flight Manual.

(2) Insert the information specified in figure 1 to the introductory text of paragraph (g) of this AD into the “Loading Limitations” section of the “Fuel Loading Procedures” section of the FAA-approved Boeing Model 777 Weight and Balance Control and Loading Manual.

(h) Optional Terminating Action for V/Ns WD049–WD053 Inclusive and WD011–WD015 Inclusive

For airplane V/Ns WD049 through WD053 inclusive, and WD011 through WD015 inclusive: Accomplishment of the actions specified in paragraphs (h)(1) and (h)(2) of this AD terminates the requirements of paragraph (g) of this AD.

(1) Remove the auxiliary fuel tanks in accordance with step 1. of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–28–0078, Revision 3, dated December 19, 2017.

(2) Modify the water and fuel scavenge systems in the fuel tanks, make electrical changes in the main equipment center, and install new electrical load management system (ELMS2) software, by doing all applicable actions identified as “RC” (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–28–0078, Revision 3, dated December 19, 2017.

(i) Credit for Previous Actions

(1) This paragraph provides credit for the actions specified in paragraphs (h)(1) and (h)(2) of this AD, if those actions were performed before the effective date of this AD

using Boeing Special Attention Service Bulletin 777–28–0078, Revision 2, dated October 5, 2016.

(2) This paragraph provides credit for airplane V/Ns WD049 through WD053 inclusive for the actions specified in paragraphs (h)(1) and (h)(2) of this AD, if those actions were performed before the effective date of this AD using April 27, 2015; or Boeing Special Attention Service Bulletin 777–28–0078, Revision 1, dated April 27, 2015.

(j) Parts Installation Prohibition

After completion of the actions specified in paragraph (h) of this AD, no person may install an auxiliary fuel tank on that airplane.

(k) Terminating Action for AD 2016–11–03 for V/Ns WD049–WD053 Inclusive

Accomplishment of the actions required by paragraph (g) or (h) of this AD terminates the requirements of paragraphs (g), (h), and (i) of AD 2016–11–03 for that airplane, V/Ns WD049 through WD053 inclusive only.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (l)(4)(i) and (l)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled “RC Exempt,” then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(m) Related Information

For more information about this AD, contact Kevin Nguyen, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3555; email: Kevin.Nguyen@faa.gov.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Service Bulletin 777-28-0078, Revision 3, dated December 19, 2017.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; internet <https://www.myboeingfleet.com>.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on June 29, 2018.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018-14702 Filed 7-11-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2017-0757; Product Identifier 2017-SW-022-AD; Amendment 39-19327; AD 2018-14-07]

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain serial numbered Bell Helicopter Textron Canada Limited (BHTC) Model 429 helicopters. This AD requires marking a serial number on life-limited forward spars and actuator fitting assemblies. The actions of this AD are intended to prevent an unsafe condition on these products.

DATES: This AD is effective August 16, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of August 16, 2018.

ADDRESSES: For service information identified in this final rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437-2862 or (800) 363-8023; fax (450) 433-0272; or at <http://www.bellcustomer.com/files/>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0757.

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0757; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the Transport Canada Civil Aviation (Transport Canada) AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Helene Gandy, Aviation Safety Engineer, Regulations & Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5413; email helene.gandy@faa.gov.

SUPPLEMENTARY INFORMATION:**Discussion**

On January 26, 2018, at 83 FR 3628, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Bell Model 429 helicopters, serial number (S/N) 57150, 57168, 57176, 57210 through 57216, 57265, 57266, 57267, and 57287, with a forward spar part number (P/N) 429-031-213-103 or 429-031-213-104 or actuator fitting assembly P/N 429-031-222-101 or 429-031-222-102 installed.

The NPRM proposed to require marking a serial number on life-limited forward spars and actuator fitting

assemblies. The proposed requirements were intended to prevent the forward spar or actuator fitting assembly from remaining in service after reaching its life limit. This condition could result in failure of a forward spar or actuator fitting assembly and subsequent collapse of the landing gear.

The NPRM was prompted by AD No. CF-2017-02, dated January 16, 2017, issued by Transport Canada, which is the aviation authority for Canada, to correct an unsafe condition for Bell Model 429 helicopters, S/N 57150, 57168, 57176, 57210, 57211 through 57216, 57265, 57266, 57267, and 57287. Transport Canada advises that forward spars P/N 429-031-213-103 and 429-031-213-104 and actuator fitting assembly P/N 429-031-222-101 and 429-031-222-102 have life limits of 30,000 and 19,000 Retirement Index Numbers, respectively. However, Transport Canada states these parts are not serialized, and therefore their accumulated usage is difficult to track, which creates a risk that these parts could remain in service beyond their life limits. This condition could result in failure of the part.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the NPRM.

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to our bilateral agreement with Canada, Transport Canada, its technical representative, has notified us of the unsafe condition described in the Transport Canada AD. We are issuing this AD because we evaluated all information provided by Transport Canada and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the Transport Canada AD

The Transport Canada AD requires compliance within 12 months from its effective date, unless already accomplished. This AD requires compliance within 800 hours time-in-service.

Related Service Information Under 1 CFR Part 51

We reviewed Bell Helicopter Alert Service Bulletin 429-16-34, dated November 10, 2016, which specifies

procedures for permanently marking each forward spar and actuator fitting assembly with the serial number of the helicopter.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

We also reviewed Bell Helicopter Model 429 Maintenance Manual BHT-429-MM-1, Chapter 4, Airworthiness Limitations Schedule, Revision 26, dated September 9, 2016, which specifies airworthiness life limits and inspection intervals for parts installed on Model 429 helicopters.

Costs of Compliance

We estimate that this AD affects 6 helicopters of U.S. Registry and that labor costs average \$85 per work-hour. We estimate that marking the forward spars and actuator fitting assemblies requires 1 work-hour, and no parts are needed. Based on these estimates, we expect a total cost of \$85 per helicopter and \$510 for the U.S. fleet.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that

section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on helicopters identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2018-14-07 Bell Helicopter Textron

Canada Limited: Amendment 39-19327; Docket No. FAA-2017-0757; Product Identifier 2017-SW-022-AD.

(a) Applicability

This AD applies to Bell Helicopter Textron Canada Limited Model 429 helicopters, serial number (S/N) 57150, 57168, 57176, 57210 through 57216, 57265, 57266, 57267, and 57287, with a forward spar part number (P/N) 429-031-213-103 or 429-031-213-104 or actuator fitting assembly P/N 429-031-222-101 or 429-031-222-102 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a forward spar or actuator fitting assembly remaining in service after reaching its life limit. This condition could result in failure of a forward spar or actuator fitting assembly and subsequent collapse of the landing gear.

(c) Effective Date

This AD becomes effective August 16, 2018.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 800 hours time-in-service, clean and identify each forward spar and actuator fitting assembly with the helicopter serial number in accordance with the Accomplishment Instructions, paragraphs 3 through 5 and with reference to Figure 1 of Bell Helicopter Alert Service Bulletin 429-16-34, dated November 10, 2016.

(2) After the effective date of this AD, do not install a forward spar P/N 429-031-213-103 or 429-031-213-104 or actuator fitting assembly P/N 429-031-222-101 or 429-031-222-102 on any helicopter unless it has been marked with a serial number in accordance with paragraph (e)(1) of this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, FAA, may approve AMOCs for this AD. Send your proposal to: Helene Gandy, Aviation Safety Engineer, Regulations & Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5413; email 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) Bell Helicopter Model 429 Maintenance Manual BHT-429-MM-1, Chapter 4, Airworthiness Limitations Schedule, Revision 26, dated September 9, 2016, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437-2862 or (800) 363-8023; fax (450) 433-0272; or at <http://www.bellcustomer.com/files/>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in Transport Canada AD No. CF-2017-02, dated January 16, 2017. You may view the Transport Canada AD on the internet at <http://www.regulations.gov> in Docket No. FAA-2017-0757.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 1100, Placards and Markings.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Bell Helicopter Alert Service Bulletin 429-16-34, dated November 10, 2016.

(ii) Reserved.

(3) For Bell Helicopter Textron Canada Limited service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437-2862 or (800) 363-8023; fax (450) 433-0272; or at <http://www.bellcustomer.com/files/>.

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Fort Worth, Texas, on June 1, 2018.

James A. Grigg,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018-14701 Filed 7-11-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-1118; Product Identifier 2017-NE-40-AD; Amendment 39-19313; AD 2018-13-01]

RIN 2120-AA64

Airworthiness Directives; Rolls-Royce Corporation Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Rolls-Royce Corporation (RRC) model 250-C turboshaft engines. This AD was prompted by several reports of engine power loss, one of which resulted in a fatal helicopter accident. This AD requires removal of the power turbine governor (PTG) bearing assembly, part number (P/N) 2544198, and its replacement with a bearing assembly eligible for installation. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 16, 2018.

ADDRESSES: For service information identified in this final rule, contact Rolls-Royce Corporation, 450 South Meridian Street, Mail Code NB-02-05, Indianapolis, IN 46225; phone: 317-230-3774; email: indy.pubs.services@

rolls-royce.com; internet: www.rolls-royce.com. You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7759. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-1118.

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-1118; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800-647-5527) is Docket Operations, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: John Tallarovic, Aerospace Engineer, Chicago ACO Branch, FAA, 2300 E. Devon Ave., Des Plaines, IL 60018; phone: 847-294-8180; fax: 847-294-7834; email: john.m.tallarovic@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Rolls-Royce Corporation (RRC) model 250-C turboshaft engines. The NPRM published in the **Federal Register** on February 1, 2018 (83 FR 4609). The NPRM was prompted by several reports of loss of engine power on certain RRC model 250-C turboshaft engines installed on single-engine helicopters. One of these instances of power loss resulted in a fatal helicopter accident on May 4, 2016. The NPRM proposed to require removal of the affected PTG bearing assembly and replace it with a bearing assembly with a new design. We are issuing this AD to address the unsafe condition on these products.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Specify the New Bearing Assembly

The NTSB and Honeywell Aerospace requested that the AD prohibit the installation of bearing assembly, P/N 2544198, and specify the installation of the new bearing assembly, P/N 2526146. The NTSB expressed concern that differences between the proposed AD and the actions described in the Honeywell SB and Rolls-Royce CEBs could lead to the reinstallation of a dual-spool bearing into an affected PTG.

We partially agree. We agree with the request to prohibit the installation of another bearing assembly, P/N 2544198, because our intent is to remove them from service. We disagree with the request to specify the installation of the new bearing assembly, P/N 2526146, because of the possibility of a new bearing P/N being introduced or the specified P/N being discontinued in the future. We added an installation prohibition paragraph to this AD to prohibit the installation of bearing assembly, P/N 2544198.

Request To Re-Identify the PTG After Changing the Bearing Assembly

The NTSB and Honeywell Aerospace requested that the AD require re-identifying the PTG P/N after changing the bearing assembly in accordance with the related service information. Honeywell Aerospace reasoned that maintenance personnel and operators could easily determine if the service bulletin has been accomplished. This increases the efficiency of operations and reduces the potential for misunderstandings about whether the bearing assembly has been replaced.

We disagree. While re-identifying the PTG after changing the bearing assembly is helpful for maintenance personnel, we are not requiring this action within this AD. During the replacement of the bearing assembly, P/N 2544198, the related service information instructs personnel to re-identify the PTG. We did not change this AD.

Request To Reduce the Compliance Time

Honeywell Aerospace requested that we reduce the compliance time to 50 hours or within 90 days for PTGs that have greater than 750 hours. The commenter reasoned that the original compliance schedule was established 10 years ago based on field experience at that time. The fatal accident referenced in the NPRM occurred on a PTG with 1,048.7 hours since new.

We disagree. The compliance time for removing the bearing assembly, P/N 2544198, in this AD is based on Rolls-

Royce Corporation Commercial Engine Bulletin (CEB) 1402, Revision 2, dated February 4, 2009. The failure history shows that the number of bearing assembly failures fell sharply following the initial publication of RRC CEB 1402 in 2008. The replacement strategy has proven successful. As a result, we believe that the majority of the fleet has replaced the bearing assembly, P/N 2544198, and only a few remain in service. Besides the fatal accident, there have not been any other bearing failures noted between 2012 and 2018. We, therefore, find it unnecessary to reduce the compliance time as noted by the commenter. We did not change this AD.

Request To Increase the Number of Affected Engines

Honeywell Aerospace noted that only 1,200 engines installed on airplanes of U.S. registry may be affected, compared with the 2,928 mentioned in the NPRM, based on a review of modification records provided to Honeywell by repair stations.

We disagree. We are estimating the total number of engines affected by this AD based on the data available to us. We did not change this AD.

Request To Clarify the Affected Engines

An individual commenter requested that we clarify that only those engine models that have bearing assembly, P/N 2544198, installed are affected.

We agree. We have updated paragraph (c) of this AD to clarify that engines with bearing assembly, P/N 2544198, installed are affected.

Request To Identify the Model, Brand, and P/N of the PTG

Aircraft Maintenance Netherlands requested that this AD identify the model, brand, and P/N of the affected PTG that must be replaced. The commenter reasoned that various PTG models can be installed on the affected engines.

We disagree. This AD provides the overall engine model applicability. The

related service information provides specific information regarding the PTGs, including the manufacturer, model, and P/Ns. We did not change this AD.

Question on Not Issuing the AD Earlier

An individual commenter asked why an AD was not issued in 2009 when RRC issued a statement regarding the failure of the bearing assembly.

The FAA uses a risk-based approach to make continued operational safety decisions. When RRC issued CEB 1402, Revision 2, in 2009, our evaluation of the fleet risk did not support an AD. We update our fleet risk evaluation periodically as new information becomes available and have now determined that an AD is justified. We did not change this AD.

Question if Replacement Part Verification Testing Was Completed

An individual commenter asked if tests or procedures were completed to verify that the replacement bearing assembly resolves the failure of bearing assembly, P/N 2544198, due to the lack of lubrication.

We note that replacement parts, such as this replacement bearing assembly, undergo design analysis and testing before being approved for use by the FAA. No change is requested. We did not change this AD.

Request for Clarification on the Number of Affected Engines

An individual commenter noted that the NPRM estimates that 2,928 model 250-C turboshaft engines are affected, however, the RRC website estimates that there are an estimated 16,000 model 250-C engines currently in service.

This AD applies to all RRC model 250-C turboshaft engines that could have the bearing assembly, P/N 2544198, installed. Many of those engines have already had the bearing assembly, P/N 2544198, replaced when new parts became available. Based on the available data, we estimate that 2,928 engines may still have the bearing

assembly, P/N 2544198, installed. We did not change this AD.

Question on the Availability of a Replacement Bearing Assembly

An individual commenter asked if RRC still needs to design a new bearing assembly or if a replacement bearing assembly is already available.

A replacement bearing assembly, P/N 2526146, is available for installation. We did not change this AD.

Support for the AD

An individual commenter expressed support for the NPRM as written.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information

We reviewed Rolls-Royce Corporation Commercial Engine Bulletin (CEB) 1402, Revision 2, dated February 4, 2009. The CEB provides guidance on replacing the PTG bearing assembly, P/N 2544198, with a bearing assembly eligible for installation.

Costs of Compliance

We estimate that this AD affects 2,928 engines installed on airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Remove and replace PTG bearing assembly	8 work-hours × \$85 per hour = \$680	\$1,700	\$2,380	\$6,968,640

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more

detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: “General requirements.” Under that section, Congress charges the FAA with

promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition

that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2018–13–01 Roll-Royce Corporation (Type Certificate previously held by Allison Engine Company): Amendment 39–19313; Docket No. FAA–2017–1118; Product Identifier 2017–NE–40–AD.

(a) Effective Date

This AD is effective August 16, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Corporation (RRC) model 250–C10D, 250–C18, 250–C18A, 250–C18B, 250–C18C, 250–C19, 250–C20, 250–C20B, 250–C20C, 250–C20F, 250–C20J, 250–C20R, 250–C20R/1, 250–C20R/2, 250–C20R/4, 250–C20S, 250–C20W, 250–C28, 250–C28B, 250–C28C, 250–C30, 250–C30G, 250–C30G/2, 250–C30M, 250–C30P, 250–C30S, and 250–C30U turboshaft engines with power turbine governor (PTG) bearing assembly, part number (P/N) 2544198, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7323, Turbine Governor.

(e) Unsafe Condition

This AD was prompted by several reports of loss of power, one of which resulted in a fatal helicopter accident. We are issuing this AD to prevent failure of the PTG bearing assembly. The unsafe condition, if not addressed, could result in failure of the PTG, failure of the engine, in-flight shutdown, and forced autorotation landing or accident.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

- (1) Remove the bearing assembly, P/N 2544198, from the PTG in accordance with the compliance times in Figure 1 to paragraph (g) of this AD, or within 90 days after the effective date of this AD, whichever occurs later.

Figure 1 to Paragraph (g) – Compliance Times

PTG Operational Hours (Time Since New/Time Since Last Overhaul).	Compliance Time
0 to 750	Not later than 750 hours
751 to 1000	Not later than 1,000 hours
1001 to 1250	Not later than 1,250 hours
1251 to 1500	Not later than 1,500 hours
1501 or greater	At the next removal of the PTG for any reason

(2) After such removal, replace the affected PTG bearing assembly with a part eligible for installation before further flight.

(h) Installation Prohibition

After the effective date of this AD, do not install PTG bearing assembly, P/N 2544198, on any engine.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Chicago ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the Chicago ACO Branch, send it to the attention

of the person identified in paragraph (j) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

For more information about this AD, contact John Tallarovic, Aerospace Engineer,

Chicago ACO Branch, FAA, 2300 E Devon Ave., Des Plaines, IL 60018; phone: 847-294-8180; fax: 847-294-7834; email: john.m.tallarovic@faa.gov.

(k) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on July 6, 2018.

Karen M. Grant,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018-14801 Filed 7-11-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2018-0662]

RIN 1625-AA08

Special Local Regulation; Marine City Water Ski Show, St. Clair River, Marine City, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for certain navigable waters of the St. Clair River, Marine City, MI. This action is necessary and is intended to ensure safety of life on navigable waters immediately prior to, during, and immediately after the Marine City Water Ski Show.

DATES: This temporary final rule is effective from 1 p.m. through 5 p.m. on August 4, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0662 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email Tracy Girard, Prevention Department, Sector Detroit, Coast Guard; telephone (313) 568-9564, or email Tracy.M.Girard@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 NPRM Notice of Proposed Rulemaking
 § Section
 COTP Captain of the Port

U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The Coast Guard just recently received the final details of this water ski show, which does not provide sufficient time to publish an NPRM prior to the event. Thus, delaying the effective date of this rule to wait for a comment period to run would be contrary to public interest because it would inhibit the Coast Guard's ability to protect participants, mariners and vessels from the hazards associated with this event. It is impracticable to publish an NPRM because we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would inhibit the Coast Guard's ability to protect participants, mariners and vessels from the hazards associated with this event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Detroit (COTP) has determined that the likely combination of recreation vessels, commercial vessels, and an unknown number of spectators in close proximity to a water ski show along the water pose extra and unusual hazards to public safety and property. Therefore, the COTP is establishing a special local regulation around the event location to help minimize risks to safety of life and property during this event.

IV. Discussion of the Rule

This rule establishes a special local regulation from 1 p.m. through 5 p.m. on August 4, 2018. The special local regulation will encompass all U.S. navigable waters of the St. Clair River,

Marine City, MI, bound by: 200 feet seaward of latitude position 42°43.382' N and 200 feet seaward of latitude position 42°42.983' N (NAD 83). The special local regulation will be enforced from 1 p.m. to 1:45 p.m. and from 4 p.m. to 4:45 p.m. on August 4, 2018. No vessel or person will be permitted to enter the special local regulation without obtaining permission from the COTP or his designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-year of the special local regulation. Vessel traffic will be able to safely transit around this special local regulation zone which will impact a small designated area of the St. Clair River from 1 p.m. until 5 p.m. on August 4, 2018. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF-FM marine channel 16 about the special local regulation and the rule allows vessels to seek permission to enter the area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601-612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a

significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the special local regulation may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments,

because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation lasting less than four hours that will prohibit entry into a designated area. It is categorically excluded from further review under paragraph L[61] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 33 CFR 1.05–1.

■ 2. Add § 100.T09–0662 to read as follows:

§ 100.T09–0662 Special Local Regulation; Marine City Water Ski Show, St. Clair River, Marine City, MI.

(a) *Regulated areas.* The following regulated area is established to include all U.S. navigable waters of the St. Clair River, Marine City, MI, bound by: 200 feet seaward of latitude position 42°43.382' N and 200 feet seaward of latitude position 42°42.983' N (NAD 83).

(b) *Enforcement date.* The regulated area described in paragraph (a) of this section will be in effect from 1 p.m. though 5 p.m. on August 4, 2018. The special local regulation will be enforced from 1 p.m. to 1:45 p.m. and from 4 p.m. to 4:45 p.m. on August 4, 2018.

(c) *Special local regulations.* (1) Vessels transiting through the regulated area are to maintain the minimum speeds for safe navigation.

(2) Vessel operators desiring to operate in the regulated area must contact the Coast Guard Patrol Commander to obtain permission to do so. The Captain of the Port Detroit (COTP) or his on-scene representative may be contacted via VHF Channel 16 or at 313–568–9560. Vessel operators given permission to operate within the regulated area must comply with all directions given to them by the COTP or his on-scene representative.

(3) The “on-scene representative” of the COTP Detroit is any Coast Guard commissioned, warrant or petty officer or a Federal, State, or local law enforcement officer designated by or assisting the Captain of the Port Detroit to act on his behalf.

Dated: July 5, 2018.

Kevin D. Floyd,

Commander, U.S. Coast Guard, Acting Captain of the Port Detroit.

[FR Doc. 2018–14919 Filed 7–11–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

RIN 1625-AA00

[Docket Number USCG-2018-0578]

Safety Zone; Alaska Marine Highway System Port Valdez Ferry Terminal, Port Valdez; Valdez, AK

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is republishing its 2014 rule that established a permanent safety zone on the navigable waters of Port Valdez within a 200-yard radius of the Alaska Marine Highway System (AMHS) Port Valdez Ferry Terminal. The safety zone restricts all vessels except AMHS vessels from entering within 200-yards of the AMHS Port Valdez Ferry Terminal whenever an AMHS ferry is underway within 200 yards of the terminal and there is a declared Commercial Salmon Fishery Opener. This safety zone is necessary to provide for the safety of life, property and the environment during periods of vessel traffic congestion during a declared Commercial Salmon Fishery Opener.

DATES: This rule is effective July 12, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0578 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email LTJG, Carlos M. Quintero, MSU Valdez, U.S. Coast Guard; telephone 907-835-7209, email Carlos.M.Quintero@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

AMHS Alaska Marine Highway System
 CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 § Section
 U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (5 U.S.C. 553(b)). This

provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are impracticable, unnecessary, or contrary to the public interest. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with respect to this rule because it is unnecessary to do so. This is a republication, without change, of a previously issued rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard finds that good cause exists because it is unnecessary to do so. This is a republication, without change of a previously issued rule.

On February 4, 2014, the Coast Guard published a rule that established a permanent safety zone on the navigable waters of Port Valdez within a 200-yard radius of the Alaska Marine Highway System (AMHS) Port Valdez Ferry Terminal (79 FR 6468). The safety zone restricts all vessels except AMHS vessels from entering within 200-yards of the AMHS Port Valdez Ferry Terminal whenever an AMHS ferry is underway within 200 yards of the terminal and there is a declared Commercial Salmon Fishery Opener. That original rule, however, contained a clerical error that prevented the Office of the Federal Register from codifying the rule into the Code of Federal Regulations. The 2014 final rule inadvertently used a pre-existing number assigned to a different regulation. Because the rule could not be codified at the stated location, the Office of the Federal Register, instead, added an editorial note to 33 CFR 165.1712 noting the publication of the 2014 AMHS Port Valdez Ferry Terminal rule.

The purpose of this rule is to republish that 2014 rule, without change, to a different section number so that it can be codified into the Code of Federal Regulations.

The authority to re-issue this safety zone is 33 U.S.C. 1231. This safety zone continues to be necessary to provide for the safety of life, property and the environment during periods of vessel traffic congestion during a declared Commercial Salmon Fishery Opener.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses

based on a number of these statutes and Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771. This regulatory action determination is based on the fact that this is a republication, without change, of a previously published rule.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601-612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Small businesses may send comments on the actions of federal employees who enforce, or otherwise determine compliance with, federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain

about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a state, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the

republishing, without change, of a previously published rule. It is categorically excluded from further review under paragraph L60a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.1714 to read as follows:

§ 165.1712a Safety Zone; Alaska Marine Highway System Port Valdez Ferry Terminal, Port Valdez, Valdez, AK.

(a) *Location.* The following area is a safety zone: All navigable waters of Port Valdez extending 200 yards in all directions from the edges of the Alaska Marine Highway System Terminal dock located in Port Valdez at 61°07'26" N and 146°21'50" W.

(b) *Enforcement period.* The rule will be enforced whenever there is an Alaska Marine Highway System Ferry vessel transiting within the area described in paragraph (a) of this section and there is a Commercial Salmon Fishery Opener that includes the navigable waters within the safety zone. Each enforcement period will be announced by a broadcast notice to mariners when the Commercial Salmon Fishery Opener is announced.

(c) *Definitions.* The following definitions apply to this section:

(1) The term “designated representative” means any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port, Prince William Sound, to act on his or her behalf.

(2) The term “official patrol vessel” may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP, Prince William Sound.

(3) The term “AMHS vessel” means any vessel owned or operated by the

Alaska Marine Highway System, including, but not limited to: M/V AURORA, M/V CHENEGA, M/V COLUMBIA, M/V FAIRWEATHER, M/V KENNICOTT, M/V LECONTE, M/V LITUYA, M/V MALASPINA, M/V MATANUSKA, M/V TAKU and M/V TUSTUMENA.

(d) *Regulations.* (1) The general regulations contained in 33 CFR 165.23, as well as the requirements in paragraphs (d)(2) through (5) of this section, apply.

(2) No vessels, except for AMHS ferries and vessels owned or operated by AMHS will be allowed to transit the safety zone without the permission of the COTP Prince William Sound or the designated representative during periods of enforcement.

(3) All persons and vessels shall comply with the instructions of the COTP or the designated representative. Upon being hailed by a U.S. Coast Guard vessel or other official patrol vessel by siren, radio, flashing light or other means, the operator of the hailed vessel shall proceed as directed.

(4) Vessel operators desiring to enter or operate within the regulated area may contact the COTP or the designated representative via VHF channel 16 or 907–835–7205 (Prince William Sound Vessel Traffic Service) to request permission to do so.

(5) The COTP, Prince William Sound may be aided by other Federal, state, borough, and local law enforcement officials in the enforcement of this regulation. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

Dated: July 6, 2018.

M.R. Franklin,

Commander, U.S. Coast Guard, Captain of the Port, Prince William Sound.

[FR Doc. 2018–14863 Filed 7–11–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2017–0152; FRL–9980–62—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Interstate Transport Requirements for the 2012 Fine Particulate Matter Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the State of Delaware. This revision pertains to the infrastructure requirement for interstate transport of pollution with respect to the 2012 fine particulate matter (PM_{2.5}) national ambient air quality standards (NAAQS). EPA is approving this revision in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on August 13, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2017-0152. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <http://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Joseph Schulingkamp, (215) 814-2021, or by email at schulingkamp.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 2015, the State of Delaware, through the Department of Natural Resources and Environmental Control (DNREC) submitted a SIP revision addressing the infrastructure requirements under section 110(a)(2) of the CAA for the 2012 PM_{2.5} NAAQS. On September 22, 2017, EPA approved all portions of Delaware's submittal except for the portion addressing section 110(a)(2)(D)(i)(I) regarding the interstate transport of emissions. See 82 FR 44318. As explained in the final rule, EPA intended to take separate action on that portion of Delaware's submittal and is doing so with today's proposed action. On May 15, 2018 (83 FR 22436), EPA published a notice of proposed rulemaking (NPR) for the State of Delaware. In the NPR, EPA proposed approval of Delaware's submittal to address the infrastructure requirements under section 110(a)(2)(D)(i) of the CAA for the 2012 PM_{2.5} NAAQS.

II. Summary of SIP Revision and EPA Analysis

Delaware's December 14, 2015 SIP submittal asserted that the State's SIP presently contains adequate provisions prohibiting sources from emitting air pollutants in amounts which will contribute significantly to nonattainment or interfere with maintenance of the 2012 PM_{2.5} NAAQS. Delaware also asserted under Delaware Code, Title 7, Chapter 60, Subsection 6010(c), "Rules and regulations; plans," that the State has the legal authority to regulate sources whose emission could transport to areas in nonattainment or to areas currently attaining the NAAQS. Delaware also describes ambient air quality data for New Castle, Kent, and Sussex Counties as all being below the NAAQS.

EPA used the information in the 2016 PM_{2.5} Memorandum¹ and additional information to evaluate the submittal and came to the same conclusion as Delaware. As discussed in greater detail in the technical support document (TSD) for this action, EPA identified the potential downwind nonattainment and maintenance receptors identified in the 2016 PM_{2.5} Memorandum, and then evaluated them to determine if Delaware's emissions could potentially contribute to nonattainment and maintenance problems in 2021, the attainment year for moderate PM_{2.5} nonattainment areas. EPA concluded Delaware was not significantly contributing to nonattainment nor interfering with maintenance with 2012 PM_{2.5} NAAQS by any other state. A detailed summary of Delaware's submittal and EPA's review and rationale for approval of this SIP revision as meeting CAA section 110(a)(2)(D)(i)(I) for the 2012 PM_{2.5} NAAQS may be found in the NPR and TSD for this rulemaking action, which are available online at www.regulations.gov, Docket number EPA-R03-OAR-2017-0152.

III. Public Comments

One anonymous public comment was received during the public comment period, but the comment was determined to not be relevant nor specific to this rulemaking action. Thus no response is provided.

¹ "Information on the Interstate Transport "Good Neighbor" Provision for the 2012 Fine Particulate Matter National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I)." Memorandum from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards (March 17, 2016). A copy is included in the docket for this rulemaking action.

IV. Final Action

EPA is approving the December 14, 2015 SIP revision addressing the interstate transport requirements for the 2012 PM_{2.5} NAAQS to the Delaware SIP because the submittal adequately addresses section 110(a)(2)(D)(i)(I) of the CAA.

V. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other

required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 10, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action, addressing Delaware’s interstate transport for the 2012 PM_{2.5} NAAQS, may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter.

Dated: June 19, 2018.

Cosmo Servidio,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart I—Delaware

■ 2. In § 52.420, the table in paragraph (e) is amended by adding a second entry for Section 110(a)(2) Infrastructure Requirements for the 2012 PM_{2.5} NAAQS after the first entry. The revised text reads as follows:

§ 52.470 Identification of plan.

* * * * *
(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Section 110(a)(2) Infrastructure Requirements for the 2012 PM _{2.5} NAAQS.	Statewide	12/14/2015	7/12/2018, [Insert Federal Register citation].	Docket 2017–0152. This action addresses the infrastructure element of CAA section 110(a)(2)(D)(i)(I).
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

[FR Doc. 2018–14838 Filed 7–11–18; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2018–0104; FRL–9980–43—Region 9]

Approval of California Air Plan Revisions, Yolo-Solano Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the Yolo-Solano Air Quality Management District (YSAQMD or “District”) portion of the California State Implementation Plan

(SIP). This revision concerns emissions of volatile organic compounds (VOCs) from architectural coatings. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on August 13, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2018–0104. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <http://>

www.regulations.gov, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Arnold Lazarus, EPA Region IX, (415) 972–3024, Lazarus.Arnold@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, “we,” “us” and “our” refer to the EPA.

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Proposed Action

On May 3, 2018 (83 FR 19495), the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule No.	Rule title	Revised	Submitted
YSAQMD	2.14	Architectural Coatings	10/12/2016	01/24/2017

We proposed to approve this rule because we determined that it complies with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA’s proposed action provided a 30-day public comment period. During this period, we received one comment in support of regulating VOC emissions, and another that was not germane to this rule.

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the YSAQMD rule described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA’s role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735,

October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a

copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 10, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 22, 2018.
Deborah Jordan,
Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

- 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

- 2. Section 52.220 is amended by adding paragraphs (c)(293)(i)(B)(2) and (c)(497)(i)(D)(2) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *
 (c) * * *
 (293) * * *

(j) * * *
(B) * * *

(2) Previously approved on January 2, 2004 in paragraph (c)(293)(i)(B)(1) of this section and now deleted with replacement in (c)(497)(i)(D)(2), Rule 2.14, adopted on November 14, 2001.

* * * * *

(497) * * *

(i) * * *

(D) * * *

(2) Rule 2.14, “Architectural Coatings,” revised on October 12, 2016.

* * * * *

[FR Doc. 2018–14946 Filed 7–11–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2014–0741; FRL–9980–84–OAR]

National Emission Standards for Hazardous Air Pollutants for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of final action denying petition for reconsideration.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is providing notice that it has responded to a petition for reconsideration of the final National Emission Standards for Hazardous Air Pollutants (NESHAP) for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills published in the **Federal Register** on October 11, 2017. The Acting Administrator denied the petition in a separate letter to the petitioners. The letter, which provides a full explanation of the agency’s rationale for the denial, is in the rulemaking docket.

DATES: July 12, 2018.

FOR FURTHER INFORMATION CONTACT: Dr. Kelley Spence, Sector Policies and Programs Division (E143–03), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–3158; fax number: (919) 541–0516; email address: spence.kelley@epa.gov.

SUPPLEMENTARY INFORMATION:

I. How can I get copies of this document and other related information?

This **Federal Register** document, the petition for reconsideration, and the

letter denying the petition for reconsideration are available in the docket the EPA established under Docket ID No. EPA–HQ–OAR–2014–0741. All documents in the docket are listed on the www.regulations.gov website. Although listed, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the EPA Docket Center (EPA/DC), Room 3334, EPA WJC West Building, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air Docket is (202) 566–1742.

II. Judicial Review

Section 307(b)(1) of the Clean Air Act (CAA) indicates which Federal Courts of Appeals have venue for petitions for review of final EPA actions. This section provides, in part, that the petitions for review must be filed in the United States Court of Appeals for the District of Columbia Circuit if: (1) The agency action consists of “nationally applicable regulations promulgated, or final action taken, by the Administrator,” or (2) such actions are locally or regionally applicable, if “such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.”

The EPA has determined that its action denying the petition for reconsideration is nationally applicable for purposes of CAA section 307(b)(1) because the action directly affects the NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills, which are nationally applicable CAA section 112 standards. Any petitions for review of the letter denying the petition for reconsideration must be filed in the United States Court of Appeals for the District of Columbia Circuit by September 10, 2018.

III. Description of Action

On October 11, 2017, pursuant to sections 112(d)(6) and (f)(2) of the CAA, the EPA published the final residual risk and technology review (RTR) of the

“National Emission Standards for Hazardous Air Pollutants for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills.” 82 FR 47328. Following publication of the final RTR amendments, the Administrator received a petition for reconsideration of two aspects of the final RTR pursuant to CAA section 307(d)(7)(B). The petitioners, Earthjustice on behalf of Crossett Concerned Citizens for Environmental Justice, Louisiana Environmental Action Network, PT AirWatchers, and Sierra Club, claimed: (1) It was impracticable to object to the EPA’s rationale for not setting additional standards for uncontrolled emissions when the EPA was conducting the review required by CAA section 112(d)(6), and their objections on this issue are of central relevance to the outcome of the rule; and (2) it was impracticable to object during the comment period to the EPA’s use of census block centroids to account for the residual risk to the most exposed individual, and their objections on this issue are of central relevance to the outcome of the rule.

CAA section 307(d)(7)(B) requires the EPA to convene a proceeding for reconsideration of a rule if a party raising an objection to the rule “can demonstrate to the Administrator that it was impracticable to raise such objection within [the public comment period] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.” The requirement to convene a proceeding to reconsider a rule is, thus, based on the petitioner demonstrating to the EPA both: (1) That it was impracticable to raise the objection during the comment period, or that the grounds for such objection arose after the comment period, but within the time specified for judicial review (*i.e.*, within 60 days after publication of the final rulemaking in the **Federal Register**, see CAA section 307(b)(1)); and (2) that the objection is of central relevance to the outcome of the rule.

The EPA carefully reviewed the petition for reconsideration and evaluated the issues raised to determine if they meet the CAA section 307(d)(7)(B) criteria for reconsideration. In a separate letter to the petitioners, the EPA Acting Administrator, Andrew R. Wheeler, denied the petition for reconsideration. The letter is available in the docket for this action.

Dated: July 9, 2018.

Andrew R. Wheeler,

Acting Administrator.

[FR Doc. 2018-15023 Filed 7-11-18; 8:45 am]

BILLING CODE 6560-50-P

Proposed Rules

Federal Register

Vol. 83, No. 134

Thursday, July 12, 2018

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1206

[Document. No. AMS–SC–17–0002]

Mango Promotion, Research, and Information Order; Reopening and Extension of Comment Period on Amendment To Include Frozen Mangos

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Reopening and extension of comment period.

SUMMARY: Notice is hereby given that the comment period on the proposed rule to amend the Mango Promotion, Research, and Information Order to include frozen mangos is reopened and extended. Also, the comment period is extended for the frozen mangos information and collection requirements by the Office of Management and Budget (OMB) which is necessary to include frozen mangos under the current program.

DATES: Comments must be received by August 13, 2018. Pursuant to the Paperwork Reduction Act (PRA), comments on the information collection burden that would result from this proposal must be received by August 13, 2018.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments may be submitted on the internet at: <http://www.regulations.gov> or to the Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; facsimile: (202) 205–2800. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection, including name and address, if provided, in the above office during regular business hours or it can

be viewed at <http://www.regulations.gov>.

Pursuant to the PRA, comments regarding the accuracy of the burden estimate, ways to minimize the burden, including the use of automated collection techniques or other forms of information technology, or any other aspect of this collection of information, should be sent to the above address. In addition, comments concerning the information collection should also be sent to the Desk Office for Agriculture, Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street NW, Room 725, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jeanette Palmer, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; telephone: (202) 720–9915; facsimile: (202) 205–2800; or electronic mail: Jeanette.Palmer@ams.usda.gov.

SUPPLEMENTARY INFORMATION: A proposed rule was published in the **Federal Register** on April 6, 2018 (83 FR 14771). That rule proposed to amend the Mango Promotion, Research, and Information Order to include frozen mangos.

The rule also announced the Agricultural Marketing Service's intent to request approval from OMB of new information collection requirements and recordkeeping requirements for the frozen mango industry. Information collection and recordkeeping requirements for the fresh mango program (part 1206) have previously been approved under OMB control nos. 0581–0093 and 0505–0001. Upon approval of this action and associated burden, AMS would submit a Justification for Change to merge this new burden for frozen mangos into the currently approved collection for fresh mangos.

USDA received a letter from industry requesting that the comment period be extended to allow additional time for interested persons to review the proposal and submit comments.

USDA is reopening and extending the comment period an additional 30 days to allow interested persons more time to review the proposed rule, perform an analysis, and submit written comments.

Authority: 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

Dated: July 9, 2018.

Bruce Summers,
Administrator.

[FR Doc. 2018–14940 Filed 7–11–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0634; Product Identifier 2018–NM–050–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, Model CL–600–2D24 (Regional Jet Series 900) airplanes, and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. This proposed AD was prompted by reports of a fractured main landing gear (MLG) orifice support tube (OST). This proposed AD would require replacing the MLG OST, and revising the maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and airworthiness limitations. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by August 27, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Fax:** 202–493–2251.
- **Mail:** U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5

p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 866-538-1247 or direct-dial telephone 514-855-2999; fax 514-855-7401; email ac.yul@aero.bombardier.com; internet <http://www.bombardier.com>. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0634; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7329; fax 516-794-5531; email 9-avs-nyaco-cos@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA-2018-0634; Product Identifier 2018-NM-050-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing

date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF-2018-02, dated January 16, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bombardier, Inc., Model CL-600-2C10 (Regional Jet Series 700, 701 & 702) airplanes, Model CL-600-2D15 (Regional Jet Series 705) airplanes, Model CL-600-2D24 (Regional Jet Series 900) airplanes, and Model CL-600-2E25 (Regional Jet Series 1000) airplanes. The MCAI states:

Five cases of fractured Main Landing Gear (MLG) Orifice Support Tube (OST) have been reported. Subsequent analysis determined that the MLG OST is unable to withstand the loads generated during a hard landing event. A MLG OST fracture cannot be detected during routine maintenance and if not corrected, a fractured MLG OST can lead to aeroplane structural damage and/or collapse of the MLG.

This [Canadian] AD mandates the replacement of the existing MLG OSTs with a re-designed part, and the implementation of a new airworthiness limitation task.

You may examine the MCAI in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0634.

Related Service Information Under 1 CFR Part 51

Bombardier has issued Service Bulletin SB 670BA-32-058, dated September 26, 2016. The service information describes procedures for replacing each MLG OST.

Bombardier has also issued Temporary Revision ALI-0593, dated December 18, 2017. The service information describes new life limits for the MLG OSTs.

These service information are reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

This AD requires revisions to certain operator maintenance documents to include new actions (e.g., inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (i) of this proposed AD. The request should include a description of changes to the required actions that will ensure the continued damage tolerance of the affected structure.

Proposed AD Requirements

This proposed AD would require replacing the MLG OST and revising the maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and airworthiness limitations.

Costs of Compliance

We estimate that this proposed AD affects 542 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement (left- and right-hand sides)	24 work-hours × \$85 per hour = \$2,040	* \$0	\$2,040	\$1,105,680

* We have received no definitive data that would enable us to provide cost estimates for the parts cost in this AD.

We have determined that revising the maintenance or inspection program

takes an average of 90 work-hours per operator, although we recognize that

this number may vary from operator to operator. In the past, we have estimated

that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be \$7,650 (90 work-hours × \$85 per work-hour).

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Bombardier, Inc.: Docket No. FAA-2018-0634; Product Identifier 2018-NM-050-AD.

(a) Comments Due Date

We must receive comments by August 27, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Bombardier, Inc., airplanes specified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, certificated in any category.

(1) Model CL-600-2C10 (Regional Jet Series 700, 701 & 702) airplanes, serial numbers 10003 through 10345 inclusive.

(2) Model CL-600-2D15 (Regional Jet Series 705) airplanes and Model CL-600-2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15429 inclusive.

(3) Model CL-600-2E25 (Regional Jet Series 1000) airplanes, serial numbers 19001 through 19052 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 32, Main landing gear.

(e) Reason

This AD was prompted by reports of a fractured main landing gear (MLG) orifice support tube (OST). We are issuing this AD to address a fractured MLG OST, which can lead to structural damage to the airplane and collapse of the MLG.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Replacement

Within the compliance times specified in figure 1 to paragraph (g) of this AD: Replace each MLG OST, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin SB 670BA-32-058, dated September 26, 2016.

Figure 1 to paragraph (g) of this AD — *Compliance Times*

Airplane Models	Compliance Time
CL-600-2C10 (Regional Jet Series 700, 701 & 702) airplanes	Within 21,000 flight cycles from the effective date of this AD, or before MLG OST(s) accumulate 40,000 total flight cycles, whichever occurs first
CL-600-2D15 (Regional Jet Series 705) airplanes and CL-600-2D24 (Regional Jet Series 900) airplanes equipped with MLG OST(s) that have accumulated fewer than 23,100 flight cycles as of the effective date of this AD	Within 20,000 flight cycles from the effective date of this AD, or before MLG OST(s) accumulate 29,100 total flight cycles, whichever occurs first
CL-600-2D15 (Regional Jet Series 705) airplanes and CL-600-2D24 (Regional Jet Series 900) airplanes equipped with MLG OST(s) that have accumulated 23,100 flight cycles or more as of the effective date of this AD	Within 6,000 flight cycles from the effective date of this AD
CL-600-2E25 (Regional Jet Series 1000) airplanes	Before MLG OST(s) accumulate 20,000 total flight cycles

(h) Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate Bombardier Temporary Revision ALI-0593, dated December 18, 2017. The initial compliance time for accomplishing the actions is at the applicable time specified in Bombardier Temporary Revision ALI-0593, dated December 18, 2017; or within 90 days after the effective date of this AD; whichever occurs later.

(i) No Alternative Actions or Intervals

After the maintenance or inspection program has been revised as required by paragraph (h) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In

accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7300; fax 516-794-5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF-2018-02, dated January 16, 2018, for related information. This MCAI may be found in the AD docket on the internet at

<http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0634.

(2) For more information about this AD, contact Aziz Ahmed, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7329; fax 516-794-5531; email 9-avs-nyaco-cos@faa.gov.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 866-538-1247 or direct-dial telephone 514-855-2999; fax 514-855-7401; email ac.yul@aero.bombardier.com; internet <http://www.bombardier.com>. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

Issued in Des Moines, Washington, on July 3, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018-14804 Filed 7-11-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2018-0281; Product Identifier 2018-NE-06-AD]

RIN 2120-AA64

Airworthiness Directives; Hoffmann Propeller GmbH & Co. KG Propellers**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Hoffmann Propeller GmbH & Co. KG model HO-V 62 propellers. This proposed AD was prompted by the failure of the propeller blade lag screws. This proposed AD would require removal of the affected propeller blades and installation of modified propeller blades marked with change letter "A" or "B." We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by August 27, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of

Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Hoffmann Propeller GmbH & Co. KG, Sales and Service, K pferlingstrasse 9, 83022 Rosenheim, Germany; phone: +49 (0) 8031 1878 0; fax: +49 (0) 8031 1878 78; email: info@hoffmann-prop.com. You may view this service information at the FAA, Engine & Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7759.

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0281; or in person at Docket Operations

between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800-647-5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Maureen Maisttison, Aerospace Engineer, AIR-7B1, FAA, 1200 District Ave, Burlington, MA 01803; phone: 781-238-7076; fax: 781-238-7151; email: maureen.maisttison@faa.gov.

SUPPLEMENTARY INFORMATION:**Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2018-0281; Product Identifier 2018-NE-06-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2017-0220, dated November 10, 2017 (referred to hereinafter as "the MCAI"), to address the unsafe condition on these products. The MCAI states:

In 1983, occurrences were reported of fatigue failure of propeller blade lag screws, at rotation speeds between 2950 and 3250 revolutions per minute (RPM) in flight.

This condition, if not detected and corrected, could lead to in-flight propeller blade detachment, possibly resulting in damage to the powered sailplane and/or injury to persons on the ground.

To address this potential unsafe condition, Hoffmann issued Service Bulletin (SB) 4, providing the necessary instructions. Consequently, LBA Germany issued AD 83-150 (later revised), which applied only to HO-V 62 propellers with R/L 160T blades, when in combination with a Limbach L 2000 engine, to require a limitation of continuous operation to 2 900 RPM, to prohibit aerobatic flights, calibrate the tachometer, install a

placard, and inspection of the propeller blades. LBA AD 83-150/4 also required overhaul and replacement of the affected propeller blades with modified blades, either having 5 lag screws with 12 mm diameter, or 6 screws, and required implementing a time between overhaul (TBO) of 600 flight hours (FH).

Since that AD was issued, based on a stress analysis of lag screws on blades with continuous operating speed above 2 900 RPM, it was determined that the 6-screws configuration or the 5 screws configuration with increased strength is necessary to ensure safe propeller operation. In addition, since the LBA AD applied only to a limited population (Limbach engine only), many propellers have not been modified as described in Hoffmann SB 4C. Consequently, Hoffmann issued SB E34 Revision B, to provide blade replacement instructions.

You may obtain further information by examining the MCAI in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0281.

Related Service Information

We reviewed Hoffmann Propeller GmbH & Co. KG Service Bulletin (SB) E34, Rev. B, dated September 18, 2017. The SB describes the instructions for the removal and installation of the propeller blades.

FAA's Determination

This product has been approved by EASA, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all the relevant information provided by EASA and determined the unsafe condition previously described is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require removal of the affected propeller blades and installation of the modified propeller blades marked with change letter "A" or "B" on the blade.

Differences Between This Proposed AD and the MCAI or Service Information

EASA AD 2017-0220 partially restates the requirements of AD 83-150, issued on December 21, 1984, by German aviation authority Luftfahrt-Bundesamt (LBA), which is based on Propellerwerk Hoffmann Rosenheim SB 4, Revision C, dated February 20, 1984. EASA AD 2017-0220 also adds new requirements based on the issuance of

Hoffmann Propeller GmbH & Co. KG SB E34, Rev. B dated September 18, 2017. In restating LBA AD 83–150, EASA AD 2017–0220 maintains a requirement to remove certain propellers from service within 10 flight hours after December 21, 1984, but not later than 31 March 31, 1985. Service Bulletin E34 requires a mandatory immediate maximum propeller rotational speed limitation until the permanent corrective action is completed, within 50 flight hours. The EASA AD 2017–

0220 partially restated requirements of SB 4. Additionally, Hoffmann Propeller GmbH & Co. KG SB E34 Revision B and SB 4 Revision C temporarily prohibit acrobatic flight. EASA AD 2017–0220 also adds a new requirement for a mandatory maximum propeller rotational speed limitation within 30 days until the propeller is replaced within 50 flight hours. This proposed AD does not require a propeller speed limitation but would require removal of the affected propeller

blades and installation of modified propeller blades within 30 days of the effective date of this AD.

Costs of Compliance

We estimate that this proposed AD affects 50 propellers installed on airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace Blades between overhaul	3.0 work-hours × \$85 per hour = \$255.00	\$3,150.00	\$3,405.00	\$85,125.00
Replace Blades at overhaul	0 work-hours × \$85 per hour = \$0.00	3,150.00	3,150.00	78,750.00

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national

Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Hoffmann Propeller GmbH & Co. KG: Docket No. FAA–2018–0281; Product Identifier 2018–NE–06–AD.

(a) Comments Due Date

We must receive comments by August 27, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Hoffmann Propeller GmbH & Co. KG model HO–V 62 propellers without modified blades marked with change letter “A” or “B” suffix to the S/N.

(d) Subject

Joint Aircraft System Component (JASC) Code 6110, Propeller Assembly.

(e) Unsafe Condition

This AD was prompted by the failure of the propeller blade lag screws. We are issuing the AD to prevent failure of the propeller. The unsafe condition, if not addressed, could result in the release of the propeller blade, damage to the aircraft, injury and/or loss of life.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Within 30 days of the effective date of this AD, remove the applicable propeller blades and install modified propeller blades marked with a change letter “A” or “B” suffix to the S/N marked on the blade.

(h) Installation Prohibition

After the effective date of this AD, do not install a propeller blade if it is not marked with a change letter “A” or “B” suffix to the S/N marked on the blade.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards

District Office, as appropriate. If sending information directly to the manager of the Boston ACO Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

(1) For more information about this AD, contact Maureen Maisttison, Aerospace Engineer, AIR-7B1, FAA, 1200 District Ave, Massachusetts, 01803; phone: 781-238-7076; fax: 781-238-7151; email: maureen.maisttison@faa.gov.

(2) Refer to European Aviation Safety Agency AD 2017-0220, dated November 10, 2017, for more information. You may examine the EASA AD in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating it in Docket No. FAA-2018-0281.

(3) For service information identified in this proposed AD, contact Hoffmann Propeller GmbH & Co. KG, Sales and Service, K pferlingstrasse 9, 83022 Rosenheim, Germany; phone: +49 (0) 8031 1878 0; fax: +49 (0) 8031 1878 78; email: info@hoffmann-prop.com. You may view this referenced service information at the FAA, Engine & Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7759.

Issued in Burlington, Massachusetts, on July 6, 2018.

Karen M. Grant,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018-14862 Filed 7-11-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2011-F-0171]

RIN 0910-AH83

Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) proposes to revise the type size labeling requirements for front of package (FOP) calorie declarations for packaged food sold from glass front vending machines. We are taking this

action in response to requests from the vending and packaged foods industries to reduce the regulatory burden and increase flexibility, while continuing to provide calorie declarations for certain articles of food sold from vending machines.

DATES: Submit either electronic or written comments on the proposed rule by September 25, 2018. Please note that late, untimely filed comments will not be considered.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2011-F-0171 for "Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size." Received

comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371, Marjan.Morravej@fda.hhs.gov.

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I. Executive Summary

A. Purpose of This Proposed Rule

We are proposing to amend our vending machine labeling regulations in 21 CFR part 101 by revising § 101.8(b)(2) (21 CFR 101.8(b)(2)), in order to revise the type size requirement when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from certain vending machines. When using FOP labeling, our existing regulations at § 101.8(b)(2) require that the type size of the calorie declaration for articles of food sold from certain vending machines be at least 50 percent of the size of the largest printed matter on the label. We propose, instead, to require that the type size of the calorie declaration on the front of the package be at least 150 percent (one and one-half times) the size of the net quantity of contents (*i.e.*, net weight) declaration on the package of the vended food. We are proposing this change to reduce regulatory burdens that the vending and packaged foods industries shared with us after the final rule implementing the vending machine labeling requirements (79 FR 71259, December 1, 2014) was issued, while continuing to provide calorie declarations for certain articles of food sold from vending machines. Electronic comments must be submitted on or before September 25, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of September 25, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule would revise the type size requirement for calories labeled on the front of the package of vended foods in § 101.8(b)(2). We are proposing that the type size be anchored to the net quantity of contents statement, such that the minimum type size is 150 percent (one and one-half times) the size of the net quantity of contents, instead of being based on the largest printed matter on the label. The proposed rule would only apply when calories are displayed on the front of the package of foods sold in glass front vending machines.

C. Legal Authority

This action is consistent with our authority in section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)(5)(H)). The FD&C Act, at section 403(q)(5)(H), requires certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines. In addition, we are issuing this proposed rule consistent with our authority in sections 201(n), 403(a)(1), and 403(f), of the FD&C Act (21 U.S.C. 321(n), 343(a)(1), and 343(f)). Further, we are issuing this proposed rule under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. We discuss our legal authority in greater detail in Section III, “Legal Authority.”

D. Costs and Benefits

In response to requests from the vending and packaged foods industries to reduce the regulatory burden and increase flexibility, FDA is proposing to revise the existing type size requirements when calories are displayed on the front of the package of foods sold in glass front vending machines. Because this rule only proposes minor revisions to FOP calorie labeling type size requirements, we estimate there are no costs to vending machine operators and potential costs savings to vending machine operators and packaged food manufacturers. We welcome data that would help us to better estimate these impacts.

II. Background

A. Requirements for Calorie Labeling of Articles of Food in Vending Machines and Our Consideration of Front of Package Labeling Issues

Section 403(q)(5)(H) of the FD&C Act requires certain vending machine operators to provide calorie declarations for certain articles of food sold from

vending machines. Under section 403(q)(5)(H)(viii) of the FD&C Act, if an article of food is sold from a vending machine that does not permit a prospective purchaser to examine the Nutrition Facts label before purchasing the article, or does not otherwise provide visible nutrition information at the point of purchase; and is operated by a person who is engaged in the business of owning or operating 20 or more vending machines, the vending machine operator must “provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.”

In the **Federal Register** of December 1, 2014 (79 FR 71259), we issued a final rule to implement the vending machine labeling requirements in section 403(q)(5)(H) of the FD&C Act. The final rule, which became effective on December 1, 2016, requires vending machine operators that own or operate 20 or more vending machines (or that voluntarily register with us to be subject to the final rule) to provide calorie declarations for certain articles of food sold from vending machines. The final rule describes which foods are subject to the calorie declaration requirement. The final rule also establishes type size, color, and contrast requirements for calorie declarations in, or on, the vending machines and for calorie declarations on signs adjacent to the vending machines. The final rule also clarifies that vending machine operators do not have to provide calorie information for a food if a prospective purchaser can view certain calorie information on the front of the package, in the Nutrition Facts label on the food, or in a reproduction of the Nutrition Facts label for the food, subject to certain requirements. The calorie declaration requirements covered in the final rule are codified at § 101.8.

In the **Federal Register** of August 1, 2016 (81 FR 50303), we issued a final rule that extended the compliance date for final calorie declaration requirements for certain food products sold from glass-front vending machines to July 26, 2018. The extended compliance date applies only to those products in glass front vending machines that provide FOP calorie disclosures and that comply with all aspects of the final vending machine labeling rule except that the disclosure is not 50 percent of the size of the largest print on the label.

In the preamble of the proposed rule (published in the **Federal Register** of April 6, 2011 (76 FR 19237 at 19244)), we stated that FOP labeling could be a

way to provide “visible nutrition information,” as long as the criteria for color, font, and type size are met, and total calories contained in the vended food are included. We also tentatively concluded that the visible nutrition information must be in a type size reasonably related to the most prominent printed matter on the labeling, among other things, such that a purchaser is able to notice and read the information. The preamble to the proposed rule (76 FR 19237 at 19244) explained that we considered “reasonably related” to mean a type size at least 50 percent of the size of the largest print on the label. This type size as specified in the preamble to the proposed rule is consistent with interpretations we have used in food labeling guidance when determining the type size of the statement of identity on packaged foods (Ref. 1).

In the preamble to the final rule (79 FR 71259 at 71269), we noted that many comments supported the idea that FOP labeling could provide visible nutrition information; these comments said that FOP labeling is the most efficient way to satisfy section 403(q)(5)(H)(viii) of the FD&C Act. Other comments stated that vending machine operators are likely to prefer food products with FOP labeling because operators selling such food products in their vending machines would not have to provide calorie declarations in compliance with section 403(q)(5)(H)(viii)(I)(bb) of the FD&C Act.

We also discussed several comments that said that interpreting “reasonably related” to mean a type size that is at least 50 percent of the size of the largest print on the label would require a type size that is too large. One comment suggested revising the rule to specify a ratio for the size of the FOP calorie disclosure relative to other printed material on the label. The comment stated that “reasonably related” would be hard to enforce, and we should require the FOP calorie disclosure to be at least two-thirds the size of the largest type size of any other writing on the package, with a minimum size of one-half square inch. Other comments stated we should omit type size or prominence requirements for the FOP calorie disclosure.

In response to comments to the proposed rule, we revised the rule by removing the words “reasonably related” at § 101.8(b)(2) and instead required the calorie labeling print to be “at least 50 percent of the size of the largest printed matter on the label.” We also noted that vending machine operators had other options for satisfying section 403(q)(5)(H)(viii) of the FD&C Act, including using a

vending machine that provides electronic reproductions of Nutrition Facts labels, as provided in § 101.8(b)(1), or posting signs with calorie declarations, as provided in § 101.8(c).

B. Challenges of Existing Type Size Requirement, and Proposed Change to “150 Percent of the Size of the Net Quantity of Contents Declaration”

Since the publication of the final rule, several industry representatives indicated that the 50 percent type size requirement for FOP calorie labeling presents significant technical challenges to the packaged foods industry (Refs. 2 and 3). They said it would make the calorie declaration very large on some products and would make label redesign difficult or not practical. They explained that, for glass front vending machines without electronic displays, FOP labeling assures that consumers will get accurate calorie information for vended foods. The industry representatives also said that many packaged food manufacturers who wish to help vending machine operators comply with the regulations by providing packaged foods with FOP labeling will have to redesign their labels at great expense. They noted the existence of several voluntary FOP labeling programs where calorie information is presented in a FOP type size that ranges from 100 to 150 percent of the size of the net quantity of contents statement on the principal display panel. They acknowledged these labeling programs do not meet our type size requirements, and said that complying with the type size requirement for calorie labeling would significantly disrupt their FOP nutrition labeling programs because there would no longer be enough room on the label to accommodate both the voluntary FOP information and our calorie labeling requirement. Thus, they said that the nutrition information beyond calorie labeling that is presently provided under industry FOP programs may no longer be included. Additionally, they said that, while the existing FOP labeling may not be at least 50 percent of the size of the largest printed matter on the label, as required by our rule, the calorie information is nonetheless visible to consumers. Finally, they stated that, in most cases, industry would be able to comply with a rule that linked the FOP type size for calorie labeling if it were no larger than 150 percent of the type size of the net quantity of contents statement. Other industry representatives also have expressed support for using the 150

percent standard for purposes of the FOP type size requirement (Refs. 4–7).

Consequently, the proposed rule would remove the requirement specifying the FOP labeling be at least 50 percent of the size of the largest printed matter on the label and instead link the type size to the size of the net quantity of contents statement. Specifically, the proposed rule would revise § 101.8(b)(2) pertaining to “articles of food not covered” to state that the visible nutrition information must be in a type size at least 150 percent of the size of the net quantity of contents declaration on the front of the package.

This revision, if finalized, would allow for greater flexibility for the use of FOP calorie labeling in glass front vending machines, while still ensuring that a FOP calorie declaration would be visible for the consumer, regardless of the size of the package. It also would minimize the need for label changes for foods that currently have voluntary FOP calorie declarations that are 150 percent of the size of the net quantity of content statement provided the calorie declarations meet the other criteria in the final rule. It is our understanding that many packaged food products sold in glass front vending machines that currently bear FOP calorie labeling would meet the 150 percent requirement that we are proposing. However, to more fully understand the current marketplace, we specifically invite comment and data on the percentage of food products commonly sold in glass front vending machines bearing voluntary FOP calorie labeling, and for those products that currently bear voluntary FOP calorie labeling, the type size of the FOP calorie labeling used on the products.

C. Other Approaches

Data and information currently available to FDA indicate that the proposed rule is consistent with some existing voluntary FOP calorie declarations currently used on food product labels and it is feasible for other foods that may be sold in vending machines. We also evaluated two other approaches for providing visible nutrition information that would meet the criteria in section 403(q)(5)(H)(viii) of the FD&C Act, such that the food would not be subject to the vending machine calorie labeling requirements. We invite comment on these two alternative approaches, described more fully below.

1. Alternative Approach A—At Least 100 Percent of the Size of the Net Quantity of Contents Declaration

The first alternative approach would be to require the visible nutrition information to be in a type size that is at least 100 percent of the size of the net quantity of contents declaration. Our existing food labeling regulations for packaged foods, at 21 CFR 101.7(i), require that the declaration of net quantity be in letters and numerals in a type size that is established in relation to the area of the principal display panel of the package and that the declaration be uniform for all packages of substantially the same size. The regulation prescribes the following size specifications for net quantity declarations:

- Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less;
- Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches;
- Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches; and
- Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than ½ inch in height if the area is more than 400 square inches.

If the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, then the lettering sizes are to be increased by one-sixteenth of an inch.

We considered requiring the visible nutrition information to be in a type size that is at least 100 percent of the size of the net quantity of contents declaration on the front of the package; in other words, the visible nutrition information would, at a minimum, be the same size as the net quantity of contents declaration. We invite comment on the impact of meeting the visible nutrition information criteria, required under section 403(q)(5)(H)(viii) of the FD&C Act, especially on food in smaller packages, such as small candy bars or single serve bags of nuts, that are sold in glass front vending machines under this alternative approach where the FOP calorie declaration is at least the same size as the net quantity of contents declaration.

FDA invites comment on the advantages and disadvantages of this alternative.

2. Alternative Approach B—Not Specifying Any Size

The second alternative approach would be to not specify any size for the visible nutrition information. This option would give the packaged food industry considerable flexibility in deciding how large—or how small—voluntary FOP calorie labeling could be, and may reduce the need for packaging changes for some manufacturers. We note that in developing the final vending machine labeling rule, we considered, but disagreed with comments asking that we omit requirements for prominence or type size of FOP calorie disclosures. As we discussed in the preamble to that final rule, “When a vending machine food is in a vending machine, a prospective purchaser cannot handle the product to make it easier for the purchaser to read the nutrition information. Therefore, ‘visible nutrition information’ on the front of package must be large enough, and prominent enough, for prospective purchasers to see and use the information” (79 FR 71259 at 71269).

We invite comment on the advantages and disadvantages of this alternative.

III. Legal Authority

We are proposing to revise the labeling requirements for providing calorie declarations for food sold from certain vending machines, as set forth in this proposed rule, consistent with our authority in section 403(q)(5)(H) of the FD&C Act. Under section 403(q)(5)(H), certain vending machine operators must provide calorie declarations for certain articles of food sold from vending machines. Under section 403(a)(1) of the FD&C Act, such information must be truthful and non-misleading. Under section 403(f) of the FD&C Act, any word, statement, or other information required by or under the FD&C Act to appear on the label or labeling of an article of food must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Under section 403(a), (f), or (q) of the FD&C Act, food to which these requirements apply is deemed misbranded if these requirements are not met. In addition, under section 201(n) of the FD&C Act, the labeling of food is misleading if it fails to reveal facts that are material in light of representations made in the labeling or with respect to consequences that may result from use. Thus, we are

issuing this proposed rule under sections 201(n), 403(a)(1), 403(f), and 403(q)(5)(H) of the FD&C Act, as well as under section 701(a) of the FD&C Act, which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Description of the Proposed Rule (Proposed § 101.8(b)(2))

The proposed rule would make a change to the existing rule for calorie labeling of food sold from vending machines, in order to reduce the regulatory burden and increase flexibility while continuing to provide calorie declarations for certain articles of food sold from vending machines. We propose to revise § 101.8(b)(2) to remove the requirement that the type size of the visible calorie declaration for articles of food be at least 50 percent of the size of the largest printed matter on the label and, instead, to require the type size to be at least 150 percent (one and one-half times) the size of the net quantity of contents (*i.e.*, net weight) declaration on the package of the vended food. We also would make a minor editorial correction to the same sentence in § 101.8(b)(2), substituting the word “prospective” in place of “perspective.”

We also would revise the first sentence of § 101.8(b)(2) by inserting a comma after the word “minimum.” This change corrects a punctuation error.

V. Proposed Effective and Compliance Dates

We are proposing that any final rule resulting from this rulemaking have an effective date of 30 days after the date of its publication in the **Federal Register**. We also are proposing that covered vending machine operators comply with any final rule resulting from this rulemaking by January 1, 2020. We are proposing this compliance date in order to provide sufficient time for the packaged food industry to revise their labels, as appropriate, consistent with any new requirements.

As discussed in section II.A., by July 26, 2018, vending machine operators with glass front vending machines will have to comply with all vending machine requirements of the final rule issued in 2014. However, it is unlikely that we will be able to complete the current rulemaking to revise the type size labeling requirements for FOP calorie declarations before the July 26, 2018 compliance date. Therefore, pending completion of this rulemaking, FDA intends to exercise enforcement discretion with respect to the July 26, 2018 compliance date for products sold in glass front vending machines that provide a FOP calorie disclosure and

the product complies with all aspects of the final vending machine labeling rule except that the disclosure is not 50 percent of the size of the largest print on the label.

Further, as previously noted, vending machine operators with glass front vending machines will have to comply by July 26, 2018, with all vending machine requirements, including complying with calorie disclosure requirements in 21 CFR 101.8(c)(2). Although these requirements cover gums, mints, and roll candy products sold in glass front machines, FDA intends to exercise enforcement discretion, at least until January 1, 2020, with respect to gums, mints, and roll candy products sold in glass front machines in packages that are too small to bear FOP labeling. FDA intends to consider this issue further.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This proposed rule has been designated as a significant regulatory action as defined by Executive Order 12866. This proposed rule is expected to be an Executive Order 13771 deregulatory action. Additional details can be found in the proposed rule’s preliminary economic analysis.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The vending machine final rule does not impose burdens to the suppliers of vending machine foods. While suppliers are not obliged to engage in FOP calorie labeling, this proposed rule, if finalized, would allow for greater flexibility for the use of FOP calorie labeling in glass front vending machines than the existing regulations,

potentially reducing the burden on covered vending machine operators of providing additional calorie labeling. Thus, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits and Costs of the Proposed Rule

FDA proposes to revise the type size labeling requirements for providing FOP calorie declarations for packaged food sold from certain vending machines. We are taking this action in response to requests from the vending and packaged foods industries to reduce the regulatory burden and increase flexibility. The proposed rule would revise the type size requirements for FOP calorie labeling on packaged foods displayed for sale in glass front vending machines.

There are currently several voluntary FOP labeling programs where calorie information is presented. If finalized, this proposal may provide an increased incentive for packaged food manufacturers to add new or amend current FOP calorie labeling to foods in order to comply with the updated standard. If so, glass front vending machine operators carrying exclusively those products will not have to provide signs with calorie information for the food, providing an opportunity to reduce operator costs. To the extent this occurs, some costs may shift from the vending machine operator to the manufacturer. Packaged food manufacturing firms may choose to incur additional costs associated with amending the FOP label in order to retain revenue streams from current customers, including vending machine operators. If total revenue is greater than total cost, this proposed rule will provide cost savings for packaged food manufacturing firms. We expect the potential cost savings to both vending machine operators and packaged food manufacturers to outweigh the costs to

packaged food manufacturers and thus the net effect to be positive, but lack the data to quantify this effect. We welcome data that would help us to better estimate these impacts.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 8) and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no new collection of information beyond what was described in the December 2014 final rule and approved under OMB control number 0910–0782. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to construe a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute. Federal law includes an express preemption provision that preempts any nutrition labeling requirement of food that is not identical to the requirement of section 403(q) of the FD&C Act, except that this provision does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment elects to comply voluntarily with the nutrition information requirements under section 403(q)(5)(H)(ix) of the FD&C Act. The proposed rule would create requirements for nutrition labeling of food under section 403(q) of the FD&C

Act that would preempt certain non-identical State and local nutrition labeling requirements.

Section 4205 of the Patient Protection and Affordable Care Act (ACA), which amended the FD&C Act to require certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines, also included a Rule of Construction providing that nothing in the amendments made by section 4205 of the ACA shall be construed: (1) To preempt any provision of State or local law, unless such provision establishes or continues into effect nutrient content disclosures of the type required under section 403(q)(5)(H) of the FD&C Act and is expressly preempted under subsection (a)(4) of such section; (2) to apply to any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food; or (3) except as provided in section 403(q)(5)(H)(ix) of the FD&C Act, to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in section 403(q)(5)(H)(i) of the FD&C Act (see Pub. L. 111–148, section 4205(d) of the ACA, 124 Stat. 119, 576 (2010)).

We interpret the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold from vending machines that must comply with the Federal requirements of section 403(q)(5)(H) of the FD&C Act, unless the State or local requirements are identical to the Federal requirements. In other words, States and localities cannot have additional or different nutrition labeling requirements for food sold either: (1) From vending machines that are operated by a person engaged in the business of owning or operating 20 or more vending machines subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act; or (2) from vending machines operated by a person not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act who voluntarily elects to be subject to those requirements by registering biannually under section 403(q)(5)(H)(ix) of the FD&C Act.

Otherwise, for food sold from vending machines not subject to the nutrition labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act, States and localities may impose nutrition labeling requirements. Under our interpretation of section 4205(d)(1) of the ACA, nutrition labeling for food sold from these vending machines would not be nutrient content

disclosures of the type required under section 403(q)(5)(H)(viii) of the FD&C Act and, therefore, would not be preempted. Under this interpretation, States and localities would be able to continue to require nutrition labeling for food sold from vending machines that are exempt from nutrition labeling under section 403(q)(5) of the FD&C Act. This interpretation is consistent with the fact that Congress included vending machine operators in the voluntary registration provision of section 403(q)(5)(H)(ix) of the FD&C Act. There would have been no need to include vending machine operators in the provision that allows opting into the Federal requirements if States and localities could not otherwise require non-identical nutrition labeling for food sold from any vending machines.

In addition, the express preemption provisions of 21 U.S.C. 343–1(a)(4) do not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food. This is clear from both the literal language of 21 U.S.C. 343–1(a)(4) with respect to the scope of preemption and from the Rule of Construction at section 4205(d)(2) of the ACA.

X. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, “Guidance for Industry: A Food Labeling Guide (4. Name of Food)”, last updated January 2013. Retrieved from <https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf>.
2. Letter from Karin F. R. Moore, Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, dated March 31, 2016.
3. Letter from Karin F. R. Moore, Senior Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Susan Mayne, Ph.D., Director, Center for

Food Safety and Applied Nutrition, dated June 28, 2016.

4. Letter from Karin F. R. Moore, Senior Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Scott Gottlieb, M.D., Commissioner of Food and Drugs, FDA, dated July 19, 2017.
5. Letter from Jason Eberstein, Director, State & Federal Government Affairs, National Automated Merchandising Association, to Scott Gottlieb, M.D., Commissioner of Food and Drugs, FDA, dated November 21, 2017.
6. Letter from Brad G. Figel, Vice President, North America Public Affairs, Mars, Inc., to Mick Mulvaney, Director, Office of Management and Budget, dated January 30, 2018.
7. Letter from Elizabeth Avery, President and CEO, SNAC International, to Dockets Management Staff, FDA, dated February 12, 2018.
8. FDA, “Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Preliminary Small Entity Analysis,” dated June 2018. Also available at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

- 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

- 2. Section 101.8 is amended by revising paragraph (b)(2) to read as follows:

§ 101.8 Vending machines.

* * * * *

(b) * * *

(2) The prospective purchaser can otherwise view visible nutrition information, including, at a minimum, the total number of calories for the article of food as sold at the point of purchase. This visible nutrition information must appear on the food label itself. The visible nutrition information must be clear and conspicuous and able to be easily read on the article of food while in the

vending machine, in a type size at least 150 percent of the size of the net quantity of contents declaration on the front of the package, and with sufficient color and contrasting background to other print on the label to permit the prospective purchaser to clearly distinguish the information.

* * * * *

Dated: July 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14906 Filed 7-11-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 328

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401

[EPA-HQ-OW-2017-0203; FRL-9980-52-OW]

RIN 2040-AF74

Definition of “Waters of the United States”—Recodification of Preexisting Rule

AGENCY: Department of Defense, Department of the Army, Corps of Engineers; Environmental Protection Agency (EPA).

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The purpose of this supplemental notice is for the Environmental Protection Agency (EPA) and the Department of the Army (agencies) to clarify, supplement and seek additional comment on an earlier proposal, published on July 27, 2017, to repeal the 2015 Rule Defining Waters of the United States (“2015 Rule”), which amended portions of the Code of Federal Regulations (CFR). As stated in the agencies’ July 27, 2017 Notice of Proposed Rulemaking (NPRM), the agencies propose to repeal the 2015 Rule and restore the regulatory text that existed prior to the 2015 Rule, as informed by guidance in effect at that time. If this proposal is finalized, the regulations defining the scope of federal Clean Water Act (CWA) jurisdiction would be those portions of the CFR as they existed before the amendments promulgated in the 2015 Rule. Those preexisting regulatory definitions are

the ones that the agencies are currently implementing in light of the agencies’ final rule published on February 6, 2018, adding a February 6, 2020 applicability date to the 2015 Rule, as well as judicial decisions preliminarily enjoining and staying the 2015 Rule.

DATES: Comments must be received on or before August 13, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2017-0203, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The agencies may publish any comment received to the public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The agencies will generally not consider comments or comment content located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets.commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Michael McDavid, Office of Water (4504-T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566-2428; email address: CWAwotus@epa.gov; or Stacey Jensen, Regulatory Community of Practice (CECW-CO-R), U.S. Army Corps of Engineers, 441 G Street NW, Washington, DC 201314; telephone number: (202) 761-6903; email address: USACE_CWA_Rule@usace.army.mil.

SUPPLEMENTARY INFORMATION: The agencies propose to repeal the Clean Water Rule: Definition of “Waters of the United States,” 80 FR 37054, and recodify the regulatory definitions of “waters of the United States” that existed prior to the August 28, 2015 effective date of the 2015 Rule. Those preexisting regulatory definitions are the ones that the agencies are currently implementing in light of the agencies’ final rule (83 FR 5200, February 6, 2018), which added a February 6, 2020 applicability date to the 2015 Rule. Judicial decisions currently enjoin the

2015 Rule in 24 States as well. If this proposal is finalized, the agencies would administer the regulations promulgated in 1986 and 1988 in portions of 33 CFR part 328 and 40 CFR parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401, and would continue to interpret the statutory term “waters of the United States” to mean the waters covered by those regulations, as the agencies are currently implementing those regulations consistent with Supreme Court decisions and longstanding practice, as informed by applicable guidance documents, training, and experience.

State, tribal, and local governments have well-defined and established relationships with the federal government in implementing CWA programs. Those relationships are not affected by this proposed rule, which would not alter the jurisdiction of the CWA compared to the regulations and practice that the agencies are currently applying. The proposed rule would permanently repeal the 2015 Rule, which amended the longstanding definition of “waters of the United States” in portions of 33 CFR part 328 and 40 CFR parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401, and restore the regulations as they existed prior to the amendments in the 2015 Rule.¹

The agencies are issuing this supplemental notice of proposed rulemaking (SNPRM) to clarify, supplement and give interested parties an opportunity to comment on certain important considerations and reasons for the agencies’ proposal. The agencies clarify herein the scope of the solicitation of comment and the actions proposed. In response to the July 27, 2017 NPRM, (82 FR 34899), the agencies received numerous comments on the impacts of repealing the 2015 Rule in its entirety. Others commented in favor of retaining the 2015 Rule, either as written or with modifications. Some commenters interpreted the proposal as restricting their opportunity to provide such comments either supporting or opposing repeal of the 2015 Rule. In this SNPRM, the agencies reiterate that this regulatory action is intended to permanently repeal the 2015 Rule in its entirety, and we invite all interested persons to comment on whether the 2015 Rule should be repealed.

¹ While EPA administers most provisions in the CWA, the Department of the Army, Corps of Engineers (Corps) administers the permitting program under section 404. During the 1980s, both agencies adopted substantially similar definitions of “waters of the United States.” See 51 FR 41206, Nov. 13, 1986, amending 33 CFR 328.3; 53 FR 20764, June 6, 1988, amending 40 CFR 232.2.

The agencies are also issuing this SNPRM to clarify that the rule adding an applicability date to the 2015 Rule does not change the agencies' decision to proceed with this proposed repeal. For the reasons discussed in this notice, the agencies propose to conclude that regulatory certainty would be best served by repealing the 2015 Rule and recodifying the scope of CWA jurisdiction currently in effect. The agencies propose to conclude that rather than achieving its stated objectives of increasing predictability and consistency under the CWA, *see* 80 FR 37055, the 2015 Rule is creating significant confusion and uncertainty for agency staff, regulated entities, states, tribes, local governments, and the public, particularly in view of court decisions that have cast doubt on the legal viability of the rule. To provide for greater regulatory certainty, the agencies propose to repeal the 2015 Rule and to recodify the pre-2015 regulations, thereby maintaining a longstanding regulatory framework that is more familiar to and better-understood by the agencies, states, tribes, local governments, regulated entities, and the public.

Further, court rulings against the 2015 Rule suggest that the interpretation of the "significant nexus" standard as applied in the 2015 Rule may not comport with and accurately implement the legal limits on CWA jurisdiction intended by Congress and reflected in decisions of the Supreme Court. At a minimum, the agencies find that the interpretation of the statute adopted in the 2015 Rule is not compelled and raises significant legal questions. In light of the substantial uncertainty associated with the 2015 Rule, including by virtue of a potential stay, injunction, or vacatur of the 2015 Rule in various legal challenges, as well as the substantial experience the agencies already possess implementing the preexisting regulations that the agencies are implementing today, the agencies propose to conclude that administrative goals of regulatory certainty would be best served by repealing the 2015 Rule.

The agencies also propose to conclude that the 2015 Rule exceeded the agencies' authority under the CWA by adopting such an interpretation of Justice Kennedy's "significant nexus" standard articulated in *Rapanos v. United States* and *Carabell v. United States*, 547 U.S. 715 (2006) ("*Rapanos*") as to be inconsistent with important aspects of that opinion and to cover waters outside the scope of the Act, even though that concurring opinion was identified as the basis for the significant nexus standard articulated in

the 2015 Rule. The agencies also propose to conclude that, contrary to conclusions articulated in support of the rule, the 2015 Rule appears to have expanded the meaning of tributaries and adjacent wetlands to include waters well beyond those regulated by the agencies under the preexisting regulations, as applied by the agencies following decisions of the Supreme Court in *Rapanos* and *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159 (2001) ("*SWANCC*"). The agencies believe that the 2015 Rule may have altered the balance of authorities between the federal and State governments, contrary to the agencies' statements in promulgating the 2015 Rule and in contravention of CWA section 101(b), 33 U.S.C. 1251(b).

I. Background

The agencies refer the public to the Executive Summary for the NPRM, 82 FR 34899 (July 27, 2017), and incorporate it by reference herein.

A. The 2015 Rule

On June 29, 2015, the agencies issued a final rule (80 FR 37054) amending various portions of the CFR that set forth definitions of "waters of the United States," a term contained in the CWA section 502(7) definition of "navigable waters," 33 U.S.C. 1362(7).

A primary purpose of the 2015 Rule was to "increase CWA program predictability and consistency by clarifying the scope of 'waters of the United States' protected under the Act." 80 FR 37054. The 2015 Rule attempted to clarify the geographic scope of the CWA by placing waters into three categories: (A) Waters that are categorically "jurisdictional by rule" in all instances (*i.e.*, without the need for any additional analysis); (B) waters that are subject to case-specific analysis to determine whether they are jurisdictional, and (C) waters that are categorically excluded from jurisdiction. Waters that are "jurisdictional by rule" include (1) waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters which are subject to the ebb and flow of the tide; (2) interstate waters, including interstate wetlands; (3) the territorial seas; (4) impoundments of waters otherwise identified as jurisdictional; (5) tributaries of the first three categories of "jurisdictional by rule" waters; and (6) waters adjacent to a water identified in the first five categories of "jurisdictional by rule" waters, including wetlands, ponds, lakes,

oxbows, impoundments, and similar waters. *See id.* at 37104.

The 2015 Rule added new definitions of key terms such as "tributaries" and revised previous definitions of terms such as "adjacent" (by adding a new definition of "neighboring" that is used in the definition of "adjacent") that would determine whether waters are "jurisdictional by rule." *See id.* at 37105. Specifically, a tributary under the 2015 Rule is a water that contributes flow, either directly or through another water, to a water identified in the first three categories of "jurisdictional by rule" waters and that is characterized by the presence of the "physical indicators" of a bed and banks and an ordinary high water mark. "These physical indicators demonstrate there is volume, frequency, and duration of flow sufficient to create a bed and banks and therefore an ordinary high water mark, and thus to qualify as a tributary." *Id.* The 2015 Rule does not delineate jurisdiction specifically based on categories with established scientific meanings such as ephemeral, intermittent, and perennial waters that are based on the source of the water and nature of the flow. *See id.* at 37076 ("Under the rule, flow in the tributary may be perennial, intermittent, or ephemeral."). Under the 2015 Rule, tributaries need not be demonstrated to possess any specific volume, frequency, or duration of flow, or to contribute flow to a traditional navigable water in any given year or specific time period. Tributaries under the 2015 Rule can be natural, man-altered, or man-made, and they do not lose their status as a tributary if, for any length, there are one or more constructed breaks (such as bridges, culverts, pipes, or dams), or one or more natural breaks (such as wetlands along the run of a stream, debris piles, boulder fields, or a stream that flows underground) so long as a bed and banks and an ordinary high water mark can be identified upstream of the break. *Id.* at 37105–06.

In the 2015 Rule, the agencies did not expressly amend the longstanding definition of "adjacent" (defined as "bordering, contiguous, or neighboring"), but the agencies added a new definition of "neighboring" that impacted the interpretation of "adjacent." The 2015 Rule defined "neighboring" to encompass all waters located within 100 feet of the ordinary high water mark of a category (1) through (5) "jurisdictional by rule" water; all waters located within the 100-year floodplain of a category (1) through (5) "jurisdictional by rule" water and not more than 1,500 feet from the ordinary high water mark of such water;

all waters located within 1,500 feet of the high tide line of a category (1) through (3) “jurisdictional by rule” water; and all waters within 1,500 feet of the ordinary high water mark of the Great Lakes. *Id.* at 37105. The entire water is considered neighboring if any portion of it lies within one of these zones. *See id.* This regulatory text did not appear in the proposed rule, and thus the agencies did not receive public comment on these numeric measures.

In addition to the six categories of “jurisdictional by rule” waters, the 2015 Rule identifies certain waters that are subject to a case-specific analysis to determine if they have a “significant nexus” to a water that is jurisdictional. *Id.* at 37104–05. The first category consists of five specific types of waters in specific regions of the country: Prairie potholes, Carolina and Delmarva bays, pocosins, western vernal pools in California, and Texas coastal prairie wetlands. *Id.* at 37105. The second category consists of all waters located within the 100-year floodplain of any category (1) through (3) “jurisdictional by rule” water and all waters located within 4,000 feet of the high tide line or ordinary high water mark of any category (1) through (5) “jurisdictional by rule” water. *Id.* These quantitative measures did not appear in the proposed rule, and thus the agencies did not receive public comment on these specific measures.

The 2015 Rule defines “significant nexus” to mean a water, including wetlands, that either alone or in combination with other similarly situated waters in the region, significantly affects the chemical, physical, or biological integrity of a category (1) through (3) “jurisdictional by rule” water. 80 FR 37106. “For an effect to be significant, it must be more than speculative or insubstantial.” *Id.* The term “in the region” means “the watershed that drains to the nearest” primary water.² *Id.* This definition is different than the test articulated by the agencies in their 2008 *Rapanos* Guidance.³ That guidance interpreted “similarly situated” to include all wetlands (not waters) adjacent to the

same tributary, a much less expansive treatment of similarly situated waters than in the 2015 Rule.

Under the 2015 Rule, to determine whether a water, alone or in combination with similarly situated waters across a watershed, has such an effect, one must look at nine functions such as sediment trapping, runoff storage, provision of life cycle dependent aquatic habitat, and other functions. It is sufficient for determining whether a water has a significant nexus if any single function performed by the water, alone or together with similarly situated waters in the watershed, contributes significantly to the chemical, physical, or biological integrity of the nearest category (1) through (3) “jurisdictional by rule” water. *Id.* Taken together, the enumeration of the nine functions and the more expansive consideration of “similarly situated” in the 2015 Rule could mean that the vast majority of water features in the United States may come within the jurisdictional purview of the federal government.⁴ Indeed, the agencies stated in the 2015 Rule that the “the chemical, physical, and biological integrity of downstream waters is directly related to the aggregate contribution of upstream waters that flow into them, including any tributaries and connected wetlands.” *Id.* at 37066.

The agencies also retained exclusions from the definition of “waters of the United States” for prior converted cropland and waste treatment systems. *Id.* at 37105. In addition, the agencies codified several exclusions that reflected longstanding agency practice, and added others such as “puddles” and “swimming pools” in response to concerns raised by stakeholders during the public comment period on the proposed 2015 Rule. *Id.* at 37096–98, 37105.

B. Legal Challenges to the 2015 Rule

Following the 2015 Rule’s publication, 31 States⁵ and 53 non-state

parties, including environmental groups, and groups representing farming, recreational, forestry, and other interests, filed complaints and petitions for review in multiple federal district⁶ and appellate⁷ courts challenging the 2015 Rule. In those cases, the challengers alleged procedural deficiencies in the development and promulgation of the 2015 Rule and substantive deficiencies in the 2015 Rule itself. Some challengers argued that the 2015 Rule was too expansive while others argued that it excluded too many waters from federal jurisdiction.

The day before the 2015 Rule’s August 28, 2015 effective date, the U.S. District Court for the District of North Dakota preliminarily enjoined the 2015 Rule in the 13 States that challenged the rule in that court.⁸ The district court found those States were “likely to succeed” on the merits of their challenge to the 2015 Rule because, among other reasons, “it appears likely that the EPA has violated its Congressional grant of authority in its promulgation of the Rule.” In particular, the court noted concern that the 2015 Rule’s definition of tributary “includes vast numbers of waters that are unlikely to have a nexus to navigable waters.” Further, the court found that “it appears likely that the EPA failed to comply with [Administrative Procedure Act (APA)] requirements when promulgating the Rule,” suggesting that certain distance-based measures were not a logical outgrowth of the proposal to the 2015 Rule. *North Dakota v. EPA*, 127 F. Supp. 3d 1047, 1051, 1056, 1058 (D.N.D. 2015). No party sought an interlocutory appeal.

The petitions for review filed in the courts of appeals were consolidated in the U.S. Court of Appeals for the Sixth Circuit. In that litigation, state and industry petitioners raised concerns about whether the 2015 Rule violates the Constitution and the CWA and whether its promulgation violated

Utah, West Virginia, Wisconsin, and Wyoming. Iowa joined the legal challenge later in the process, bringing the total to 32 States.

⁶ U.S. District Courts for the Northern and Southern District of Georgia, District of Minnesota, District of North Dakota, Southern District of Ohio, Northern District of Oklahoma, Southern District of Texas, District of Arizona, Northern District of Florida, District of the District of Columbia, Western District of Washington, Northern District of California, and Northern District of West Virginia.

⁷ U.S. Court of Appeals for the Second, Fifth, Sixth, Eighth, Ninth, Tenth, Eleventh, and District of Columbia Circuits.

⁸ Alaska, Arizona, Arkansas, Colorado, Idaho, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, and Wyoming. Iowa’s motion to intervene in the case was granted after issuance of the preliminary injunction.

² In this notice, a “primary” water is a category (1) through (3) “jurisdictional by rule” water.

³ *See* U.S. EPA and U.S. Army Corps of Engineers, Clean Water Act Jurisdiction Following the U.S. Supreme Court’s Decision in *Rapanos v. United States & Carabell v. United States* at 1 (Dec. 2, 2008) (“*Rapanos* Guidance”), available at https://www.epa.gov/sites/production/files/2016-02/documents/cwa_jurisdiction_following_rapanos120208.pdf. The agencies acknowledge that the *Rapanos* Guidance did not impose legally binding requirements, *see id.* at 4 n.17, but believe that this guidance is relevant to the discussion in this notice.

⁴ “[T]he vast majority of the nation’s water features are located within 4,000 feet of a covered tributary, traditional navigable water, interstate water, or territorial sea.” U.S. EPA and Department of the Army, Economic Analysis of the EPA-Army Clean Water Rule at 11 (May 20, 2015) (“2015 Rule Economic Analysis”) (Docket ID: EPAHQ-OW-2011-0880-20866), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-20866>.

⁵ Alabama, Alaska, Arizona, Arkansas, Colorado, Florida, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico (Environment Department and State Engineer), North Carolina (Department of Environment and Natural Resources), North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas,

procedural requirements under the APA and other statutes. Environmental petitioners also challenged the 2015 Rule, including exclusions therein. On October 9, 2015, approximately six weeks after the 2015 Rule took effect in the 37 States that were not subject to the preliminary injunction issued by the District of North Dakota, the Sixth Circuit stayed the 2015 Rule nationwide after finding, among other things, that State petitioners had demonstrated “a substantial possibility of success on the merits of their claims.” *In re EPA & Dep’t of Def. Final Rule*, 803 F.3d 804 (6th Cir. 2015) (“*In re EPA*”).

On January 13, 2017, the U.S. Supreme Court granted *certiorari* on the question of whether the courts of appeals have original jurisdiction to review challenges to the 2015 Rule. *See Nat’l Ass’n of Mfrs. v. Dep’t of Defense*, 137 S. Ct. 811 (2017). The Sixth Circuit granted petitioners’ motion to hold in abeyance the briefing schedule in the litigation challenging the 2015 Rule pending a Supreme Court decision on the question of the court of appeals’ jurisdiction. On January 22, 2018, the Supreme Court, in a unanimous opinion, held that the 2015 Rule is subject to direct review in the district courts. *Nat’l Ass’n of Mfrs. v. Dep’t of Def.*, 138 S. Ct. 617, 624 (2018). Throughout the pendency of the Supreme Court litigation (and for a short time thereafter), the Sixth Circuit’s nationwide stay remained in effect. In response to the Supreme Court’s decision, on February 28, 2018, the Sixth Circuit lifted the stay and dismissed the corresponding petitions for review. *See In re Dep’t of Def. & EPA Final Rule*, 713 Fed. App’x 489 (6th Cir. 2018).

Since the Supreme Court’s jurisdictional ruling, district court litigation regarding the 2015 Rule has resumed. At this time, the 2015 Rule continues to be subject to a preliminary injunction issued by the District of North Dakota as to 13 States: Alaska, Arizona, Arkansas, Colorado, Idaho, Missouri, Montana, Nebraska, Nevada, North Dakota, South Dakota, Wyoming, and New Mexico. The 2015 Rule also is subject to a preliminary injunction issued by the U.S. District Court for the Southern District of Georgia as to 11 more States: Georgia, Alabama, Florida, Indiana, Kansas, Kentucky, North Carolina, South Carolina, Utah, West Virginia, and Wisconsin. *See Georgia v. Pruitt*, No. 15–cv–79 (S.D. Ga.). In another action, the U.S. District Court for the Southern District of Texas is considering preliminary injunction motions filed by parties including the States of Texas, Louisiana, and

Mississippi. *See Texas v. EPA*, No. 3:15–cv–162 (S.D. Tex.); *Am. Farm Bureau Fed’n et al. v. EPA*, No. 3:15–cv–165 (S.D. Tex.). At least three additional States are seeking a preliminary injunction in the U.S. District Court for the Southern District of Ohio as well. *See, e.g., States’ Supplemental Memorandum in Support of Preliminary Injunction, Ohio v. EPA*, No. 2:15–cv–02467 (S.D. Ohio June 20, 2018) (brief filed by the States of Ohio, Michigan, and Tennessee in support of the States’ motion for a preliminary injunction against the 2015 Rule).

C. Executive Order 13778, the Notice of Proposed Rulemaking, and the Applicability Date Rule

The agencies are engaged in a two-step process intended to review and repeal or revise, as appropriate and consistent with law, the definition of “waters of the United States” as set forth in the 2015 Rule. This process began in response to Executive Order 13778 issued on February 28, 2017, by the President entitled “Restoring the Rule of Law, Federalism, and Economic Growth by Reviewing the ‘Waters of the United States’ Rule.” Section 1 of the Executive Order states, “[i]t is in the national interest to ensure the Nation’s navigable waters are kept free from pollution, while at the same time promoting economic growth, minimizing regulatory uncertainty, and showing due regard for the roles of the Congress and the States under the Constitution.” The Order directed the EPA and the Army to review the 2015 Rule for consistency with the policy outlined in Section 1 of the Order and to issue a proposed rule rescinding or revising the 2015 Rule as appropriate and consistent with law (Section 2). The Executive Order also directed the agencies to “consider interpreting the term ‘navigable waters’ . . . in a manner consistent with” Justice Scalia’s plurality opinion in *Rapanos* (Section 3).

On March 6, 2017, the agencies published a notice of intent to review the 2015 Rule and provide notice of a forthcoming proposed rulemaking consistent with the Executive Order. 82 FR 12532. Shortly thereafter, the agencies announced that they would implement the Executive Order in a two-step approach. On July 27, 2017, the agencies published a NPRM (82 FR 34899) that proposed to rescind the 2015 Rule and restore the regulatory text that governed prior to the promulgation of the 2015 Rule, which the agencies have been implementing since the judicial stay of the 2015 Rule consistent with Supreme Court decisions and

informed by applicable guidance documents and longstanding agency practice. The agencies invited comment on the NPRM over a 62-day period.

Shortly after the Supreme Court decided that the courts of appeals do not have original jurisdiction to review challenges to the 2015 Rule and directed the Sixth Circuit to dismiss the consolidated challenges to the 2015 Rule for lack of jurisdiction, the agencies issued a final rule (83 FR 5200, Feb. 6, 2018), after providing notice and an opportunity for public comment, that added an applicability date to the 2015 Rule. The applicability date was established as February 6, 2020. When adding the applicability date to the 2015 Rule, the agencies clarified that they will continue to implement nationwide the previous regulatory definition of “waters of the United States,” consistent with the practice and procedures the agencies implemented before and immediately following the issuance of the 2015 Rule pursuant to the preliminary injunction issued by the District of North Dakota and the nationwide stay issued by the Sixth Circuit. The agencies further explained that the final applicability date rule would ensure regulatory certainty and consistent implementation of the CWA nationwide while the agencies reconsider the 2015 Rule and potentially pursue further rulemaking to develop a new definition of “waters of the United States.” The applicability date rule was challenged in a number of district courts. Generally, the challenges raise concerns that the agencies’ action was arbitrary and capricious because the agencies did not address substantive comments regarding the 2015 Rule, as well as procedural concerns with respect to the length of the public comment period for the proposed applicability date rule. At this time, these challenges remain pending in the district courts where they were filed.

D. Comments on the Original Notice of Proposed Rulemaking

The agencies accepted comments on the NPRM from July 27, 2017, through September 27, 2017. The agencies received more than 685,000 comments on the NPRM from a broad spectrum of interested parties. The agencies are continuing to review those extensive comments. Some commenters expressed support for the agencies’ proposal to repeal the 2015 Rule, stating, among other things, that the 2015 Rule exceeds the agencies’ statutory authority. Other commenters opposed the proposal, stating, among other things, that repealing the 2015 Rule will increase

regulatory uncertainty and adversely impact water quality.

Based on the agencies' careful and ongoing review of the comments submitted in response to the NPRM, the agencies believe that it is in the public interest to provide further explanation and allow interested parties additional opportunity to comment on the proposed repeal of the 2015 Rule. Because some commenters interpreted the NPRM as restricting their ability to comment on the legal and policy reasons for or against the repeal of the 2015 Rule while others submitted comments addressing these topics, the agencies wish to make clear that comments on that subject are solicited. Additionally, some commenters appeared to be confused by whether the agencies proposed a temporary or interim, as opposed to a permanent, repeal of the 2015 Rule. While the agencies did refer to the July 2017 proposal as an "interim action" (82 FR 34902), that was in the context of explaining that the proposal to repeal the 2015 Rule is the first step of a two-step process, as described above, and that the agencies are planning to take the additional, second step of conducting a separate notice and comment rulemaking to propose a new definition of "waters of the United States." In this notice, the agencies are clarifying that, regardless of the timing or ultimate outcome of that additional rulemaking, the agencies are proposing a permanent repeal of the 2015 Rule at this stage. This was also our intent in the NPRM. Finally, some commenters did not fully understand the precise action the NPRM proposed to take, *e.g.*, repealing, staying, or taking some other action with respect to the 2015 Rule. The agencies are issuing this SNPRM and are inviting all interested persons to comment on whether the agencies should repeal the 2015 Rule and recodify the regulations currently being implemented by the agencies.

E. Comments on This Supplemental Notice of Proposed Rulemaking

As discussed in the next sections, the agencies are proposing to permanently repeal the 2015 Rule. The agencies welcome comment on all issues that are relevant to the consideration of whether to repeal the 2015 Rule. In response to the initial NPRM, many commenters have already provided comment on considerations and issues that weigh in favor of or against repeal, including many of the issues articulated below. The agencies will consider all of those previously submitted comments, in addition to any new comments submitted in response to this SNPRM,

in taking a final action on this rulemaking. As such, commenters need not resubmit comments already provided in response to the agencies' July 27, 2017 NPRM (82 FR 34899).

II. Proposal To Repeal the 2015 Rule

A. Legal Authority To Repeal

The agencies' ability to repeal an existing regulation through notice-and-comment rulemaking is well-grounded in the law. The APA defines rulemaking to mean "agency process for formulating, amending, or repealing a rule." 5 U.S.C. 551(5). The CWA complements this authority by providing the Administrator with broad authority to "prescribe such regulations as are necessary to carry out the functions under this Act." 33 U.S.C. 1361(a). This broad authority includes regulations that repeal or revise CWA implementing regulations promulgated by a prior administration.

The Supreme Court has made clear that "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change," and "[w]hen an agency changes its existing position, it 'need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (citations omitted). The NPRM discussed how the agencies may revise or repeal the regulatory definition of "waters of the United States" so long as the agencies' action is based on a reasoned explanation. See 82 FR 34901. The agencies can do so based on changes in circumstance, or changes in statutory interpretation or policy judgments. See, *e.g.*, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514–15 (2009); *Ctr. for Sci. in Pub. Interest v. Dep't of Treasury*, 797 F.2d 995, 998–99 & n.1 (D.C. Cir. 1986). The agencies' interpretation of the statutes they administer, such as the CWA, are not "instantly carved in stone"; quite the contrary, the agencies "must consider varying interpretations and the wisdom of [their] policy on a continuing basis, . . . for example, in response to . . . a change in administrations." *Nat'l Cable & Telecomm'ns Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981–82 (2005) ("*Brand X*") (internal quotation marks omitted) (quoting *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 863–64 (1984)) (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 59 (1983) (Rehnquist, J., concurring in part and dissenting in part)). The Supreme Court and lower courts have acknowledged an agency's

ability to repeal regulations promulgated by a prior administration based on changes in agency policy where "the agency adequately explains the reasons for a reversal of policy." See *Brand X*, 545 U.S. at 981. A revised rulemaking based "on a reevaluation of which policy would be better in light of the facts" is "well within an agency's discretion," and "[a] change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal" of its regulations and programs. *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1038 & 1043 (D.C. Cir. 2012) ("*NAHB*").

B. Legal Background

1. The Clean Water Act

Congress amended the Federal Water Pollution Control Act (FWPCA), or Clean Water Act (CWA) as it is commonly called,⁹ in 1972 to address longstanding concerns regarding the quality of the nation's waters and the federal government's ability to address those concerns under existing law. Prior to 1972, the ability to control and redress water pollution in the nation's waters largely fell to the Corps under the Rivers and Harbors Act of 1899. Congress had also enacted the Water Pollution Control Act of 1948, Public Law 80–845, 62 Stat. 1155 (June 30, 1948), to address interstate water pollution, and subsequently amended that statute in 1956 (giving the statute its current formal name), 1961, and 1965. The early versions of the CWA promoted the development of pollution abatement programs, required states to develop water quality standards, and authorized the federal government to bring enforcement actions to abate water pollution.

These early statutory efforts, however, proved inadequate to address the decline in the quality of the nation's waters, see *City of Milwaukee v. Illinois*, 451 U.S. 304, 310 (1981), so Congress performed a "total restructuring" and "complete rewriting" of the existing statutory framework in 1972, *id.* at 317 (quoting legislative history of 1972 amendments). That restructuring resulted in the enactment of a comprehensive scheme designed to prevent, reduce, and eliminate pollution in the nation's waters generally, and to regulate the discharge of pollutants into navigable waters specifically. See, *e.g.*,

⁹ The FWPCA is commonly referred to as the CWA following the 1977 amendments to the FWPCA. Public Law 95–217, 91 Stat. 1566 (1977). For ease of reference, the agencies will generally refer to the FWPCA in this notice as the CWA or the Act.

S.D. Warren Co. v. Maine Bd. of Env'tl. Prot., 547 U.S. 370, 385 (2006) (“[T]he Act does not stop at controlling the ‘addition of pollutants,’ but deals with ‘pollution’ generally[.]”).

The objective of the new statutory scheme was “to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.” 33 U.S.C. 1251(a). In order to meet that objective, Congress declared two national goals: (1) “that the discharge of pollutants into the navigable waters be eliminated by 1985;” and (2) “that wherever attainable, an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water be achieved by July 1, 1983. . . .” *Id.* at 1251(a)(1)–(2).

Congress established several key policies that direct the work of the agencies to effectuate those goals. For example, Congress declared as a national policy “that the discharge of toxic pollutants in toxic amounts be prohibited; . . . that Federal financial assistance be provided to construct publicly owned waste treatment works; . . . that areawide waste treatment management planning processes be developed and implemented to assure adequate control of sources of pollutants in each State; . . . [and] that programs for the control of nonpoint sources of pollution be developed and implemented in an expeditious manner so as to enable the goals of this Act to be met through the control of both point and nonpoint sources of pollution.” *Id.* at 1251(a)(3)–(7).

Congress envisioned a major role for the states in implementing the CWA, and the CWA also recognizes the importance of preserving the states’ independent authority and responsibility in this area. The CWA balances the traditional power of states to regulate land and water resources within their borders with the need for a federal water quality regulation to protect the waters of the United States. For example, the statute reflects “the policy of the Congress to recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution” and “to plan the development and use . . . of land and water resources. . . .” *Id.* at 1251(b). Congress also declared as a national policy that states manage the major construction grant program and implement the core permitting programs authorized by the statute, among other responsibilities. *Id.* Congress added that “nothing in this Act shall . . . be construed as impairing or in any

manner affecting any right or jurisdiction of the States with respect to the waters (including boundary waters) of such States.” *Id.* at 1370. Congress also pledged to provide technical support and financial aid to the states “in connection with the prevention, reduction, and elimination of pollution.” *Id.* at 1251(b).

To carry out these policies, Congress broadly defined “pollution” to mean “the man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water,” *id.* at 1362(19), to parallel the broad objective of the Act “to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters,” *id.* at 1251(a). Congress then crafted a non-regulatory statutory framework to provide technical and financial assistance to the states to prevent, reduce, and eliminate pollution in the broader set of the nation’s waters. For example, section 105 of the Act, “Grants for research and development,” authorized EPA “to make grants to any State or States or interstate agency to demonstrate, in *river basins or portions thereof*, advanced treatment and environmental enhancement techniques to control pollution from all sources, . . . including nonpoint sources, . . . [and] for research and demonstration projects for prevention of pollution of *any waters* by industry *including, but not limited to, the prevention, reduction, and elimination of the discharge of pollutants.*” 33 U.S.C. 1255(b)–(c) (emphases added); *see also id.* at 1256(a) (authorizing EPA to issue “grants to States and to interstate agencies to assist them in administering programs for the prevention, reduction, and elimination of pollution”). Section 108, “Pollution control in the Great Lakes,” authorized EPA to enter into agreements with any state to develop plans for the “elimination or control of pollution, *within all or any part of the watersheds* of the Great Lakes.” *Id.* at 1258(a) (emphasis added); *see also id.* at 1268(a)(3)(C) (defining the “Great Lakes System” as “all the streams, rivers, lakes, and other bodies of water within the drainage basin of the Great Lakes”). Similar broad pollution control programs were created for other major watersheds, including, for example, the Chesapeake Bay, *see id.* at 1267(a)(3), Long Island Sound, *see id.* at 1269(c)(2)(D), and Lake Champlain, *see id.* at 1270(g)(2).

For the narrower set of the nation’s waters identified as “navigable waters” or “the waters of the United States,” *id.* at 1362(7), Congress created a federal regulatory permitting program designed to address the discharge of pollutants

into those waters. Section 301 contains the key regulatory mechanism: “Except as in compliance with this section and sections 302, 306, 307, 318, 402, and 404 of this Act, the discharge of any pollutant by any person shall be unlawful.” *Id.* at 1311(a). A “discharge of a pollutant” is defined to include “any addition of any pollutant to *navigable waters* from any point source,” such as a pipe, ditch or other “discernible, confined and discrete conveyance.” *Id.* at 1362(12), (14) (emphasis added). The term “pollutant,” as compared to the broader term “pollution,” *id.* at 1362(19), means “dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water.” *Id.* at 1362(6). Thus, it is unlawful to discharge pollutants into navigable waters (defined in the Act as “the waters of the United States”) from a point source unless the discharge complies with certain enumerated sections of the CWA, including obtaining authorizations to discharge pollutants pursuant to the section 402 National Pollutant Discharge Elimination System (NPDES) permit program and the section 404 dredged or fill material permit program. *See id.* at 1342 and 1344.

Under this statutory scheme, the states are responsible for developing water quality standards for waters of the United States within their borders and reporting on the condition of those waters to EPA every two years. *Id.* at 1313, 1315. States are also responsible for developing total maximum daily loads (TMDLs) for waters that are not meeting established water quality standards and must submit those TMDLs to EPA for approval. *Id.* at 1313(d). States also have authority to issue water quality certifications or waive certification for every federal permit or license issued within their borders that may result in a discharge to navigable waters. *Id.* at 1341. A change to the interpretation of “waters of the United States” may change the scope of waters subject to CWA jurisdiction and thus may change the scope of waters for which states may assume these responsibilities under the Act.

These same regulatory authorities can be assumed by Indian tribes under section 518 of the CWA, which authorizes EPA to treat eligible Indian tribes in a manner similar to states for a variety of purposes, including administering each of the principal

CWA regulatory programs. *Id.* at 1377(e). In addition, states and tribes retain sovereign authority to protect and manage the use of those waters that are not navigable waters under the CWA. *See, e.g., id.* at 1251(b), 1251(g), 1370, 1377(a). Forty-seven states administer the CWA section 402 permit program for those waters of the United States within their boundaries, and two administer the section 404 permit program. At present, no tribes administer the section 402 or 404 programs.

The agencies must develop regulatory programs designed to ensure that the full statute is implemented as Congress intended. *See, e.g., Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (“A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.”). This includes pursuing the overall “objective” of the CWA to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters,” 33 U.S.C. 1251(a), while implementing the specific “policy” directives from Congress to, among other things, “recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution” and “to plan the development and use . . . of land and water resources,” *id.* at 1251(b). *See Webster’s II, New Riverside University Dictionary* (1994) (defining “policy” as a “plan or course of action, as of a government[,] designed to influence and determine decisions and actions;” an “objective” is “something worked toward or aspired to: Goal”). To maintain that balance, the agencies must determine what Congress had in mind when it defined “navigable waters” in 1972 as simply “the waters of the United States”—and must do so in light of, *inter alia*, the policy directive to preserve and protect the states’ rights and responsibilities.

Congress’ authority to regulate navigable waters derives from its power to regulate the “channels of interstate commerce” under the Commerce Clause. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824); *see also United States v. Lopez*, 514 U.S. 549, 558–59 (1995) (describing the “channels of interstate commerce” as one of three areas of congressional authority under the Commerce Clause). The Supreme Court explained in *SWANCC* that the term “navigable” indicates “what Congress had in mind as its authority for enacting the Clean Water Act: its traditional jurisdiction over waters that were or had been navigable in fact or which could reasonably be so made.” 531 U.S. 159, 172 (2001). The Court further explained

that nothing in the legislative history of the Act provides any indication that “Congress intended to exert anything more than its commerce power over navigation.” *Id.* at 168 n.3.

The Supreme Court has cautioned that one must look to the underlying purpose of the statute to determine the scope of federal authority being exercised over navigable waters under the Commerce Clause. *See PPL Montana, LLC v. Montana*, 132 S. Ct. 1215, 1228 (2012). The Supreme Court did that in *United States v. Riverside Bayview Homes*, for example, and determined that Congress had intended “to exercise its powers under the Commerce Clause to regulate at least some waters that would not be deemed ‘navigable’ under the classical understanding of that term.” 474 U.S. 121, 133 (1985) (“[T]he evident breadth of congressional concern for protection of water quality and aquatic ecosystems suggests that it is reasonable for the Corps to interpret the term ‘waters’ to encompass wetlands adjacent to waters as more conventionally defined.”); *see also SWANCC*, 531 U.S. at 167 (noting that the *Riverside Bayview* “holding was based in large measure upon Congress’ unequivocal acquiescence to, and approval of, the Corps’ regulations interpreting the CWA to cover wetlands adjacent to navigable waters”).

The classical understanding of the term navigable was first articulated by the Supreme Court in *The Daniel Ball*:

Those rivers must be regarded as public navigable rivers in law which are navigable in fact. And they are navigable in fact when they are used, or are susceptible of being used, in their ordinary condition, as highways of commerce, over which trade and travel are or may be conducted in the customary modes of trade and travel on water. And they constitute navigable waters of the United States within the meaning of the Acts of Congress, in contradistinction from the navigable waters of the States, when they form in their ordinary condition by themselves, or by uniting with other waters, a continued highway over which commerce is or may be carried on with other States or foreign countries in the customary modes in which such commerce is conducted by water. 77 U.S. (10 Wall.) 557, 563 (1871). Over the years, this traditional test has been expanded to include waters that had been used in the past for interstate commerce, *see Economy Light & Power Co. v. United States*, 256 U.S. 113, 123 (1921), and waters that are susceptible for use with reasonable improvement, *see United States v. Appalachian Elec. Power Co.*, 311 U.S. 377, 407–10 (1940).

By the time the 1972 CWA amendments were enacted, the Supreme Court had also made clear that Congress’ authority over the channels of interstate

commerce was not limited to regulation of the channels themselves, but could extend to activities necessary to protect the channels. *See Oklahoma ex rel. Phillips v. Guy F. Atkinson Co.*, 313 U.S. 508, 523 (1941) (“Congress may exercise its control over the non-navigable stretches of a river in order to preserve or promote commerce on the navigable portions.”). The Supreme Court had also clarified that Congress could regulate waterways that formed a part of a channel of interstate commerce, even if they are not themselves navigable or do not cross state boundaries. *See Utah v. United States*, 403 U.S. 9, 11 (1971).

These developments were discussed during the legislative process leading up to the passage of the 1972 CWA amendments, and certain members referred to the scope of the amendments as encompassing waterways that serve as “links in the chain” of interstate commerce as it flows through various channels of transportation, such as railroads and highways. *See, e.g.*, 118 Cong. Rec. 33756–57 (1972) (statement of Rep. Dingell); 118 Cong. Rec. 33699 (Oct. 4, 1972) (statement of Sen. Muskie).¹⁰ Other references suggest that congressional committees at least contemplated applying the “control requirements” of the Act “to the navigable waters, portions thereof, and their tributaries.” S. Rep. No. 92–414, 92nd Cong., 1st Sess. at 77 (1971). And in 1977, when Congress authorized State assumption over the section 404 dredged or fill material permitting program, Congress limited the scope of assumable waters by requiring the Corps to retain permitting authority over Rivers and Harbors Act waters (as identified by the *Daniel Ball* test) plus wetlands adjacent to those waters, minus historic use only waters. *See* 33 U.S.C. 1344(g)(1).¹¹ This suggests that Congress had in mind a broader scope of waters subject to CWA jurisdiction than waters traditionally understood as navigable. *See SWANCC*, 531 U.S. at 171; *Riverside Bayview*, 474 U.S. at 138 n.11.

Thus, Congress intended to assert federal authority over more than just waters traditionally understood as navigable, and Congress rooted that

¹⁰ The agencies recognize that individual member statements are not a substitute for full congressional intent, but they do help provide context for issues that were discussed during the legislative debates. For a detailed discussion of the legislative history of the 1972 CWA amendments, *see* Albrecht & Nickelsburg, *Could SWANCC Be Right? A New Look at the Legislative History of the Clean Water Act*, 32 ELR 11042 (Sept. 2002).

¹¹ For a detailed discussion of the legislative history supporting the enactment of section 404(g), *see Final Report of the Assumable Waters Subcommittee* (May 2017), App. F.

authority in “its commerce power over navigation.” *SWANCC*, 531 U.S. at 168 n.3. However, there must necessarily be a limit to that authority and to what water is subject to federal jurisdiction. How the agencies should exercise that authority has been the subject of dispute for decades, but the Supreme Court on three occasions has analyzed the issue and provided some instructional guidance.

2. U.S. Supreme Court Precedent

a. Adjacent Wetlands

In *Riverside Bayview*, the Supreme Court considered the Corps’ assertion of jurisdiction over “low-lying, marshy land” immediately abutting a water traditionally understood as navigable on the grounds that it was an “adjacent wetland” within the meaning of the Corps’ then-existing regulations. 474 U.S. at 124. The Court addressed the question whether non-navigable wetlands may be regulated as “waters of the United States” on the basis that they are “adjacent to” navigable-in-fact waters and “inseparably bound up with” them because of their “significant effects on water quality and the aquatic ecosystem.” *See id.* at 131–35 & n.9.

In analyzing the meaning of adjacency, the Court captured the difficulty in determining where the limits of federal jurisdiction end, noting that the line is somewhere between open water and dry land:

In determining the limits of its power to regulate discharges under the Act, the Corps must necessarily choose some point at which water ends and land begins. Our common experience tells us that this is often no easy task: The transition from water to solid ground is not necessarily or even typically an abrupt one. Rather, between open waters and dry land may lie shallows, marshes, mudflats, swamps, bogs—in short, a huge array of areas that are not wholly aquatic but nevertheless fall far short of being dry land. Where on this continuum to find the limit of “waters” is far from obvious.

Id. at 132 (emphasis added). Within this statement, the Supreme Court identifies a basic principle for adjacent wetlands: The limits of jurisdiction lie within the “continuum” or “transition” “between open waters and dry land.” Observing that Congress intended the CWA “to regulate at least some waters that would not be deemed ‘navigable,’” the Court therefore held that it is “a permissible interpretation of the Act” to conclude that “a wetland that actually abuts on a navigable waterway” falls within the “definition of ‘waters of the United States.’” *Id.* at 133, 135. Thus, a wetland that abuts a navigable water traditionally understood as navigable is subject to CWA permitting because it is

“inseparably bound up with the ‘waters’ of the United States.” *Id.* at 134. “This holds true even for wetlands that are not the result of flooding or permeation by water having its source in adjacent bodies of open water.” *Id.* The Court also noted that the agencies can establish categories of jurisdiction for adjacent wetlands. *See id.* at 135 n.9.

The Supreme Court in *Riverside Bayview* declined to decide whether wetlands that are not adjacent to navigable waters could also be regulated by the agencies. *See id.* at 124 n.2 & 131 n.8. In *SWANCC*, however, the Supreme Court analyzed a similar question in the context of an abandoned sand and gravel pit located some distance from a traditional navigable water, with excavation trenches that ponded—some only seasonally—and served as habitat for migratory birds. 531 U.S. at 162–65. The Supreme Court rejected the government’s stated rationale for asserting jurisdiction over these “nonnavigable, isolated, intrastate waters.” *Id.* at 171–72. In doing so, the Supreme Court noted that *Riverside Bayview* upheld “jurisdiction over wetlands that actually abutted on a navigable waterway” because the wetlands were “inseparably bound up with the ‘waters’ of the United States.” *Id.* at 167.¹² As summarized by the *SWANCC* majority:

It was the significant nexus between the wetlands and “navigable waters” that informed our reading of the CWA in *Riverside Bayview Homes*. Indeed, we did not “express any opinion” on the “question of authority of the Corps to regulate discharges of fill material into wetlands that are not adjacent to bodies of open water. . . . In order to rule for [the Corps] here, we would have to hold that the jurisdiction of the Corps extends to ponds that are not adjacent to open water. But we conclude that the text of the statute will not allow this.

Id. at 167–68 (internal citations omitted). That is because the text of section 404(a)—the permitting provision at issue in the case—included the word “navigable” as its operative phrase, and signaled a clear direction to the Court that “Congress had in mind . . . its traditional jurisdiction over waters that were or had been navigable in fact or which could reasonably be so made.” *Id.* at 172.

¹² For additional context, at oral argument during *Riverside Bayview*, the government attorney characterized the wetland at issue as “in fact an adjacent wetland, adjacent—by adjacent, I mean it is immediately next to, abuts, adjoins, borders, whatever other adjective you might want to use, navigable waters of the United States.” Transcript of Oral Argument at 16, *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121 (1985) (No. 84–701).

The Court dismissed the argument that the use of the abandoned ponds by migratory birds fell within the power of Congress to regulate activities that in the aggregate have a substantial effect on interstate commerce, or that the targeted use of the ponds as a municipal landfill was commercial in nature. *Id.* at 173. Such arguments, the Court noted, raised “significant constitutional questions.” *Id.* “Where an administrative interpretation of a statute invokes the outer limits of Congress’ power, we expect a clear indication that Congress intended that result.” *Id.* at 172–73 (“Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority.”). This is particularly true “where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power.” *Id.* at 173; *see also Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242–43 (1985) (finding that where Congress intends to alter the “usual constitutional balance between the States and the Federal Government,” it must make its intention to do so “unmistakably clear in the language of the statute”); *Gregory v. Ashcroft*, 501 U.S. 452, 460–61 (1991) (“[The] plain statement rule . . . acknowledged[es] that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere.”). “Rather than expressing a desire to readjust the federal-state balance in this manner, Congress chose [in the CWA] to ‘recognize, preserve, and protect the primary responsibilities and rights of States . . . to plan the development and use . . . of land and water resources. . . .’” *SWANCC*, 531 U.S. at 174 (quoting 33 U.S.C. 1251(b)). The Court therefore found no clear statement from Congress that it had intended to permit federal encroachment on traditional state power, and construed the CWA to avoid the significant constitutional questions related to the scope of federal authority authorized therein. *Id.*

The Supreme Court considered the concept of adjacency again several years later in consolidated cases arising out of the Sixth Circuit. *See Rapanos v. United States*, 547 U.S. 715 (2006). In one case, the Corps had determined that wetlands on three separate sites were subject to CWA jurisdiction because they were adjacent to ditches or man-made drains that eventually connected to traditional navigable waters several miles away through other ditches, drains, creeks, and/or rivers. *Id.* at 719–20, 729. In another case, the Corps had asserted

jurisdiction over a wetland separated from a man-made drainage ditch by a four-foot-wide man-made berm. *Id.* at 730. The ditch emptied into another ditch, which then connected to a creek, and eventually connected to Lake St. Clair, a traditional navigable water, approximately a mile from the parcel at issue. The berm was largely or entirely impermeable, but may have permitted occasional overflow from the wetland to the ditch. *Id.* The Court, in a fractured opinion, vacated and remanded the Sixth Circuit's decision upholding the Corps' asserted jurisdiction over the four wetlands at issue, with Justice Scalia writing for the plurality and Justice Kennedy concurring in the judgment. *Id.* at 757 (plurality), 787 (Kennedy, J.).

The plurality determined that CWA jurisdiction only extended to adjacent "wetlands with a continuous surface connection to bodies that are 'waters of the United States' in their own right, so that there is no clear demarcation between 'waters' and wetlands." *Id.* at 742. The plurality then concluded that "establishing that wetlands . . . are covered by the Act requires two findings: first, that the adjacent channel contains a 'wate[r] of the United States,' (i.e., a relatively permanent body of water connected to traditional interstate navigable waters); and second, that the wetland has a continuous surface connection with that water, making it difficult to determine where the 'water' ends and the 'wetland' begins." *Id.* (alteration in original).

In order to reach the adjacency conclusion of this two-part test, the plurality interpreted the *Riverside Bayview* decision, and subsequent SWANCC decision characterizing *Riverside Bayview*, as authorizing jurisdiction over wetlands that physically abutted traditional navigable waters. *Id.* at 740–42. The plurality focused on the "inherent ambiguity" described in *Riverside Bayview* in determining where on the continuum between open waters and dry land the scope of federal jurisdiction should end. *Id.* at 740. It was "the inherent difficulties of defining precise bounds to regulable waters," *id.* at 741 n.10, according to the plurality, that prompted the Court in *Riverside Bayview* to defer to the Corps' inclusion of adjacent wetlands as "waters" subject to CWA jurisdiction based on ecological considerations. *Id.* at 740–41 ("When we characterized the holding of *Riverside Bayview* in SWANCC, we referred to the close connection between waters and the wetlands they gradually blend into: 'It was the significant nexus between the wetlands and 'navigable

waters' that informed our reading of the CWA in *Riverside Bayview Homes.*"). The plurality also noted that "SWANCC rejected the notion that the ecological considerations upon which the Corps relied in *Riverside Bayview* . . . provided an *independent* basis for including entities like 'wetlands' (or 'ephemeral streams') within the phrase 'the waters of the United States.'" SWANCC found such ecological considerations irrelevant to the question whether physically isolated waters come within the Corps' jurisdiction." *Id.* at 741–42 (emphasis in original).

Justice Kennedy disagreed with the plurality's determination that adjacency requires a "continuous surface connection" to covered waters. *Id.* at 772. In reading the phrase "continuous surface connection" to mean a continuous "surface-water connection," *id.* at 776, and interpreting the plurality's standard to include a "surface-water-connection requirement," *id.* at 774, Justice Kennedy stated that "when a surface-water connection is lacking, the plurality forecloses jurisdiction over wetlands that abut navigable-in-fact waters—even though such navigable waters were traditionally subject to federal authority," *id.* at 776, even after the *Riverside Bayview* Court "deemed it irrelevant whether 'the moisture creating the wetlands . . . find[s] its source in the adjacent bodies of water,'" *id.* at 772 (internal citations omitted). This is one reason why Justice Kennedy stated that "*Riverside Bayview*'s observations about the difficulty of defining the water's edge cannot be taken to establish that when a clear boundary is evident, wetlands beyond that boundary fall outside the Corps' jurisdiction." *Id.* at 773.

The plurality did not directly address the precise distinction raised by Justice Kennedy, but did note in response that the "*Riverside Bayview* opinion required" a "continuous *physical* connection," *id.* at 751 n.13 (emphasis added), and focused on evaluating adjacency between a "water" and a wetland "in the sense of possessing a continuous surface connection that creates the boundary-drawing problem we addressed in *Riverside Bayview.*" *Id.* at 757. The plurality also noted that its standard includes a "physical-connection requirement" between wetlands and covered waters. *Id.* at 751 n.13. In other words, the plurality appeared to be more focused on the abutting nature rather than the source of water creating the wetlands at issue in *Riverside Bayview* to describe the legal constructs applicable to adjacent wetlands, *see id.* at 747; *see also*

Webster's II, New Riverside University Dictionary (1994) (defining "abut" to mean "to border on" or "to touch at one end or side of something"), and indeed agreed with Justice Kennedy and the *Riverside Bayview* Court that "[a]s long as the wetland is 'adjacent' to covered waters . . . its creation *vel non* by inundation is irrelevant." *Id.* at 751 n.13.¹³

Because physically disconnected wetlands do not raise the same boundary-drawing concerns presented by actually abutting wetlands, the plurality determined that the rationale in *Riverside Bayview* does not apply to such features. The plurality stated that "[w]etlands with only an intermittent, physically remote hydrologic connection to 'waters of the United States' do not implicate the boundary-drawing problem of *Riverside Bayview*, and thus lack the necessary connection to covered waters that we described as a 'significant nexus' in SWANCC[.]" *Id.* at 742. The plurality supported this position by referring to the Court's treatment of isolated waters in SWANCC as non-jurisdictional. *Id.* at 726, 741–42 ("[W]e held that 'nonnavigable, isolated, intrastate waters'—which, unlike the wetlands at issue in *Riverside Bayview*, did not 'actually abut[t] on a navigable waterway,'—were not included as 'waters of the United States.'"). The plurality found "no support for the inclusion of physically unconnected wetlands as covered 'waters'" based on *Riverside Bayview*'s treatment of the Corps' definition of adjacent. *Id.* at 746–47; *see also id.* at 746 ("[T]he Corps' definition of 'adjacent' . . . has been extended beyond reason.").

Concurring in the judgment, Justice Kennedy focused on the "significant nexus" between the adjacent wetlands and traditional navigable waters as the basis for determining whether a wetland is a water subject to CWA jurisdiction: "It was the significant nexus between wetlands and navigable waters . . . that informed our reading of the [Act] in *Riverside Bayview Homes*. Because such a nexus was lacking with respect to isolated ponds, [in SWANCC] the Court held that the plain text of the statute did not permit the Corps' action." *Id.* at 767 (internal quotations and citations omitted). Justice Kennedy noted that the wetlands at issue in *Riverside Bayview* were "adjacent to [a] navigable-in-fact waterway[.]" while the "ponds and

¹³The agencies' *Rapanos* Guidance recognizes the plurality's "continuous surface connection" does not refer to a continuous surface *water* connection. *See, e.g., Rapanos* Guidance at 7 n.28 ("A continuous surface connection does not require surface water to be continuously present between the wetland and the tributary.").

mudflats” considered in *SWANCC* “were isolated in the sense of being unconnected to other waters covered by the Act.” *Id.* at 765–66. “Taken together, these cases establish that in some instances, as exemplified by *Riverside Bayview*, the connection between a nonnavigable water or wetland and a navigable water may be so close, or potentially so close, that the Corps may deem the water or wetland a ‘navigable water’ under the Act. In other instances, as exemplified by *SWANCC*, there may be little or no connection. Absent a significant nexus, jurisdiction under the Act is lacking.” *Id.* at 767.

According to Justice Kennedy, whereas the isolated ponds and mudflats in *SWANCC* lack the “significant nexus” to navigable waters, it is the “conclusive standard for jurisdiction” based on “a reasonable inference of ecological interconnection” between adjacent wetlands and navigable-in-fact waters that allows for their categorical inclusion as waters of the United States. *Id.* at 780 (“[T]he assertion of jurisdiction for those wetlands [adjacent to navigable-in-fact waters] is sustainable under the act by showing adjacency alone.”). Justice Kennedy surmised that it may be that the same rationale “without any inquiry beyond adjacency . . . could apply equally to wetlands adjacent to certain major tributaries,” noting that the Corps could establish by regulation categories of tributaries based on volume of flow, proximity to navigable waters, or other factors that “are significant enough that wetlands adjacent to them are likely, in the majority of cases, to perform important functions for an aquatic system incorporating navigable waters.” *Id.* at 780–81. However, “[t]he Corps’ existing standard for tributaries” provided Justice Kennedy “no such assurance” to infer the categorical existence of a requisite nexus between waters traditionally understood as navigable and wetlands adjacent to nonnavigable tributaries. *Id.* at 781. That is because:

the breadth of [the tributary] standard—which seems to leave wide room for regulation of drains, ditches, and streams remote from any navigable-in-fact water and carrying only minor water volumes towards it—precludes its adoption as the determinative measure of whether adjacent wetlands are likely to play an important role in the integrity of an aquatic system comprising navigable waters as traditionally understood. Indeed, in many cases wetlands adjacent to tributaries covered by this standard might appear little more related to navigable-in-fact waters than were the isolated ponds held to fall beyond the Act’s scope in *SWANCC*.

Id. at 781–82.

Justice Kennedy stated that, absent development of a more specific regulation, the Corps “must establish a significant nexus on a case-by-case basis when it seeks to regulate wetlands based on adjacency to nonnavigable tributaries. Given the potential overbreadth of the Corps’ regulations, this showing is necessary to avoid unreasonable applications of the statute.” *Id.* at 782. Justice Kennedy explained that “wetlands possess the requisite nexus, and thus come within the statutory phrase ‘navigable waters,’ if the wetlands, either alone or in combination with similarly situated lands in the region, significantly affect the chemical, physical, and biological integrity of other covered waters more readily understood as ‘navigable.’” *Id.* at 780. “Where an adequate nexus is established for a particular wetland, it may be permissible, as a matter of administrative convenience or necessity, to presume covered status for other comparable wetlands in the region.” *Id.* at 782.

In describing this significant nexus test, Justice Kennedy relied, in part, on the overall objective of the CWA to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.” *Id.* at 779 (quoting 33 U.S.C. 1251(a)). Justice Kennedy also agreed with the plurality that “environmental concerns provide no reason to disregard limits in the statutory text.” *Id.* at 778. With respect to wetlands adjacent to nonnavigable tributaries, Justice Kennedy therefore determined that “mere adjacency . . . is insufficient. A more specific inquiry, based on the significant-nexus standard, is . . . necessary.” *Id.* at 786. Not requiring adjacent wetlands to possess a significant nexus with navigable waters, Justice Kennedy noted, would allow a finding of jurisdiction “whenever wetlands lie alongside a ditch or drain, however remote and insubstantial, that eventually may flow into traditional navigable waters. The deference owed the Corps’ interpretation of the statute does not extend so far.” *Id.* at 778–79.

Based on the agencies’ review of this Supreme Court precedent, although the plurality and Justice Kennedy established different standards to determine the jurisdictional status of wetlands adjacent to nonnavigable tributaries, they both appear to agree in principle that the determination must be made using a two-part test that considers: (1) The proximity of the wetland to the tributary; and (2) the status of the tributary with respect to downstream traditional navigable waters. The plurality and Justice

Kennedy also agree that the proximity between the wetland and the tributary must be close. The plurality refers to that proximity as a “continuous surface connection” or “continuous physical connection,” as demonstrated in *Riverside Bayview*. *Id.* at 742, 751 n.13. Justice Kennedy recognized that “the connection between a nonnavigable water or wetland and a navigable water may be so close, or potentially so close, that the Corps may deem the water or wetland a ‘navigable water’ under the Act.” *Id.* at 767. The second part of the two-part tests established by the plurality and Justice Kennedy is addressed in the next section.

b. Tributaries

The definition of tributaries was not addressed in either *Riverside Bayview* or *SWANCC*. And while the focus of *Rapanos* was on whether the Corps could regulate wetlands adjacent to nonnavigable waters, the plurality and concurring opinions provide some guidance on the regulatory status of tributaries to navigable-in-fact waters.

The plurality and Justice Kennedy both recognized that the jurisdictional scope of the CWA is not restricted to traditional navigable waters. *See id.* at 731 (plurality) (“[T]he Act’s term ‘navigable waters’ includes something more than traditional navigable waters.”); *id.* at 767 (Justice Kennedy) (“Congress intended to regulate at least some waters that are not navigable in the traditional sense.”). Both also agree that federal authority under the Act is not without limit. *See id.* at 731–32 (plurality) (“[T]he waters of the United States . . . cannot bear the expansive meaning that the Corps would give it.”); *id.* at 778–79 (Justice Kennedy) (“The deference owed to the Corps’ interpretation of the statute does not extend” to “wetlands” which “lie alongside a ditch or drain, however remote or insubstantial, that eventually may flow into traditional navigable waters.”).

With respect to tributaries specifically, both the plurality and Justice Kennedy focus in large part on a tributary’s contribution of flow to, and connection with, traditional navigable waters. The plurality would include as waters of the United States “only relatively permanent, standing or flowing bodies of water” and would define such “waters” as including streams, rivers, oceans, lakes and other bodies of waters that form geographical features, noting that all such “terms connote continuously present, fixed bodies of water” *Id.* at 732–33, 739. On the other hand, the plurality would likely exclude ephemeral streams

and related features. *Id.* at 733–34, 739, 741. Justice Kennedy would likely exclude some streams considered jurisdictional under the plurality’s test. *Id.* at 769 (noting that under the plurality’s test, “[t]he merest trickle, if continuous, would count as a ‘water’ subject to federal regulation, while torrents thundering at irregular intervals through otherwise dry channels would not”).

In addition, both the plurality and Justice Kennedy would likely include some intermittent streams as waters of the United States. *See id.* at 732–33 & n.5 (plurality); *id.* at 769–70 (Justice Kennedy). The plurality noted that its reference to “relatively permanent” waters did “not necessarily exclude streams, rivers, or lakes that might dry up in extraordinary circumstances, such as drought,” or “seasonal rivers, which contain continuous flow during some months of the year but no flow during dry months” *Id.* at 732 n.5 (emphasis in original). However, neither the plurality nor Justice Kennedy defined with precision where to draw the line. Nevertheless, the plurality provided that “navigable waters” must have “at bare minimum, the ordinary presence of water,” *id.* at 734, and Justice Kennedy noted that the Corps can identify by regulation categories of tributaries based on volume of flow, proximity to navigable waters, or other factors that “are significant enough that wetlands adjacent to them are likely, in the majority of cases, to perform important functions for an aquatic system incorporating navigable waters.” *Id.* at 780–81. And both the plurality and Justice Kennedy agreed that the Corps’ assertion of jurisdiction over the wetlands adjacent to the “drains, ditches, and streams remote from any navigable-in-fact water,” *id.* at 781 (Kennedy), at issue in *Rapanos* raised significant jurisdictional questions. *Id.* at 737–38 (plurality); *id.* at 781–82 (Kennedy).

3. Principles and Considerations

From this legal foundation, a few important principles emerge from which the agencies can evaluate their authorities. First, the power conferred on the agencies to regulate the waters of the United States is grounded in Congress’ commerce power over navigation. The agencies can choose to regulate beyond waters more traditionally understood as navigable given the broad purposes of the CWA, including some tributaries to those traditional navigable waters, but must provide a reasonable basis grounded in the language and structure of the Act for determining the extent of jurisdiction.

The agencies also can choose to regulate wetlands adjacent to the traditional navigable waters and some tributaries, if the wetlands are in close proximity to the tributaries, such as in the transitional zone between open waters and dry land. In the agencies’ view, it would not be consistent with Justice Kennedy’s *Rapanos* opinion or the *Rapanos* plurality opinion to regulate wetlands adjacent to all tributaries, no matter how small or remote from navigable water. The Court’s opinion in *SWANCC* also calls into serious question the agencies’ authority to regulate nonnavigable, isolated, intrastate waters that lack a sufficient connection to traditional navigable waters, and suggests that the agencies should avoid regulatory interpretations of the CWA that raise constitutional questions regarding the scope of their statutory authority. The agencies can, however, regulate certain waters by category, which could improve regulatory predictability and certainty and ease administrative burden while still effectuating the purposes of the Act.

In developing a clear and predictable regulatory framework, the agencies also must respect the primary responsibilities and rights of States and Tribes to regulate their land and water resources. *See* 33 U.S.C. 1251(b), 1370. The oft-quoted objective of the CWA to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters,” *id.* at 1251(a), must be implemented in a manner consistent with Congress’ policy directives to the agencies. The Supreme Court long ago recognized the distinction between federal waters traditionally understood as navigable and waters “subject to the control of the States.” *The Daniel Ball*, 77 U.S. (10 Wall.) 557, 564–65 (1871). Over a century later, the Supreme Court in *SWANCC* reaffirmed the State’s “traditional and primary power over land and water use.” 531 U.S. at 174; *accord Rapanos*, 547 U.S. at 738 (Scalia, J., plurality opinion). Ensuring that States and Tribes retain authority over their land and water resources pursuant to CWA section 101(b) and section 510 helps carry out the overall objective of the CWA, and ensures that the agencies are giving full effect and consideration to the entire structure and function of the Act, including Congress’ intent as reflected in dozens of non-regulatory grant, research, nonpoint source, groundwater, and watershed planning programs to assist the states in controlling pollution in the nation’s waters, not just its navigable waters.

Further, the agencies are cognizant that the “Clean Water Act imposes substantial criminal and civil penalties

for discharging any pollutant into waters covered by the Act without a permit. . . .” *U.S. Army Corps of Eng’rs v. Hawkes Co.*, 136 S. Ct. 1807, 1812 (2016); *see also Sackett v. EPA*, 566 U.S. 120, 132–33 (2012) (Alito, J., concurring) (“[T]he combination of the uncertain reach of the Clean Water Act and the draconian penalties imposed for the sort of violations alleged in this case still leaves most property owners with little practical alternative but to dance to the EPA’s tune.”). As the Chief Justice observed in *Hawkes*, “[i]t is often difficult to determine whether a particular piece of property contains waters of the United States, but there are important consequences if it does.” 136 S. Ct. at 1812; *see also id.* at 1816–17 (Kennedy, J., concurring) (“[T]he reach and systemic consequences of the Clean Water Act remain a cause for concern,” and the Act “continues to raise troubling questions regarding the Government’s power to cast doubt on the full use and enjoyment of private property throughout the Nation.”). Given the significant civil and criminal penalties associated with the CWA, it is important for the agencies to promote regulatory certainty while striving to provide fair and predictable notice of the limits of federal jurisdiction. *See, e.g., Sessions v. Dimaya*, 138 S. Ct. 1204, 1223–25 (2018) (Gorsuch, J., concurring in part and concurring in the judgment) (characterizing fair notice as possibly the most fundamental of the protections provided by the Constitution’s guarantee of due process, and stating that vague laws are an exercise of “arbitrary power . . . leaving the people in the dark about what the law demands and allowing prosecutors and courts to make it up”).

C. Proposed Reasons for Repeal

The agencies’ proposal is based on our view that regulatory certainty may be best served by repealing the 2015 Rule and recodifying the preexisting scope of CWA jurisdiction. Specifically, the agencies are concerned that rather than achieving their stated objectives of increasing regulatory predictability and consistency under the CWA, retaining the 2015 Rule creates significant uncertainty for agency staff, regulated entities, and the public, which is compounded by court decisions that have increased litigation risk and cast doubt on the legal viability of the rule. To provide for greater regulatory certainty, the agencies propose to revert to the pre-2015 regulations, a regulatory regime that is more familiar to and better-understood by the agencies, States, Tribes, local governments, regulated entities, and the public.

Further, as a result of the agencies' review and reconsideration of their statutory authority and in light of the court rulings against the 2015 Rule that have suggested that the agencies' interpretation of the "significant nexus" standard as applied in the 2015 Rule was expansive and does not comport with and accurately implement the limits on jurisdiction reflected in the CWA and decisions of the Supreme Court, the agencies are also concerned that the 2015 Rule lacks sufficient statutory basis. The agencies are proposing to conclude in the alternative that, at a minimum, the interpretation of the statute adopted in the 2015 Rule is not compelled, and a different policy balance can be appropriate.

Considering the substantial uncertainty associated with the 2015 Rule resulting from its legal challenges, and the substantial experience the agencies and others possess with the longstanding regulatory framework currently being administered by the agencies, the agencies conclude that clarity, predictability, and consistency may be best served by repealing the 2015 Rule and thus are proposing to do so. The agencies may still propose changes to the definition of "waters of the United States" in a future rulemaking.

Further, the agencies are concerned that certain findings and assumptions supporting adoption of the 2015 Rule were not correct, and that these conclusions, if erroneous, may separately justify repeal of the 2015 Rule. The agencies are concerned and seek comment on whether the 2015 Rule significantly expanded jurisdiction over the preexisting regulatory program, as implemented by the agencies, and whether that expansion altered State, tribal, and local government relationships in implementing CWA programs. The agencies therefore propose to repeal the 2015 Rule in order to restore those preexisting relationships and better serve the balance of authorities envisioned in CWA section 101(b).

1. The 2015 Rule Fails To Achieve Regulatory Certainty

The agencies are proposing to repeal the 2015 Rule because it does not appear to achieve one of its primary goals of providing regulatory certainty and consistency. When promulgating the 2015 Rule, the agencies concluded the rule would "increase CWA program predictability and consistency by clarifying the scope of 'waters of the United States' protected under the Act." 80 FR 37054. The agencies stated that the 2015 "rule reflect[ed] the judgment

of the agencies in balancing the science, the agencies' expertise, and the regulatory goals of providing clarity to the public while protecting the environment and public health, consistent with the law." *Id.* at 37065. Since then, developments in the litigation against the 2015 Rule and concerns raised since the rule's promulgation indicate that maintaining the 2015 Rule would produce substantial uncertainty and confusion among state and federal regulators and enforcement officials, the regulated public, and other interested stakeholders. To provide for greater regulatory certainty, the agencies propose to repeal the 2015 Rule and restore a longstanding regulatory framework that is more familiar to and better-understood by the agencies, our co-regulators, and regulated entities, until the agencies propose and finalize a replacement definition.

a. Litigation to Date

As noted above, the 2015 Rule has been challenged in legal actions across multiple district courts, in which plaintiffs have raised a number of substantive and procedural claims against the rule. Petitions for review were also filed in multiple courts of appeals and were consolidated in the U.S. Court of Appeals for the Sixth Circuit. To date, all three of the courts that substantively have considered the 2015 Rule—the Sixth Circuit, the District of North Dakota, and the Southern District of Georgia—have found that petitioners seeking to overturn the rule are likely to succeed on the merits of at least some of their claims against the rule.

In the Sixth Circuit, the court granted a nationwide stay of the 2015 Rule after finding, among other factors, that the petitioners showed a "substantial possibility of success on the merits" of their claims against the 2015 Rule, including claims that the rule was inconsistent with Justice Kennedy's opinion in *Rapanos* and that the rule's distance limitations were not substantiated by specific scientific support. *In re EPA*, 803 F.3d 804, 807 (6th Cir. 2015).

The District of North Dakota made similar findings in issuing a preliminary injunction against the 2015 Rule. There, the court found that the plaintiff-States are "likely to succeed on the merits of their claim" that the rule violated the congressional grant of authority to the agencies under the CWA because the rule "likely fails" to meet Justice Kennedy's significant nexus test. *North Dakota v. EPA*, 127 F. Supp. 3d 1047, 1055–56 (D.N.D. 2015). The court also

found that the plaintiff-States have a fair chance of success on the merits of their procedural claims that the agencies failed to comply with APA requirements in promulgating the rule. *Id.* at 1056–57.

The Southern District of Georgia also preliminarily enjoined the 2015 Rule, holding that the State plaintiffs had demonstrated "a likelihood of success on their claims that the [2015] WOTUS Rule was promulgated in violation of the CWA and the APA." *Georgia v. Pruitt*, No. 15–cv–79, 2018 U.S. Dist. LEXIS 97223, at *14 (S.D. Ga. June 8, 2018) ("*Georgia*") (granting preliminary injunction). The court determined that the 2015 Rule likely failed to meet the standard expounded in *SWANCC* and *Rapanos*, and that the rule was likely fatally defective because it "allows the Agencies to regulate waters that do not bear any effect on the 'chemical, physical, and biological integrity' of any navigable-in-fact water." *Id.* at *17–18. The court also held that the plaintiffs "have demonstrated a likelihood of success on both of their claims under the APA" that the 2015 Rule "is arbitrary and capricious" and "that the final rule is not a logical outgrowth of the proposed rule." *Id.* at *18.

These rulings indicate that substantive or procedural challenges to the 2015 Rule are likely to be successful, particularly claims that the rule is not authorized under the CWA and was promulgated in violation of the APA. A successful challenge to the 2015 Rule could result in a court order vacating the rule in all or part, in all or part of the country, and potentially resulting in different regulatory regimes being in effect in different parts of the country, which would likely lead to substantial regulatory confusion, uncertainty, and inconsistency.

Notably, the agencies face an increasing risk of a court order vacating the 2015 Rule. The District of North Dakota is proceeding to hear the merits of the plaintiff-States' claims against the 2015 Rule in that case, and the plaintiff-States in the Southern District of Georgia have requested a similar merits-briefing schedule. *See* Scheduling Order, *North Dakota v. EPA*, No. 15–cv–59 (D.N.D. May 2, 2018); Response to Defendants' Updated Response to Plaintiff States' Motion for Preliminary Injunction at 11–12, *Georgia*, No. 15–cv–79 (S.D. Ga. May 29, 2018). Although the applicability date rule ensures that the 2015 Rule will not go into effect until February 6, 2020, the prospect of a court order vacating the 2015 Rule creates additional regulatory uncertainty.

b. Stakeholder Confusion Regarding the Scope of the 2015 Rule and Extent of Federal CWA Jurisdiction

Statements made in the litigation against the 2015 Rule and in comments regarding the 2015 Rule indicate that there has been substantial disagreement and confusion as to the scope of the 2015 Rule and the extent of federal CWA jurisdiction more broadly. In the Sixth Circuit, for example, State petitioners asserted that the 2015 Rule covers waters outside the scope of the CWA pursuant to *SWANCC* and *Rapanos* and “extends jurisdiction to virtually every potentially wet area of the country.”¹⁴ Industry petitioners contended that the rule’s “uncertain standards are impossible for the public to understand or the agencies to apply consistently.”¹⁵ In contrast, environmental petitioners found that *SWANCC* and *Rapanos* led to widespread confusion over the scope of the CWA and that the pre-2015 regulatory regime could theoretically apply to “almost all waters and wetlands across the country.”¹⁶ These petitioners asserted that the 2015 Rule violated the CWA by failing to cover certain waters, including waters that may possess a “significant nexus” to traditional navigable waters.¹⁷ Whether such comments are accurate or not, they indicate continued widespread disagreement and confusion over the meaning of the 2015 Rule and extent of jurisdiction it entails.

Some comments received on the July 27, 2017 NPRM also demonstrate continued confusion over the scope and various provisions of the 2015 Rule. For example, one commenter found that the rule’s definitions of “adjacent,” “significant nexus” and other key terms lack clarity and thus lead to regulatory uncertainty.¹⁸ This same commenter contended that the rule could raise constitutional concerns related to the appropriate scope of federal authority and encouraged the agencies to undertake a new rulemaking to more clearly articulate the extent of federal CWA authority. Another commenter echoed these concerns, alleging that the 2015 Rule resulted in a “vague and

indecipherable explanation” of the definition of “waters of the United States” that has caused confusion and uncertainty as to the extent of jurisdiction that can be asserted by federal, state and local authorities.¹⁹

The agencies have received comments from numerous other individuals and entities expressing confusion and concern about the extent of federal CWA jurisdiction asserted under the 2015 Rule, and the agencies are continuing to review and consider these comments.

c. Impact on State Programs

Like other commenters on the proposal to the 2015 Rule, some States expressed confusion regarding the scope of the proposal and, uniquely, the potential impacts of that uncertainty on States’ ability to implement CWA programs. Though some States have stated that the 2015 Rule “more clearly identifies what types of waters would be considered jurisdictional,”²⁰ others assert that the extent of CWA jurisdiction under the rule remained “fuzzy” and unclear.²¹ Certain States noted that this uncertainty could “create time delays in obtaining permits which previously were not required”²² and “result in increased costs to the State and other private and public interests, along with decreased regulatory efficiency.”²³ One State suggested that even if the 2015 Rule established greater regulatory clarity, the rule’s case-by-case determinations could result in permitting delays when a jurisdictional determination is required.²⁴

Similar concerns have been raised in the litigation challenging the 2015 Rule.

¹⁹ See comments submitted by Skagit County Dike, Drainage and Irrigation District No. 12 and Skagit County Dike District No. 1 (Sept. 27, 2017) (Docket ID: EPA-HQ-OW-2017-0203-11709), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2017-0203-11709>.

²⁰ See, e.g., comments submitted by State of Washington, Department of Ecology (Nov. 13, 2014) (Docket ID: EPA-HQ-OW-2011-0880-13957), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-13957>.

²¹ See, e.g., comments submitted by State of Oklahoma (Nov. 14, 2014) (Docket ID: EPA-HQ-OW-2011-0880-14625), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-14625>; see also comments submitted by National Association of Counties (Nov. 14, 2014) (Docket ID: EPA-HQ-OW-2011-0880-15081), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-15081>.

²² See comments submitted by State of Utah, Governor’s Office (Nov. 14, 2014) (Docket ID: EPA-HQ-OW-2011-0880-16534), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-16534>.

²³ See comments submitted by Wyoming Department of Environmental Quality (Nov. 14, 2014) (Docket ID: EPA-HQ-OW-2011-0880-16393), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-16393>.

²⁴ See comments submitted by State of Washington, Department of Ecology, *supra* note 20.

For example, in the Southern District of Georgia, the State of Indiana has asserted that the 2015 Rule’s definition of “waters of the United States” is “vague” and that the rule “imposes . . . unclear regulatory requirements that will result in an inefficient use of limited regulatory resources.”²⁵ In particular, the State asserts concerns that implementing the 2015 Rule will divert resources by “[d]emanding the time and attention of regulators to make the now-difficult determination of when and whether a feature is a WOTUS” and “[g]enerating unnecessary administrative appeals and lawsuits to resolve jurisdictional disputes.”²⁶

d. Agency Experience With the 1986 Regulations

The agencies have been implementing the pre-2015 regulations (hereinafter referred to as the “1986 regulations”) almost uninterrupted since 1986. Corps staff are trained on making jurisdictional determinations in the field and through national webinars and classroom or field-based trainings. From June 2007 through June 2018, the Corps issued 241,857²⁷ approved jurisdictional determinations (AJDs) under their 1986 regulations, as informed by applicable Supreme Court precedent and the agencies’ guidance.

Through over 30 years of experience, the agencies have developed significant technical expertise with the 1986 regulations and have had the opportunity to refine the application of the rules through guidance and the agencies’ experience and federal court decisions. Indeed, the 1986 regulations have been the subject of a wide body of case law, including three significant U.S. Supreme Court decisions²⁸ and dozens of cases in federal district courts and courts of appeals that have addressed the scope of analysis required. Since 1986, the agencies have issued numerous memoranda, guidance, and question-and-answer documents explaining and clarifying these regulations.²⁹

Given the longstanding nature and history of the 1986 regulations, this

²⁵ Statement of Bruno L. Pigott, *Georgia*, No. 15-cv-79 (S.D. Ga. July 21, 2015).

²⁶ *Id.*

²⁷ U.S. Army Corps of Engineers, OMBIL Regulatory Module (June 5, 2018).

²⁸ *Riverside Bayview*, 474 U.S. 121 (1985); *SWANCC*, 531 U.S. 159 (2001); *Rapanos*, 547 U.S. 715 (2006).

²⁹ The Corps maintains many of these documents on its public website, available at <https://www.usace.army.mil/Missions/Civil-Works/Regulatory-Program-and-Permits/Related-Resources/CWA-Guidance/>. The EPA maintains many of these documents as well; see also <https://www.epa.gov/wotus-rule/about-waters-united-states>.

¹⁴ Opening Brief of State Petitioners at 15, 61, *In re EPA*, No. 15-3751 (6th Cir. Nov. 1, 2016).

¹⁵ Opening Brief for the Business & Municipal Petitioners, *In re EPA*, No. 15-3751 (6th Cir. Nov. 1, 2016).

¹⁶ Brief of Conservation Groups at 11, *In re EPA*, No. 15-3751 (6th Cir. Nov. 1, 2016).

¹⁷ See, e.g., *id.* at 22, 43.

¹⁸ See comments submitted by Oregon Cattlemen’s Association (July 27, 2017) (Docket ID: EPA-HQ-OW-2017-0203-0039), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2017-0203-0039>.

regulatory regime is more familiar to the agencies, co-regulators, and regulated entities. For this reason, as between the 2015 Rule and the 1986 regulations, the 1986 regulations (as informed by applicable Supreme Court precedent and the agencies' guidance) would appear to provide for greater regulatory predictability, consistency, and certainty, and the agencies seek public comment on this issue. Though the agencies acknowledge that the 1986 regulations have posed certain implementation difficulties and were the subject of court decisions that had the effect of narrowing their scope, the longstanding nature of the regulatory regime—coupled with the agencies' and others' extensive experience with the regulatory scheme—make it preferable to the regulatory uncertainty posed by the 2015 Rule.

2. The 2015 Rule May Exceed the Agencies' Authority Under the CWA

The agencies are concerned that the 2015 Rule exceeded EPA's authority under the CWA by adopting an expansive interpretation of the "significant nexus" standard that covers waters outside the scope of the Act and stretches the significant nexus standard so far as to be inconsistent with important aspects of Justice Kennedy's opinion in *Rapanos*, even though this opinion was identified as the basis for the significant nexus standard articulated in the 2015 Rule. In particular, the agencies are concerned that the 2015 Rule took an expansive reading of Justice Kennedy's significant nexus test and exceeds the agencies' authority under the Act.

As expounded in *Rapanos*, Justice Kennedy's significant nexus standard is a test intended to limit federal jurisdiction due to the breadth of the Corps' then-existing standard for tributaries and in order to "prevent[] problematic applications of the statute." 547 U.S. at 783. "Given the potential overbreadth of the Corps' [1986] regulations," Justice Kennedy found that the showing of a significant nexus "is necessary to avoid unreasonable applications of the statute." *Id.* at 782. The agencies are concerned, upon further consideration of the 2015 Rule, that the significant nexus standard articulated in that rule could lead to similar unreasonable applications of the CWA.

Justice Kennedy wrote that adjacent "wetlands possess the requisite nexus, and thus come within the statutory phrase 'navigable waters,' if the wetlands, either alone or in combination with similarly situated lands in the region, significantly affect the chemical,

physical, and biological integrity of other covered waters more readily understood as 'navigable.'" 547 U.S. at 780. The opinion did not expressly define the relevant "region" or what was meant by "similarly situated," but it is reasonable to presume that that the Justice did not mean "similarly situated" to be synonymous with "all" waters in a region. The agencies' *Rapanos* Guidance, for example, had interpreted the term "similarly situated" more narrowly to "include all wetlands adjacent to the same tributary."³⁰ "A tributary . . . is the entire reach of the stream that is of the same order (*i.e.*, from the point of confluence, where two lower order streams meet to form the tributary, downstream to the point such tributary enters a higher order stream)."³¹ Thus, under the agencies' 2008 guidance, "where evaluating significant nexus for an adjacent wetland, the agencies will consider the flow characteristics and functions performed by the tributary to which the wetland is adjacent along with the functions performed by the wetland and all other wetlands adjacent to that tributary. This approach reflects the agencies' interpretation of Justice Kennedy's term 'similarly situated' to include all wetlands adjacent to the same tributary. . . . Interpreting the phrase 'similarly situated' to include all wetlands adjacent to the same tributary is reasonable because such wetlands are physically located in a like manner (*i.e.*, lying adjacent to the same tributary)."³²

The 2015 Rule departed from this interpretation of "similarly situated" wetlands in a "region," including applying it to other waters, not only wetlands, that were not already categorically jurisdictional as tributaries or adjacent waters. The proposed rule, for example, stated that "[o]ther waters, including wetlands, are similarly situated when they perform similar functions and are located sufficiently close together or sufficiently close to a 'water of the United States' so that they can be evaluated as a single landscape unit with regard to their effect on the chemical, physical, or biological integrity of a [primary] water." 79 FR 22263 (April 21, 2014). The 2015 Rule took it a step further and stated that "the downstream health of larger downstream waters is directly related to the aggregate health of waters located upstream, including waters such as wetlands that may not be hydrologically connected but function together to ameliorate the potential impacts of

flooding and pollutant contamination from affecting downstream waters." 80 FR 37063. The 2015 Rule thus concluded that "[a] water has a significant nexus when any single function or combination of functions performed by the water, alone or together with similarly situated waters in the region, contributes significantly to the chemical, physical, or biological integrity of the nearest [primary] water." *Id.* at 37106. The "term 'in the region' means the watershed that drains to the nearest [primary] water." *Id.*

An examination of all of the waters in "the watershed" of "the nearest [primary] water" under the 2015 Rule therefore may have materially broadened the scope of aggregation that determines jurisdiction in a "significant nexus" inquiry for waters not categorically jurisdictional from the focus in the proposed rule on waters "located sufficiently close together or sufficiently close to a 'water of the United States' so that they can be evaluated as a single landscape unit." 79 FR 22263. The agencies in finalizing the rule viewed the scientific literature through a broader lens as "the effect of landscape position on the strength of the connection to the nearest 'water of the United States,'" and that "relevant factors influencing chemical connectivity . . . , surrounding land use and land cover, the landscape setting, and deposition of chemical constituents (*e.g.*, acidic deposition)." 80 FR 37094. The agencies are concerned that this important change in the interpretation of "similarly situated waters" from the proposed 2015 Rule and the 2008 *Rapanos* Guidance may not be explainable by the scientific literature, including the Connectivity Report³³ cited throughout the preamble to the 2015 Rule, in light of the agencies' view at the time that "[t]he scientific literature does not use the term 'significant' as it is defined in a legal context." 80 FR 37062. The agencies solicit comment on whether the agencies' justification for the 2015 Rule's interpretation of "similarly situated" with reference to an entire watershed for purposes of waters not categorically jurisdictional relied on the scientific literature without due regard for the restraints imposed by the statute and case law, and whether this interpretation of Justice Kennedy's significant nexus standard is a reason, at a minimum because of the legal risk it

³⁰ *Rapanos* Guidance at 8.

³¹ *Id.* at 10.

³² *Id.*

³³ U.S. EPA, Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence (Jan. 2015) (EPA/600/R-14/475F).

creates, to repeal the 2015 Rule. As discussed, the 2015 Rule included distance-based limitations that were not specified in the proposal. In light of this, the agencies also solicit comment on whether these distance-based limitations mitigated or affected the agencies' change in interpretation of similarly situated waters in the 2015 Rule.

The agencies are also concerned that the 2015 Rule does not give sufficient effect to the term "navigable" in the CWA. See *South Carolina v. Catawba Indian Tribe*, 476 U.S. 498, 510 n.22 (1986) ("It is our duty to give effect, if possible, to every clause and word of a statute[.]") (quoting *United States v. Menasche*, 348 U.S. 528, 538–39 (1955)) (internal quotation marks omitted)). Justice Kennedy's concurring opinion in *Rapanos*, on which the 2015 Rule relied heavily for its basis, recognized the term "navigable" must have "some importance" and, if that word has any meaning, the CWA cannot be interpreted to "permit federal regulation whenever wetlands lie along a ditch or drain, however remote and insubstantial, that eventually may flow into traditional navigable waters." *Rapanos*, 547 U.S. at 778–79 (Kennedy, J., concurring in judgment). When interpreting the *Rapanos* decision and its application for determining the scope of CWA jurisdiction in 2008, the agencies wrote "[p]rincipal considerations when evaluating significant nexus include the volume, duration, and frequency of the flow of water in the tributary and the proximity of the tributary to a traditional navigable water."³⁴ The agencies are considering whether the 2015 Rule's definitions of "tributary" and "adjacent" were so broad as to eliminate consideration of these factors in a manner consistent with Justice Kennedy's opinion and the CWA.

The 2015 Rule stated that the agencies assessed "the significance of the nexus" to navigable water "in terms of the CWA's objective to 'restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'" 80 FR 37056 (quoting 33 U.S.C. 1251(a)). Under the 2015 Rule, a significant nexus may be established by an individual water or by collectively considering "similarly situated" waters across a "region," defined as "the watershed that drains to the nearest [primary] water identified." *Id.* at 37106. The agencies are now concerned that this broad reliance on biological functions, such as the provision of life cycle dependent aquatic habitat, may

not comport with the CWA and Justice Kennedy's statement in *Rapanos* that "environmental concerns provide no reason to disregard limits in the statutory text." See 547 U.S. at 778. In particular, the agencies are mindful that the Southern District of Georgia's preliminary injunction of the 2015 Rule was based in part on the court's holding that the 2015 Rule likely is flawed for the same reason as the Migratory Bird Rule: "the WOTUS Rule asserts that, standing alone, a significant 'biological effect'—including an effect on 'life cycle dependent aquatic habitat[s]'—would place a water within the CWA's jurisdiction. Thus, this WOTUS Rule will likely fail for the same reason that the rule in *SWANCC* failed." *Georgia*, 2018 U.S. Dist. LEXIS 97223, at *18 (quoting 33 CFR 328.3(c)(5)). The agencies solicit comment on whether the 2015 Rule is flawed in the same manner as the Migratory Bird Rule, including whether the 2015 Rule raises significant constitutional questions similar to the questions raised by the Migratory Bird Rule as discussed by the Supreme Court in *SWANCC*.

Moreover, the 2015 Rule relied on a scientific literature review—the Connectivity Report—to support exerting federal jurisdiction over certain waters based on nine enumerated functions. See 80 FR 37065 ("the agencies interpret the scope of 'waters of the United States' protected under the CWA based on the information and conclusions in the [Connectivity] Report"). The report notes that connectivity "occur[s] on a continuum or gradient from highly connected to highly isolated," and "[t]hese variations in the degree of connectivity are a critical consideration to the ecological integrity and sustainability of downstream waters." *Id.* at 37057. In its review of a draft version of the Connectivity Report, EPA's Science Advisory Board ("SAB") noted, "[s]patial proximity is one important determinant of the magnitude, frequency and duration of connections between wetlands and streams that will ultimately influence the fluxes of water, materials and biota between wetlands and downstream waters."³⁵ "Wetlands that are situated alongside rivers and their tributaries are likely to be connected to those waters through the exchange of water, biota and chemicals. As the distance between a wetland and a flowing water system increases, these connections become less obvious."³⁶

³⁵ Science Advisory Board, U.S. EPA. Review of the EPA Water Body Connectivity Report at 60 (Oct. 17, 2014).

³⁶ *Id.* at 55.

The Connectivity Report also recognizes that "areas that are closer to rivers and streams have a higher probability of being connected than areas farther away." Connectivity Report at ES–4.

Yet, the SAB observed that "[t]he Report is a science, not policy, document that was written to summarize the current understanding of connectivity or isolation of streams and wetlands relative to large water bodies such as rivers, lakes, estuaries, and oceans."³⁷ "The SAB also recommended that the agencies clarify in the preamble to the final rule that 'significant nexus' is a legal term, not a scientific one." 80 FR 37065. And in issuing the 2015 Rule, the agencies stated, "the science does not provide a precise point along the continuum at which waters provide only speculative or insubstantial functions to downstream waters." *Id.* at 37090.

The agencies now believe that they previously placed too much emphasis on the information and conclusions of the Connectivity Report when setting jurisdictional lines in the 2015 Rule, relying on its environmental conclusions in place of interpreting the statutory text and other indicia of Congressional intent to ensure that the agencies' regulations comport with their statutory authority to regulate. This is of particular concern to the agencies today with respect to the agencies' broad application of Justice Kennedy's phrase "similarly situated lands." As discussed previously, the agencies took an expansive reading of this phrase, in part based on "one of the main conclusions of the [Connectivity Report] . . . that the incremental contributions of individual streams and wetlands are cumulative across entire watersheds, and their effects on downstream waters should be evaluated within the context of other streams and wetlands in that watershed," see 80 FR 37066. Yet, Justice Kennedy observed in *Rapanos* that what constitutes a "significant nexus" to the waters of the United States is not a solely scientific question and that it cannot be determined by environmental effects alone. See, e.g., 547 U.S. at 777–78 (noting that although "[s]cientific evidence indicates that wetlands play a critical role in controlling and filtering runoff . . . environmental concerns provide no reason to disregard limits in the statutory text" (citations omitted)). This includes how Congress' use of the term "navigable" in the CWA and how the policies embodied in section 101(b) should inform this analysis. Justice Kennedy wrote that "the Corps deems a

³⁷ *Id.* at 2.

³⁴ *Rapanos* Guidance at 10.

water a tributary if it feeds into a traditional navigable water (or a tributary thereof) and possesses an ordinary high-water mark,” defined as a “line on the shore established by the fluctuations of water and indicated by [certain] physical characteristics.” *Id.* at 781. This “may well provide a reasonable measure of whether specific minor tributaries bear a sufficient nexus with other regulated waters to constitute ‘navigable waters’ under the Act. Yet the breadth of this standard—which seems to leave wide room for regulation of drains, ditches, and streams remote from any navigable-in-fact water and carrying only minor volumes toward it—precludes its adoption as the determinative measure of whether adjacent wetlands are likely to play an important role in the integrity of an aquatic system comprising navigable waters as traditionally understood.” *Id.* (emphasis added).

The 2015 Rule, by contrast, asserts jurisdiction categorically over any tributary, including all ephemeral and intermittent streams that meet the rule’s tributary definition, as well as all wetlands and other waters that are within certain specified distances from a broadly defined category of tributaries (e.g., all waters located within the 100-year floodplain of a category (1) through (5) “jurisdictional by rule” water and not more than 1,500 feet from the ordinary high water mark of such water). According to the rule, tributaries are characterized by the presence of the physical indicators of a bed and banks and an ordinary high water mark and eventually contribute flow (directly or indirectly) to a traditional navigable water, interstate water, or territorial sea that may be a considerable distance away. *See* 80 FR 37105. The 2015 Rule defined “ordinary high water mark” as “that line on the shore established by the fluctuations of water and indicated by physical characteristics such as a clear, natural line impressed on the bank, shelving, changes in the character of soil, destruction of terrestrial vegetation, the presence of litter and debris, or other appropriate means that consider the characteristics of the surrounding areas.” *Id.* at 37106. The 2015 Rule did not require any assessment of flow, including volume, duration, or frequency, when defining the “waters of the United States.” Instead, the 2015 Rule concluded that it was reasonable to presume that “[t]hese physical indicators demonstrate there is volume, frequency, and duration of flow sufficient to create a bed and banks and an ordinary high water mark, and thus to qualify as a tributary.” *Id.* at 37105.

The 2015 Rule thus covers ephemeral washes that flow only in response to infrequent precipitation events if they meet the definition of tributary. These results, particularly that adjacent waters, broadly defined, are categorically jurisdictional no matter how small or frequently flowing the tributary to which they are adjacent, is, at a minimum, in significant tension with Justice Kennedy’s understanding of the term significant nexus as explained in *Rapanos*. *See id.* at 781–82 (“[I]n many cases wetlands adjacent to tributaries covered by [the Corps’ 1986 tributary] standard might appear little more related to navigable-in-fact waters than were the isolated ponds held to fall beyond the Act’s scope in *SWANCC*”).

The agencies are mindful that courts that have considered the merits of challenges to the 2015 Rule have similarly observed that the rule may conflict with Justice Kennedy’s opinion in *Rapanos*, particularly the rule’s definition of “tributary.” The District of North Dakota found that the definitions in the 2015 Rule raise “precisely the concern Justice Kennedy had in *Rapanos*, and indeed the general definition of tributary [in the 2015 Rule] is strikingly similar” to the standard for tributaries that concerned Justice Kennedy in *Rapanos*. *North Dakota*, 127 F. Supp. 3d at 1056. The Southern District of Georgia also found that the 2015 Rule’s definition of “tributary” “is similar to the one” at issue in *Rapanos*, and that “it carries with it the same concern that Justice Kennedy had there.” *Georgia*, 2018 U.S. Dist. LEXIS 97223, at *17. Likewise, the Sixth Circuit stated in response to petitioners’ “claim that the Rule’s treatment of tributaries, ‘adjacent waters,’ and waters having a ‘significant nexus’ to navigable waters is at odds with the Supreme Court’s ruling in *Rapanos*” that “[e]ven assuming, for present purposes, as the parties do, that Justice Kennedy’s opinion in *Rapanos* represents the best instruction on the permissible parameters of ‘waters of the United States’ as used in the Clean Water Act, it is far from clear that the new Rule’s distance limitations are harmonious with the instruction.” *In re EPA*, 803 F.3d at 807 & n.3 (noting that “[t]here are real questions regarding the collective meaning of the [Supreme] Court’s fragmented opinions in *Rapanos*”).

One example that illustrates this point is the “seasonally ponded, abandoned gravel mining depressions” specifically at issue in *SWANCC*, 531 U.S. at 164, which the Supreme Court determined were “nonnavigable, isolated, intrastate waters,” *id.* at 166–72, and not

jurisdictional. These depressions are located within 4,000 feet of Poplar Creek, a tributary to the Fox River, and may have the ability to store runoff or contribute other ecological functions in the watershed. Thus, they would be subject to, and might satisfy, a significant nexus determination under the 2015 Rule’s case-specific analysis. However, Justice Kennedy himself stated in *Rapanos*, which informed the significant nexus standard articulated in the rule, that, “[b]ecause such a [significant] nexus was lacking with respect to isolated ponds, the [SWANCC] Court held the plain text of the statute did not permit” the Corps to assert jurisdiction over them. 547 U.S. at 767. Other potential examples of the breadth of the significant nexus standard articulated in the 2015 Rule are provided below in the next section.

3. Concerns Regarding the 2015 Rule’s Effect on the Scope of CWA Jurisdiction

The agencies asserted in the preamble to the 2015 Rule that “State, tribal, and local governments have well-defined and longstanding relationships with the Federal government in implementing CWA programs and these relationships are not altered by the final rule.” 80 FR 37054. The agencies further noted that “[c]ompared to the current regulations and historic practice of making jurisdictional determinations, the scope of jurisdictional waters will decrease” under the 2015 Rule. *Id.* at 37101. When compared to more recent practice, however, the agencies determined that the 2015 Rule would result “in an estimated increase between 2.84 and 4.65 percent in positive jurisdictional determinations annually.” *Id.* The agencies thus concluded that the 2015 Rule would “result in a small overall increase in positive jurisdiction determinations compared to those made under the *Rapanos* Guidance” and that the “net effect” of the regulatory changes would “be marginal at most.” Brief for Respondents at 32–33 & n.6, *In re EPA*, No. 15–3571 (6th Cir. Jan. 13, 2017). Since publication of the final rule, the agencies have received information about the impact of these changes, including through filings in litigation against the 2015 Rule and comments received in response to the July 27, 2017 NPRM. After further analysis and reconsideration of how the 2015 Rule is likely to impact jurisdictional determinations, including how the data on those impacts relate to the specific regulatory changes made in the 2015 Rule, the agencies are now considering whether the definitional changes in the 2015 Rule would have a more substantial impact on the scope of

jurisdictional determinations made pursuant to the CWA than acknowledged in the analysis for the rule and would thus impact the balance between federal, state, tribal, and local government in a way that gives inadequate consideration to the overarching Congressional policy to “recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution” and “to plan the development and use . . . of land and water resources. . . .” 33 U.S.C. 1251(b).

Between the agencies’ “historic” (i.e., 1986 regulations) and “recent” practices of making jurisdictional determinations under the *Rapanos* Guidance, the Supreme Court held that the agencies’ application of the 1986 regulation was overbroad in some important respects. See *SWANCC*, 531 U.S. at 174 (reversing and remanding the assertion of jurisdiction); *Rapanos*, 547 U.S. at 715 (vacating and remanding, for further analysis, the assertion of CWA jurisdiction). Throughout the rulemaking process for the 2015 Rule, the agencies stressed in public statements,³⁸ fact sheets,³⁹ blog posts,⁴⁰ and before Congress⁴¹ that the rule would not significantly expand the jurisdictional reach of the CWA. Some commenters questioned the accuracy of these statements during the rulemaking process for the 2015 Rule and in response to the July 27, 2017 NPRM. The court in *North Dakota* questioned the scope of waters subject to the 2015 Rule, and based its preliminary injunction in principal part on those doubts, stating, for example, that “the definition of tributary” in the 2015 Rule

“includes vast numbers of waters that are unlikely to have a nexus to navigable waters within any reasonable understanding of the term.” 127 F. Supp. 3d at 1056; see also *In re EPA*, 803 F.3d at 807 (finding that “it is far from clear that the new Rule’s distance limitations are harmonious” with Justice Kennedy’s significant nexus test in *Rapanos*); *Georgia*, 2018 U.S. Dist. LEXIS 97223, at *17 (holding that the 2015 Rule’s “tributary” definition “is similar to the one invalidated in *Rapanos*, and it carries with it the same concern that Justice Kennedy had there”).

Given the concerns raised by some commenters and the federal courts, the agencies have reviewed data previously relied upon to conclude that the 2015 Rule would have no or “marginal at most” impacts on jurisdictional determinations, Brief for Respondents at 32 n.6, *In re EPA*, No. 15–3571 (6th Cir. Jan. 13, 2017), and are reconsidering the validity of this conclusion. The agencies solicit comment on whether the agencies appropriately characterized or estimated the potential scope of CWA jurisdiction that could change under the 2015 Rule, including whether the documents supporting the 2015 Rule appropriately considered the data relevant to and were clear in that assessment.

For example, the agencies relied upon an examination of the documents supporting the estimated 2.84 to 4.65 percent annual increase in positive approved jurisdictional determinations (A)Ds to conclude that the 2015 Rule would only “result in a small overall increase in positive jurisdictional determinations compared to those made under the *Rapanos* Guidance.” See Brief for Respondents at 32, *In re EPA*, No. 15–3571 (6th Cir. Jan. 13, 2017). However, others have raised concerns that this information and other data show the 2015 Rule may have expanded jurisdiction more significantly, particularly with respect to so-called “other waters” that are not adjacent to navigable waters and their tributaries.

In developing the 2015 Rule, the agencies examined records in the Corps’ Operation and Maintenance Business Information Link, Regulatory Module (ORM2) database that documents jurisdictional determinations associated with various aquatic resource types, including an isolated waters category. “The isolated waters category is used in the Corps’ ORM2 database to represent intrastate, non-navigable waters; including wetlands, lakes, ponds, streams, and ditches, that lack a direct surface connection to other waterways. These waters are hereafter referred to as

‘ORM2 other waters.’”⁴² To examine how assertion of jurisdiction could change under the 2015 Rule, the agencies reviewed ORM2 aquatic resource records from Fiscal Year (FY)13 and FY14 and placed them into three groups: Streams (ORM2 categories of traditionally navigable waters, relatively permanent waters, and non-relatively permanent waters), wetlands adjacent to the stream category group, and other waters. Of the 160,087 records for FY13 and FY14, streams represented 65 percent of the total records available, wetlands represented 29 percent, and other waters represented 6 percent.

From this baseline, the agencies assumed that 100 percent of the records classified as streams would meet the jurisdictional tests established in the final rule, and 100 percent of the records classified as adjacent wetlands would meet the definition of adjacent in the final rule. These assumptions resulted in a relatively minor projected increase in positive jurisdictional determinations under the final rule for these categories: 99.3 to 100 percent for the streams category, and 98.9 to 100 percent for the wetlands category.

The agencies also performed a detailed analysis of the other waters category to determine whether jurisdiction might change for those waters under the final rule. In total, “these files represented over 782 individual waters in 32 states.”⁴³

Of the existing negative determinations for other waters, the agencies made the following estimates:

- 17.1 percent of the negative jurisdictional determinations for other waters would become positive under the 2015 Rule because the aquatic resources would meet the new definition of adjacent waters. See 80 FR 37105. These waters fall within the 100-year floodplain and are within 1,500 feet of a stream included in the United States Geological Survey’s (USGS) National Hydrography Dataset (NHD).

- 15.7 percent of the other waters could become jurisdictional under category (7) of the 2015 Rule following a significant nexus analysis. See *id.* at 37104–05.

- 1.7 percent of the other waters could become jurisdictional under category (8) of the 2015 Rule following a significant nexus analysis. See *id.* at 37105.

In total, the agencies estimated that 34.5 percent of the other waters represented in the FY13 and FY14 ORM2 database could become jurisdictional under the 2015 Rule after

³⁸ Addressing farmers in Missouri in July 2014, then-EPA Administrator Gina McCarthy stated that no additional CWA permits would be required under the proposed 2015 Rule. See: <http://www.farmfutures.com/story-epas-mccarthy-ditch-myths-waters-rule-8-114845> (“The bottom line with this proposal is that if you weren’t supposed to get a permit before, you don’t need to get one now.”).

³⁹ U.S. EPA. Facts About the Waters of the U.S. Proposal at 4 (July 1, 2014), available at <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OW-2011-0880-16357&attachmentNumber=38&contentType=pdf> (“The proposed rule does not expand jurisdiction.”).

⁴⁰ U.S. EPA blog post entitled “Setting the Record Straight on Waters of the US” (June 30, 2014), available at <https://blog.epa.gov/blog/2014/06/setting-the-record-straight-on-wous/> (“The proposed rule does not expand jurisdiction.”).

⁴¹ In a hearing before the House Committee on Science, Space, and Technology entitled “Navigating the Clean Water Act: Is Water Wet?” (July 9, 2014), then-Deputy EPA Administrator Bob Perciasepe told the Committee that the agencies are not expanding the jurisdiction of the CWA. See <https://science.house.gov/legislation/hearings/full-committee-hearing-navigating-clean-water-act-water-wet>.

⁴² 2015 Rule Economic Analysis at 7.

⁴³ 2015 Rule Economic Analysis at 9.

having been declared not jurisdictional under the existing regulations and agency guidance. Thus, while the agencies acknowledged in the 2015 Rule Economic Analysis that “[f]ollowing the Supreme Court decisions in *SWANCC* (2001) and *Rapanos* (2006), the agencies no longer asserted CWA jurisdiction over isolated waters,” the agencies estimated in the 2015 Rule Economic Analysis that 34.5 percent of the other waters category could become jurisdictional under the 2015 Rule.⁴⁴ By way of comparison, a similar analysis of this category of other waters performed in support of the proposed rule in 2014 (using FY09 and FY10 data from the ORM2 database) estimated that 17 percent of the negative jurisdictional for other waters would become positive.⁴⁵

While the Economic Analysis for the 2015 Rule estimated that 34.5 percent of negative jurisdictional determinations for other waters would become positive,⁴⁶ the agencies nevertheless premised the 2015 Rule on assertions that the “scope of jurisdiction in this rule is narrower than that under the existing regulation,” the scope of jurisdiction in the rule would result “in an estimated increase between 2.84 and 4.65 percent in positive jurisdictional determinations annually” based on existing practice, and that such impacts would be “small overall” and “marginal at most.” See 80 FR 37054, 37101; Brief for Respondents at 32–33 & n.6, *In re EPA*, No. 15–3571 (6th Cir. Jan. 13, 2017). The agencies are examining these statements and how this data relates specifically to the regulatory changes made in the 2015 Rule (as opposed to those provisions which already subjected many streams and wetlands to CWA jurisdiction). The agencies request comment on whether the projected increase for this category is most relevant to measuring the impacts of the 2015 Rule, whether the public had ample notice of the doubling of projected positive jurisdiction over the other waters category from the proposed to final rule, and whether the final rule could expand overall CWA positive jurisdictional determinations by a material amount inconsistent with the findings and conclusions that justified the 2015 Rule.

In particular, the agencies seek comment on the conclusions that were based on the method that estimated a

2.84 to 4.65 percent increase in overall jurisdiction, including the use of a method whereby the increase in assertion of jurisdiction in a particular category of waters (e.g., streams, wetlands, and other waters) was proportionally applied based on the raw number of records in a category relative to the total number of records across all categories in the ORM2 database, notwithstanding whether the regulatory changes in the 2015 Rule did not materially impact those other categories. For example, of the 160,087 records in the ORM2 database for FY13 and FY14, 103,591 were associated with the streams category, 46,781 were associated with the wetlands category, and 9,715 were related to the other waters category. Thus, although 34.5 percent of previously non-jurisdictional “other waters” would become jurisdictional under the 2015 Rule, the proportional method used in the 2015 Rule Economic Analysis resulted in only an estimated 2.09 percent increase in positive jurisdictional determinations for “other waters” relative to the total number of jurisdictional determinations considered.⁴⁷

In addition, the record for the 2015 Rule includes a 57-page document entitled “Supporting Documentation: Analysis of Jurisdictional Determinations for Economic Analysis

⁴⁷ The following summarizes the methodology used to derive the low-end estimated increase in jurisdiction of 2.84 percent: Streams account for 103,591 of the 160,087 total records (64.709 percent of the total ORM2 records) and 100 percent of streams are assumed to be jurisdictional under the final rule compared to 99.3 percent under previous practice (100 percent minus 99.3 percent = 0.7 percent). The relative contribution of streams to the overall change in jurisdictional determinations is thus 64.709 percent multiplied by 0.7 percent for a total of 0.45 percent. Wetlands account for 46,781 of the 160,087 total records (29.222 percent of the total ORM2 records) and 100 percent of wetlands are assumed to be jurisdictional under the final rule compared to 98.9 percent under previous practice (100 percent minus 98.9 percent = 1.1 percent). The relative contribution of wetlands to the overall estimated change in jurisdictional determinations is thus 29.222 percent multiplied by 1.1 percent for a total of 0.32 percent. Other waters account for 9,715 of the 160,087 total records (6.069 percent of the total ORM2 records) and 34.5 percent of other waters are assumed to be jurisdictional under the final rule compared to 0.0 percent under previous practice (34.5 percent minus 0.0 percent = 34.5 percent). The relative contribution of other waters to the overall estimated change in jurisdictional determinations is thus 6.069 percent multiplied by 34.5 percent for a total of 2.09 percent. The agencies then added the relative contribution to the overall estimated change in jurisdictional determinations for each category of waters (i.e., 0.45 percent for streams, 0.32 percent for wetlands, and 2.09 percent for other waters) to get a total projected change in positive jurisdictional determinations of 2.86 percent. The differences between this calculation and the reported 2.84 percent in the 2015 Rule Economic Analysis may be the result of rounding error.

and Rule,”⁴⁸ along with an accompanying 3,695 page document of approved jurisdictional determination (AJD) forms.⁴⁹ This contains the agencies’ assessment conducted in April 2015 of almost two hundred previously performed AJDs to help the agencies better understand how waters might change jurisdictional status based on the distance limitations included in the final 2015 Rule for adjacent and case-specific waters (see 80 FR 37105), including where they might no longer be jurisdictional under the final rule. Certain examples included in the assessment suggest that the 2015 Rule could modify CWA jurisdiction over waters that were deemed not jurisdictional under the 1986 regulatory framework and Supreme Court precedent. The agencies request comment on whether the examples illustrate the concerns expressed by the recent court decisions discussed above that the 2015 Rule may have exceeded the significant nexus standard articulated by Justice Kennedy in the *Rapanos* opinion and concerns expressed by certain commenters that the 2015 Rule may have created additional regulatory uncertainty over waters that were previously thought beyond the scope of CWA jurisdiction. The examples are intended to be illustrative, and are not intended to attempt to quantify or reassess previous estimates of CWA jurisdiction, as the agencies are not aware of any map or dataset that accurately or with any precision portrays CWA jurisdiction at any point in the history of this complex regulatory program.

In the first example, a property in Chesapeake, Virginia, was reviewed by the Corps’ Norfolk District in early January 2014 and again in March 2015 and was determined not to contain jurisdictional wetlands because the wetlands on the property lacked a hydrological surface connection of any duration, frequency, or volume of flow to other jurisdictional waters. The Corps noted that the wetlands “appear to be dependent upon groundwater for hydrology, and have no surface connections” to nearby tributaries, the closest one of which was approximately 80 feet from the wetland. The agencies

⁴⁸ U.S. EPA. Supporting Documentation: Analysis of Jurisdictional Determinations for Economic Analysis and Rule (Docket ID: EPA-HQ-OW-2011-0880-20877), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-20877>.

⁴⁹ U.S. EPA and U.S. Army Corps of Engineers. Supporting Documentation: Jurisdictional Determinations (Docket ID: EPA-HQ-OW-2011-0880-20876), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-20876>.

⁴⁴ 2015 Rule Economic Analysis at 5, 12.

⁴⁵ U.S. EPA and U.S. Army Corps of Engineers. Economic Analysis of Proposed Revised Definition of Waters of the United States at 12, Exhibit 3 (Mar. 2014) (Docket ID: EPA-HQ-OW-2011-0880-0003), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-0003>.

⁴⁶ 2015 Rule Economic Analysis at 13, Figure 2.

later stated that the wetland features “would be jurisdictional under the new rule” because they are “within 100-feet of a tributary” and would thus meet the rule’s definition of “neighboring” and, in turn, “adjacent.” Further information regarding this AJD and property has been added to the docket for the NPRM and is identified as “Case Study A—AJD Number NAO–2014–2269” (see Support Document).

In another example, the Corps’ Buffalo District reviewed a small wetland approximately 583 feet away from the Johnin Ditch near Toledo, Ohio, which eventually leads north to Lake Erie. After conducting a field investigation in September 2014, the Corps determined that the wetlands were not jurisdictional because the “wetlands are isolated and there is no surface water connections [sic] and the only potential jurisdiction would be the [Migratory Bird Rule],” noting that the area previously would have been regulated under the Migratory Bird Rule prior to the Supreme Court’s *SWANCC* decision. The agencies later stated that the wetlands would be jurisdictional under the 2015 Rule. Further information regarding this AJD and property has been added to the docket for the NPRM and is identified as “Case Study B—AJD Number 2004–001914” (see Support Document).

In another example, the Corps’ Memphis District reviewed a borrow pit on a property in Mississippi County, Missouri, and concluded that the borrow pit did not contain jurisdictional wetlands. The project area was described in the AJD as follows:

The borrow pit has been abandoned for some time. Vegetation consists mainly of black willow (*Salix nigra*) and poison ivy (*Toxicodendron radicans*). A site visit was conducted on 8 December 2014. The borrow pit is bordered by agricultural land on three sides and County Road K on the western border. There are no surface water connections to other waters of the U.S. A sample was taken within the site and all three parameters for a wetland are present. The Soil Survey book for Cape Girardeau, Mississippi and Scott Counties Missouri, compiled in 1974 and 1975 from aerial photography indicates no drainage into or out of the project site. The area is an isolated wetland approximately 7.6 acres in size.

The abandoned pit in this example was 2,184 feet from the nearest “tributary,” a feature that itself appears to be a ditch in an agricultural field. The wetlands in the borrow pit were determined by the Corps to be isolated and non-jurisdictional “with no substantial nexus to interstate (or foreign) commerce” and on the basis that “prior to . . . ‘SWANCC,’ the review area would have been regulated

based solely on the ‘Migratory Bird Rule.’” A later review by the agencies, however, stated that these wetlands would be jurisdictional under the 2015 Rule. Further information regarding this property and associated AJD has been added to the docket for the NPRM and is identified as “Case Study C—AJD Number MVM–2014–460” (see Support Document).

In another example, the Corps’ New England District reviewed a “mowed wet meadow within a mowed hayfield” in Greensboro, Vermont, in August 2012 and concluded the site did not contain jurisdictional wetlands. The AJD described the wetlands as “surrounded on all sides by similar upland,” “500’–985’ away” from the nearest jurisdictional waters, and “isolated intrastate waters with no outlet, no hydrological connection to the Lamoille River, no nexus to interstate commerce, and no significant nexus to the Lamoille River (located about 1.7–1.8 miles southeast of the site).” A later review by the agencies, however, stated the wetlands would be jurisdictional under the 2015 Rule. Further information regarding this property and associated AJD has been added to the docket for the NPRM and is identified as “Case Study D—AJD Number NAE–2012–1813” (see Support Document).

In another example, the Corps’ Chicago District completed AJD number LRC–2015–31 for wetlands in agricultural fields in Kane County, Illinois, in January 2015. AJD Number LRC–2015–31 was completed using two separate AJD forms: One form for the features at the project site that were determined to be jurisdictional according to the *Rapanos* Guidance (“positive AJD form”) and a second form for the features at the site that the Corps determined were not jurisdictional under the *Rapanos* Guidance (“negative AJD form”). Only the positive AJD form was included in the docket in Supporting Documentation entitled, “Jurisdictional Determinations—Redacted.”⁵⁰ The negative AJD form is available on the Chicago District website.⁵¹

Using a field determination and desk determinations, the Corps found on the AJD form that there were “no ‘waters of the U.S.’ within Clean Water Act (CWA) jurisdiction (as defined by 33 CFR part 328) in the review area.” The Corps described the project area in the AJD form as follows: “Wetland A is a 1.37 acre high quality closed depressional

isolated wetland. Wetlands B and C (0.08 ac and 0.15 ac) are isolated wetlands that formed over a failed drain tile and are over 1,200 feet away from the closest jurisdictional waterway.” The AJD also notes, “Weland [sic] A and the area around Wetlands B and C were previously determined to be isolated in 2008. Wetland C is mapped as Prior Converted in a NRCS certified farmed wetland determination—other areas are mapped as not inventoried.” Upon later reviewing the negative AJD, however, the agencies determined the wetlands would be “now Yes JD” under the 2015 Rule. Further information regarding this property and associated positive and negative AJDs has been added to the docket for the NPRM and is identified as “Case Study E—AJD Number LRC–2015–31” (see Support Document).

In another example, the Corps’ Pittsburgh District visited a property in Butler, Pennsylvania, in October 2014 and determined the site did not contain waters of the United States because the wetland was “completely isolated and has no nexus to a TNW or interstate or foreign commerce.” The Corps noted that the wetland would have been regulated based solely on the Migratory Bird Rule prior to the decision in *SWANCC*. Upon reviewing the AJD, the agencies later stated the wetland is “[i]solated but would have flood storage function.” The agencies’ review notes that the wetland is 1,270 feet from the nearest relatively permanent water (RPW) or traditional navigable water (TNW). Given the wetland is within 4,000 feet of a tributary and the agencies have stated it possesses at least one of the nine functions relevant to the significant nexus evaluation, see 80 FR 37106 (i.e., retention and attenuation of flood waters), the wetland would be subject to a significant nexus evaluation under the 2015 Rule. It is unclear, however, whether the wetland and its flood storage function would contribute significantly to the chemical, physical, or biological integrity of the nearest category (1) through (3) water as required by the 2015 Rule to satisfy the significant nexus test. Further information regarding this property and associated AJD has been added to the docket for the NPRM and is identified as “Case Study F—AJD Number LRP 2014–855” (see Support Document).

In addition to the projected increase in positive jurisdictional determinations and the above examples of expected JD changes, an examination of the documents supporting the estimated 2.84 to 4.65 percent annual increase in positive AJDs raises concerns that the 2015 Rule may have significantly expanded jurisdiction over tributaries in

⁵⁰ *Id.* at 2082–83.

⁵¹ Available at: <http://www.lrc.usace.army.mil/Portals/36/docs/regulatory/jd/lrcnjd02-2015.pdf> (page 1 and 2).

certain States, particularly those in more arid parts of the country.

As described previously, to assess how assertion of jurisdiction may change under the 2015 Rule, the agencies reviewed ORM2 aquatic resource records from FY13 and FY14 and placed the aquatic resources into three groups: Streams, wetlands adjacent to the stream category group, and other waters. With respect to the streams category, the agencies assumed that “100 percent of the records classified as streams will meet the definition of tributary in the final rule,”⁵² resulting in a relatively minor projected increase in positive jurisdictional determinations under the final rule for streams: 99.3 percent to 100 percent, or a 0.7 percent increase.

However, the agencies have reexamined the 57-page “Supporting Documentation: Analysis of Jurisdictional Determinations for Economic Analysis and Rule” and have questions regarding the minor projected increase in positive jurisdictional determinations over streams in some states. An untitled table on page 46 of the supporting document lists an analysis of a subset of streams and the number of those streams estimated to be non-jurisdictional by State in the FY13–FY14 ORM2 records for the purpose of estimating stream mitigation costs associated with the 2015 Rule.⁵³

Investigating the percent of streams estimated to be non-jurisdictional on a State-by-State basis coupled with the 2015 Rule Economic Analysis’s assumption that 100 percent of the stream jurisdictional determinations will be positive under the 2015 Rule could indicate that there may be a significant expansion of jurisdiction over tributaries in some States beyond current practice. For example, in the FY13–FY14 ORM2 records for Arizona, the table identifies 709 of 1,070 total streams (66.3 percent) were non-jurisdictional. For Arkansas, the table identifies 116 of 213 total streams (54.5 percent) as non-jurisdictional. In South Dakota, North Dakota, Nevada, New Mexico, and Wyoming, 8.5 percent, 9.2 percent, 13.2 percent, 16.7 percent, and 57.1 percent of streams in the FY13–FY14 ORM2 database, respectively, were identified in the table as non-jurisdictional. The agencies are concerned that because the 2015 Rule may assert jurisdiction over 100 percent of streams as the agencies assumed in the 2015 Rule Economic Analysis, certain States, particularly those in the arid West, would see significant

expansions of federal jurisdiction over streams. The agencies solicit comment on whether such expansions conflict with the assumptions underlying and statements justifying the 2015 Rule, and if such expansions were consistent with the policy goals of section 101(b) of the CWA.

Several questions were raised by commenters regarding whether the 2015 Rule expanded CWA jurisdiction over intermittent and ephemeral streams, and whether the agencies accurately identified that potential expansion in the development of the 2015 Rule. Several commenters, for example, suggested that the amount of jurisdictional river and stream miles in the United States may increase from approximately 3.5 million miles to more than 8 million miles in response to the *per se* jurisdictional treatment of millions of miles of ephemeral and intermittent streams under the tributary definition.⁵⁴ To frame their analysis, those commenters compared river and stream miles reported in recent CWA section 305(b) reports submitted by States to EPA, and transmitted by EPA to Congress, to the river and stream miles depicted in maps developed by the agencies and the USGS prior to the 2015 Rule’s proposal.

Section 305(b)(1)(A) of the CWA directs each state to “prepare and submit to the Administrator . . . biennially . . . a report which shall include . . . a description of the water quality of all navigable waters in such State during the preceding year. . . .” 33 U.S.C. 1315(b)(1)(A). Section 305(b)(2) additionally directs the Administrator to “transmit such State reports, together with an analysis thereof, to Congress” *Id.* at 1315(b)(2). Over the years, those reports to Congress have identified between 3.5 and 3.7 million river and stream miles nationwide (*see* Support Document). The agencies previously observed that this analysis may not be precise, because of concerns regarding the baseline for comparison and

assumptions regarding which intermittent and ephemeral streams may be covered under the 2015 Rule.⁵⁵

The agencies are not aware of any national, regional, or state-level map that identifies all “waters of the United States” and acknowledge that there are limitations associated with existing datasets. The agencies, however, developed a series of draft maps using the NHD identifying “rivers and streams and tributaries and other water bodies” in each State, which then-EPA Administrator Gina McCarthy mentioned at a March 27, 2014 hearing before the U.S. House of Representatives Appropriations Committee Subcommittee on Interior, Environment, and Related Agencies.⁵⁶ The EPA provided a copy of those draft maps to Congress on July 28, 2014,⁵⁷ and they remain available to the public on the U.S. House of Representatives Committee on Science, Space and Technology website.⁵⁸ The draft maps identify a total of 8,086,742 river and stream miles across the 50 States (*see* Support Document).

Given the significant differences between the CWA section 305(b) reports and the draft NHD maps submitted to Congress, and the possibility that each may represent potential estimates for the relative jurisdictional scope of the 1986 regulations and practice compared to the 2015 Rule, several States have questioned whether the proposed definition of “tributary” for the 2015 Rule would expand federal jurisdiction over State water resources. Eight State departments of environmental quality, for example, stated in joint comments that “comparing the ‘waters of the United States’ reported by States to recent USGS maps released by the EPA shows a 131% increase in federal waters.”⁵⁹ Comments filed by the State

⁵⁵ *See* U.S. EPA and U.S. Army Corps of Engineers, Clean Water Rule Response to Comments—Topic 8: Tributaries at 88–89, available at https://www.epa.gov/sites/production/files/2015-06/documents/cwr_response_to_comments_8_tributaries.pdf.

⁵⁶ EPA Administrator Gina McCarthy testimony before the U.S. House of Representatives Appropriations Committee Subcommittee on Interior, Environment, and Related Agencies (March 27, 2014), available at <https://www.c-span.org/video/?318438-1/fy2015-epa-budget>.

⁵⁷ Letter from Nancy Stoner, Acting Asst. Administrator, U.S. EPA Office of Water, to Rep. Lamar Smith, Chairman, U.S. House of Representatives Committee on Science, Space, and Technology (July 28, 2014), available at https://science.house.gov/sites/republicans.science.house.gov/files/documents/epa_releases_maps_letter.pdf.

⁵⁸ EPA State and National Maps of Waters and Wetlands, available at <https://science.house.gov/epa-state-and-national-maps-waters-and-wetlands>.

⁵⁹ *See* comments submitted by Alabama Dept. of Environ. Mgmt., Arizona Dept. of Environ. Quality,

⁵² 2015 Rule Economic Analysis at 8.

⁵³ The table includes all states except Hawaii.

⁵⁴ *See* comments submitted by Arizona Department of Environmental Quality et al. (Nov. 14, 2014) (Docket ID: EPA–HQ–OW–2011–0880–15096), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-15096>; comments submitted by CropLife America (Nov. 14, 2014) (Docket ID: EPA–HQ–OW–2011–0880–14630), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-14630>; comments submitted by American Foundry Society (Nov. 14, 2014) (Docket ID: EPA–HQ–OW–2011–0880–15148), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-15148>; comments submitted by U.S. Chamber of Commerce et al. (Nov. 12, 2014) (Docket ID: EPA–HQ–OW–2011–0880–14115), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-14115>.

of Kansas on the proposed rule raised similar concerns and focused on the inclusion of ephemeral streams in the proposed definition of tributary: “In Kansas we have identified approximately 31,000 miles of perennial and intermittent waters that have been treated as WOTUS for several decades. . . . As per the preamble to the Rule and EPA/ACOE statements, the additional 133,000 miles [of ephemeral streams] would result in a 460% increase in the number of Kansas waters presumed to be jurisdictional under the Rule.”⁶⁰ Kansas added that the State does “not believe ephemeral waters have *always* been considered *de facto* tributaries for CWA jurisdictional purposes.”⁶¹ Referencing a statement made by then-EPA Administrator McCarthy in which she stated, “[u]nfortunately, 60 percent of our nation’s streams and millions of acres of wetlands currently lack clear protection from pollution under the Clean Water Act,”⁶² Kansas noted that “if those 60 percent that ‘lack clear protection’ are brought under the umbrella of the CWA, [there will be] a significantly larger expansion than estimated in the economic analysis for the Rule.”⁶³

The agencies in 2015 suggested that a feature that flows very infrequently would not form the physical indicators required to meet the 2015 Rule’s definitions of “ordinary high water mark” and “tributary.”⁶⁴ In response to comments questioning the agencies’ characterization of the change in scope of jurisdiction under the 2015 Rule, the agencies stated that the 2015 Rule was narrower in scope than the existing regulations and historical practice, and reiterated that an increase of approximately 3 percent represented the agencies’ estimate of the increased positive jurisdictional determinations

compared to recent practice.⁶⁵ In the administrative record for the 2015 Rule and in a brief filed with the Sixth Circuit (based on that record), the agencies asserted that the definition of “waters of the United States” historically has included ephemeral streams and that some federal court decisions after *SWANCC* upheld assertions of CWA jurisdiction over surface waters that have a hydrologic connection to and that form part of the tributary system of a traditional navigable water, including intermittent or ephemeral streams. 80 FR 37079; Brief for Respondents at 11, 62–64, *In re EPA*, No. 15–3571 (6th Cir. Jan. 13, 2017).⁶⁶ The agencies are requesting comment on whether these responses to these issues are adequate. While some ephemeral streams may have been jurisdictional after a case-specific analysis pursuant to the *Rapanos* Guidance,⁶⁷ and while challenges to some of those determinations have been rejected by courts, the agencies are requesting public comment on whether these prior conclusions and assertions were correct.

Given the concerns expressed by three federal courts regarding the potential scope of the 2015 Rule and comments raised during the 2015 rulemaking and submitted in response to the July 27, 2017 NPRM, the agencies are re-evaluating the 2015 Rule and the potential change in jurisdiction. While the agencies are not aware of any data that estimates with any reasonable certainty or predictability the exact baseline miles and area of waters covered by the 1986 regulations and preexisting agency practice or data that accurately forecasts of the additional waters subject to jurisdiction under the 2015 Rule, the agencies are examining whether the data and estimates used to support the 2015 Rule’s conclusions that the rule would be narrower than preexisting regulations may not have supported those conclusions, and instead the 2015 Rule may have had more than a marginal impact on CWA jurisdictional determinations and may impact well-defined and longstanding

relationships between the federal and State governments in implementing CWA programs. The agencies seek comment on this and other data that may be relevant to a proposed finding, and whether such a change in finding would, either independently or in conjunction with other factors, support the agencies’ proposal to repeal the 2015 Rule.

4. Potential Impact on Federal-State Balance

When promulgating the 2015 Rule, the agencies concluded and prominently stated that “State, tribal, and local governments have well-defined and longstanding relationships with the Federal government in implementing CWA programs and these relationships are not altered by the final rule,” 80 FR 37054. Indeed, it was “the policy of the Congress to recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution, to plan the development and use (including restoration, preservation, and enhancement) of land and water resources, and to consult with the Administrator in the exercise of his authority under this Act.” 33 U.S.C. 1251(b).

In response to the agencies’ July 27, 2017 NPRM, some commenters have suggested that the 2015 Rule—including, *inter alia*, elements of the final rule that commenters were not able to address during the comment period—may not effectively reflect the specific policy that Congress articulated in CWA section 101(b). The agencies are considering whether and are proposing to conclude that the 2015 Rule did not draw the appropriate line, for purposes of CWA jurisdiction, between waters subject to federal and State regulation, on the one hand, and waters subject to state regulation only, on the other. In comments submitted to the agencies in response to the July 27, 2017 NPRM, many States, representatives of entities within many sectors of the regulated community, and numerous other commenters expressed concerns that the 2015 Rule permits federal encroachment upon the States’ traditional and primary authority over land and water resources. Such commenters cite the Supreme Court’s recognition that “Congress chose to ‘recognize, preserve, and protect the primary responsibilities and rights of states . . . to plan the development and use’” of those resources in enacting the CWA rather than “readjust the federal-state balance,” *SWANCC*, 531 U.S. at 174 (quoting CWA section 101(b), 33 U.S.C. 1251(b)).

Indiana Dept. of Environ. Mgmt., Kansas Dept. of Health and Environ., Louisiana Dept. of Environ. Quality, Mississippi Dept. of Environ. Quality, Oklahoma Dept. of Environ. Quality, and Wyoming Dept. of Environ. Quality (Nov. 14, 2014) (Docket ID: EPA-HQ-OW-2011-0880-15096), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-15096>.

⁶⁰ See comments submitted by the State of Kansas at Appendix A (Oct. 23, 2014) (Docket ID: EPA-HQ-OW-2011-0880-16636), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-16636>.

⁶¹ *Id.* (emphasis in original).

⁶² See “Clean Water Drives Economic Growth” by Gina McCarthy (Sept. 29, 2014), available at http://www.huffingtonpost.com/gina-mccarthy/clean-water-act_b_5900734.html.

⁶³ See *supra* note 60.

⁶⁴ See, e.g., U.S. EPA and U.S. Army Corps of Engineers, Clean Water Rule Response to Comments—Topic 11: Cost/Benefits (Volume 2) at 223, available at https://www.epa.gov/sites/production/files/2015-06/documents/cwr_response_to_comments_11_econ_vol2.pdf.

⁶⁵ See, e.g., *id.* at 10–13, 17.

⁶⁶ See also U.S. EPA and Department of the Army, Technical Support Document for the Clean Water Rule: Definition of Waters of the United States at 28 (May 27, 2015), available at https://www.epa.gov/sites/production/files/2015-05/documents/technical_support_document_for_the_clean_water_rule_1.pdf.

⁶⁷ See *Rapanos* Guidance at 7 (“[R]elatively permanent” waters do not include ephemeral tributaries which flow only in response to precipitation and intermittent streams which do not typically flow year-round or have continuous flow at least seasonally. However, CWA jurisdiction over these waters will be evaluated under the significant nexus standard.”).

Under the 2015 Rule, commenters have observed that the agencies asserted categorical jurisdiction over water features that may be wholly intrastate and physically remote from navigable-in-fact waters. Such waters “adjacent” to jurisdictional waters are deemed to meet the definition of “waters of the United States” under the 2015 Rule, so long as any portion of the water is located within 100 feet of the ordinary high water mark of a category (1) through (5) “jurisdictional by rule” water; within the 100-year floodplain of a category (1) through (5) “jurisdictional by rule” water but not more than 1,500 feet from the ordinary high water mark of such water; or within 1,500 feet of the high tide line of a primary water or the ordinary high water mark of the Great Lakes. 80 FR 37085–86, 37105. The agencies also established case-specific jurisdiction over water features generally at a greater distance, including waters (including seasonal or ephemeral waters) located within 4,000 feet of the high tide line or ordinary high water mark of a category (1) through (5) water. See 80 FR 37105. For such waters, “the entire water is a water of the United States if a portion is located within the 100-year floodplain of a water identified in paragraphs (a)(1) through (3) . . . or within 4,000 feet of the high tide line or ordinary high water mark” of a category (1) through (5) water.” *Id.*

The agencies are considering whether the 2015 Rule’s coverage of waters based, in part, on their location within the 100-year floodplain of a jurisdictional water is consistent with the policy articulated in CWA section 101(b) that States should maintain primary responsibility over land and water resources. The agencies received many comments on the proposal to the 2015 Rule indicating that the potential breadth of this standard could conflict with other federal, State or local laws that regulate development within floodplains.⁶⁸ In particular, certain local governments expressed concern that the floodplain element of the rule could conflict with local floodplain ordinances or otherwise complicate local land use planning and development.⁶⁹ Though the agencies added a distance-based threshold to limit the use of the 100-year floodplain

⁶⁸ See, e.g., comments submitted by City of Chesapeake (Sept. 9, 2014) (Docket ID: EPA-HQ-OW-2011-0880-9615), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-9615>.

⁶⁹ See, e.g., comments submitted by National Association of Counties (Nov. 14, 2014) (Docket ID: EPA-HQ-OW-2011-0880-15081), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-15081>.

as a basis for categorical CWA jurisdiction with respect to adjacent waters, the agencies are concerned that the Rule’s use of this standard, including its use as a basis for requiring a case-specific significant nexus determination, could nonetheless interfere with traditional state and local police power, as suggested by some of the comments received in 2014.⁷⁰ Comments received in response to the July 27, 2017 NPRM also raise concerns about the use of the 100-year floodplain. Specifically, commenters expressed concern about the absence of suitable maps and about the accuracy of existing maps. Given these concerns, the agencies request comment on whether the 2015 Rule’s use of the 100-year floodplain as a factor to establish jurisdiction over adjacent waters and case-specific waters interferes with States’ primary responsibilities over the planning and development of land and water resources in conflict with CWA section 101(b). The agencies also seek comment on to what extent the 100-year floodplain component of the 2015 Rule conflicts with other federal regulatory programs, and whether such a conflict impacts State and local governments.

The agencies noted in 2015 “that the vast majority of the nation’s water features are located within 4,000 feet of a covered tributary, traditional navigable water, interstate water, or territorial sea.”⁷¹ The agencies’ broadening of certain key concepts and terms relative to the prior regulatory regime means that the agencies can potentially review the “vast majority” of water features in the country under the 2015 Rule, unless those features have been excluded from the definition. Similar concern was raised in response to the July 27, 2017 NPRM, for example, by the Missouri Department of Natural Resources and Department of Agriculture.⁷² The agencies seek comment on that analysis and whether the 2015 Rule readjusts the federal-state

⁷⁰ See, e.g., comments submitted by Georgia Municipal Association (Nov. 13, 2014) (Docket ID: EPA-HQ-OW-2011-0880-14527), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-14527>; comments submitted by City of St. Petersburg (Nov. 13, 2014) (Docket ID: EPA-HQ-OW-2011-0880-18897), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2011-0880-18897>.

⁷¹ 2015 Rule Economic Analysis at 11.

⁷² See comments submitted by the Missouri Department of Natural Resources and Department of Agriculture (Sept. 26, 2017) (Docket ID: EPA-HQ-OW-2017-0203-13869), available at <https://www.regulations.gov/document?D=EPA-HQ-OW-2017-0203-13869> (“The broad definition of tributary and the inclusion of a three-quarter mile buffer around every tributary and impoundment, would have cast a very broad jurisdictional umbrella over the state; requiring significant nexus determinations on all but a very few number of waters.”).

balance in a manner contrary to the congressionally determined policy in CWA section 101(b). Indeed, when issuing a preliminary injunction of the 2015 Rule, the Southern District of Georgia held that “The [2015] WOTUS Rule asserts jurisdiction over remote and intermittent waters without evidence that they have a nexus with any navigable-in-fact waters.” *Georgia*, 2018 U.S. Dist. LEXIS 97223, at *19. The agencies thus solicit comment on whether the definitions in the 2015 Rule would subject wholly intrastate or physically remote waters or wetlands to CWA jurisdiction, either categorically or on a case-by-case basis, and request information about the number and scope of such waters of which commenters may be aware.⁷³

Further, the agencies solicit comment about whether these, or any other, aspects of the 2015 Rule as finalized would, as either a *de facto* or *de jure* matter, alter federal-state relationships in the implementation of CWA programs and State regulation of State waters, and whether the 2015 Rule appropriately implements the Congressional policy of recognizing, preserving, and protecting the primary rights of states to plan the development and use of land and water resources. Because such findings would, if adopted by the agencies, negate a key finding underpinning the 2015 Rule, the agencies request comment on whether to repeal the 2015 Rule on this basis.

5. Additional Bases for Repealing the 2015 Rule That the Agencies Are Considering

In addition to our proposed conclusions that the 2015 Rule failed to provide regulatory certainty and that it exceeded the agencies’ authority under the CWA, the agencies are also considering several other supplemental bases for repealing the 2015 Rule. These are discussed below along with requests for public comment.

Some commenters have suggested that the 2015 Rule may exceed Congress’ power under the Commerce Clause. The Supreme Court in *SWANCC* found that, in enacting the CWA, Congress had in mind as its authority “its traditional jurisdiction over waters that were or had been navigable in fact or which could reasonably be so made.” 531 U.S. at 172. The Court went on to construe the CWA to avoid the significant constitutional

⁷³ This includes whether the 2015 Rule is supported by a “clear and manifest” statement under the CWA to change the scope of traditional state regulatory authority. See *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 544 (1994); see also *Bond v. United States*, 134 S. Ct. 2077, 2089–90 (2014); *SWANCC*, 531 U.S. at 172–74.

questions raised by the agencies' assertion that the "Migratory Bird Rule" falls within Congress' power to regulate intrastate activities that 'substantially affect' interstate commerce." *Id.* at 173. The agencies are evaluating the concerns, reflected in certain comments received by the agencies, that many features that are categorically jurisdictional under the 2015 Rule, such as wetlands that fall within the distance thresholds of the definition of "neighboring," test the limits of the scope of the Commerce Clause because they may not have the requisite effect on the channels of interstate commerce.⁷⁴

For example, according to certain litigants challenging the 2015 Rule, the "seasonally ponded, abandoned gravel mining depressions" specifically at issue in *SWANCC*, 531 U.S. at 164, which the Supreme Court determined were "nonnavigable, isolated, intrastate waters," *id.* at 166–72, might be subject to case-specific jurisdiction under the 2015 Rule. The depressions appear to be located within 4,000 feet of Poplar Creek, a tributary to the Fox River, and may have the ability to store runoff or contribute other ecological functions in the watershed.

The agencies request comment, including additional information, on whether the water features at issue in *SWANCC* or other similar water features could be deemed jurisdictional under the 2015 Rule, and whether such a determination is consistent with or otherwise well-within the agencies' statutory authority, would be unreasonable or go beyond the scope of the CWA, and is consistent with Justice Kennedy's significant nexus test expounded in *Rapanos* wherein he stated, "[b]ecause such a [significant] nexus was lacking with respect to isolated ponds, the [*SWANCC*] Court held that the plain text of the statute did not permit" the Corps to assert jurisdiction over them. *See* 547 U.S. at 767.

The examples identified in Section II.C.3 above raise similar issues. The abandoned borrow pit, for example, discussed in Case Study C—AJD Number MVM—2014–460, was determined by the Corps in December 2014 to be an isolated water located 2,184 feet from a relatively permanent body of water "with no substantial nexus to interstate (or foreign) commerce" (*see* Support Document), yet

the agencies later stated the feature would be jurisdictional under the 2015 Rule. In addition, the wetlands at issue in Case Study B—AJD Number 2004–001914 (*see* Support Document) described above in Section II.C.3 were located 583 feet from the Johlin Ditch outside Toledo, Ohio, situated east of an existing medical building and west of an agricultural area. The wetlands were determined by the Corps to be isolated, lacking a surface connection to a water of the United States and a substantial nexus to interstate commerce. Those wetlands, however, were later stated by the agencies to be subject to CWA jurisdiction under the 2015 Rule. The agencies therefore solicit comment on whether the 2015 Rule would cover such wetlands and, if so, whether that would exceed the CWA's statutory limits. *See, e.g., SWANCC*, 531 U.S. at 171–72, 174 ("[W]e find nothing approaching a clear statement from Congress that it intended § 404(a) to reach an abandoned sand and gravel pit" that is "isolated.>").

Interested parties are encouraged to provide comment on whether the 2015 Rule is consistent with the statutory text of the CWA and relevant Supreme Court precedent, the limits of federal power under the Commerce Clause as specifically exercised by Congress in enacting the CWA, and any applicable legal requirements that pertain to the scope of the agencies' authority to define the term "waters of the United States." The agencies also solicit comment on any other issues that may be relevant to the agencies' consideration of whether to repeal the 2015 Rule, such as whether any potential procedural deficiencies limited effective public participation in the development of the 2015 Rule.⁷⁵

D. The Agencies' Next Steps

In defining the term "waters of the United States" under the CWA, Congress gave the agencies broad discretion to articulate reasonable limits on the meaning of that term, consistent with the Act's text and its policies as set forth in CWA section 101. In light of the substantial litigation risk regarding waters covered under the 2015 Rule, and based on the agencies' experience and expertise in applying the CWA, the agencies propose to repeal the 2015 Rule and put in place the prior regulation. This is based on the concerns articulated above and the agencies' concern that there may be significant disruption to the implementation of the Act and to the

public, including regulated entities, if the 2015 Rule were vacated in part. The agencies therefore propose to exercise their discretion and policy judgment by repealing the 2015 Rule permanently and in its entirety because the agencies believe that this approach is the most appropriate means to remedy the deficiencies of the 2015 Rule identified above, address the litigation risk surrounding the 2015 Rule, and restore a regulatory process that has been in place for years.

The agencies have considered other alternatives that could have the effect of addressing some of the potential deficiencies identified, including proposing revisions to specific elements of the 2015 Rule, issuing revised implementation guidance and implementation manuals, and proposing a further change to the February 6, 2020 applicability date of the 2015 Rule. The agencies are soliciting comments on whether any of these alternative approaches would fully address and ameliorate potential deficiencies in and litigation risk associated with the 2015 Rule. Consistent with the President's Executive Order, the agencies are also evaluating options for revising the definition of "waters of the United States."

The agencies are proposing to permanently repeal the 2015 Rule at this time, and are taking comment on whether this proposal is the best and most efficient approach to address the potential deficiencies identified in this notice and to provide the predictability and regulatory certainty that alternative approaches may not provide.

E. Effect of Repeal

The 2015 Rule amended longstanding regulations contained in portions of 33 CFR part 328 and 40 CFR parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401 by revising, removing, and redesignating certain paragraphs and definitions in those regulations. In this action, the agencies would repeal the 2015 Rule and restore the regulations in existence immediately prior to the 2015 Rule. As such, if the agencies finalize this proposal and repeal the 2015 Rule and thus repeal those amendments, the regulatory definitions of "waters of the United States" in effect would be those portions of 33 CFR part 328 and 40 CFR parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401 as they existed immediately prior to the 2015 Rule's amendments. *See, e.g., API v. EPA*, 883 F.3d 918, 923 (DC Cir. 2018) (regulatory criterion in effect immediately before enactment of criterion that was vacated by the court "replaces the now-vacated" criterion). Thus, if the agencies

⁷⁴ Though the agencies have previously said that the 2015 Rule is consistent with the Commerce Clause and the CWA, the agencies are in the process of considering whether it is more appropriate to draw a jurisdictional line that ensures that the agencies regulate well within our constitutional and statutory bounds.

⁷⁵ *See, e.g., Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (DC Cir. 1983).

determine that repeal of the 2015 Rule is appropriate, the agencies concurrently would recodify the prior regulation in the CFR, which would not have the effect of creating a regulatory vacuum, and the agencies need not consider the potential consequences of such a regulatory vacuum in light of this. If this proposed rule is finalized, the agencies propose to apply the prior definition until a new definition of CWA jurisdiction is finalized.

The current regulatory scheme for determining CWA jurisdiction is “familiar, if imperfect,” *In re EPA*, 803 F.3d at 808, and the agencies and regulated public have significant experience operating under the longstanding regulations that were replaced by the 2015 Rule. The agencies would continue to implement those regulations, as they have for many years, consistent with Supreme Court decisions and practice, other case law interpreting the rule, and informed by agency guidance documents. Apart from a roughly six-week period when the 2015 Rule was in effect in 37 States, the agencies have continued to implement the preexisting regulatory definitions as a result of the court orders discussed in Section I.B. above, as well as the final rule adding an applicability date to the 2015 Rule (83 FR 5200, Feb. 6, 2018). While the agencies acknowledge that the 1986 and 1988 regulations have been criticized and their application has been narrowed by various legal decisions, including *SWANCC* and *Rapanos*, the longstanding nature of the regulatory framework and its track record of implementation makes it preferable until the agencies propose and finalize a replacement definition. The agencies believe that, until a new definition is completed, it is important to retain the status quo that has been implemented for many years rather than the 2015 Rule, which has been and continues to be mired in litigation.

In other words, restoration of the prior regulatory text in the CFR, interpreted in a manner consistent with Supreme Court decisions, and informed by applicable agency guidance documents and longstanding practice, will ensure that the scope of CWA jurisdiction will be administered in the same manner as it is now; as it was during the Sixth Circuit’s lengthy, nationwide stay of the 2015 Rule; and as it was for many years prior to the promulgation of the 2015 Rule. To be clear, the agencies are not proposing a new definition of “waters of the United States” in this specific rulemaking separate from the definition that existed immediately prior to the 2015 Rule. The agencies also are not proposing to take this action in order to

fill a regulatory gap because no such gap exists today. *See* 83 FR 5200, 5204. Rather, the agencies are solely proposing to repeal the 2015 amendments to the above-referenced portions of the CFR and recodify the prior regulatory text as it existed immediately prior to the 2015 Rule’s amendments.

III. Minimal Reliance Interests Implicated by a Repeal of the 2015 Rule

More than 30,000 AJDs of individual aquatic resources and other features have been issued since August 28, 2015, the effective date of the 2015 Rule. However, less than two percent of the AJDs of individual aquatic resources were issued under the 2015 Rule provisions in the six weeks the rule was in effect in a portion of the country.⁷⁶ The 2015 Rule was in effect in only 37 States for about six weeks between the 2015 Rule’s effective date and the Sixth Circuit’s October 9, 2015 nationwide stay order, *see In re EPA*, 803 F.3d 804 (6th Cir. 2015), and only 540 AJDs for aquatic resources and other features were issued during that short window of time. The remainder of the AJDs issued since August 28, 2015, were issued under the regulations defining the term “waters of the United States” that were in effect immediately before the effective date of the 2015 Rule.

“Sudden and unexplained change, . . . or change that does not take account of legitimate reliance on prior [agency] interpretation, . . . may be arbitrary, capricious [or] an abuse of discretion[,] [b]ut if these pitfalls are avoided, change is not invalidating[.]” *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996) (internal quotation marks and citations omitted). Therefore, in proposing to repeal the 2015 Rule, the agencies are considering any interests that may have developed in reliance on the 2015 Rule, as well as the potential harm to such reliance interests from repealing the Rule against the benefits. The agencies solicit comment on whether the AJDs that were issued under the 2015 Rule’s brief tenure (and any ensuing reliance interests that were developed) would be adversely affected by the Rule’s repeal. If the potential for such harm exists, the agencies also solicit comment on whether those harms outweigh the potential benefits of repealing the 2015 Rule.

⁷⁶ *See* Clean Water Act Approved Jurisdictional Determinations, available at <https://watersgeo.epa.gov/cwa/CWA-AJDs>, as of May 9, 2018. The 2015 Rule was enjoined in 13 States by the U.S. District Court for the District of North Dakota and has never gone into effect in those States.

In staying the 2015 Rule nationwide, the Sixth Circuit found no indication “that the integrity of the nation’s waters will suffer imminent injury if the [2015 Rule] is not immediately implemented and enforced.” *In re EPA*, 803 F.3d at 808. The Sixth Circuit wrote that the “burden—potentially visited nationwide on governmental bodies, state and federal, as well as private parties—and the impact on the public in general, implicated by the Rule’s effective redrawing of jurisdictional lines over certain of the nation’s waters” was of “greater concern.” *Id.* As a result, the Sixth Circuit held that “the sheer breadth of the ripple effects caused by the Rule’s definitional changes counsels strongly in favor of maintaining the status quo for the time being.” *Id.* For the reasons expounded in this notice and the NPRM, the agencies believe that any potential adverse reliance interests are outweighed by the benefits of the agencies’ proposed action. The agencies therefore propose to repeal the 2015 Rule and request comment on that proposal.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review; Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review prior to the NPRM and again prior to issuance of the SNPRM. Any changes made in response to OMB recommendations have been documented in the docket.

While economic analyses are informative in the rulemaking context, the agencies are not relying on the economic analysis performed pursuant to Executive Orders 12866 and 13563 and related procedural requirements as a basis for this proposed action. *See, e.g., NAHB*, 682 F.3d at 1039–40 (noting that the quality of an agency’s economic analysis can be tested under the APA if the “agency decides to rely on a cost-benefit analysis as part of its rulemaking”).

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Cost

This rule is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the economic analysis that was published together with the NPRM.

C. Paperwork Reduction Act

This proposed rule does not impose any new information collection burdens under the Paperwork Reduction Act.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

The proposed repeal of the 2015 Rule is a deregulatory action that would effectively maintain the status quo as the agencies are currently implementing it, and avoid the imposition of potentially significant adverse economic impacts on small entities in the future. Details on the estimated cost savings of this proposed rule can be found in the economic analysis that was published together with the NPRM. Accordingly, after considering the potential economic impacts of the proposed repeal action on small entities, we certify that this proposed action will not have a significant economic impact on a substantial number of small entities.

E. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), signed into law on March 22, 1995, an agency must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated cost to state, local, or tribal governments in the aggregate, or to the private sector, of \$100 million or more. Under section 205 of the UMRA, the agency must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires the agency to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. This proposed action does not contain any unfunded mandate as described in the UMRA, and does not significantly or uniquely affect small governments. The definition of “waters of the United States” applies broadly to CWA programs. The proposed action imposes no enforceable duty on any state, local, or tribal governments, or the private sector, and does not contain regulatory requirements that significantly or uniquely affect small governments.

F. Executive Order 13132: Federalism

Executive Order 13132 requires the agencies to develop an accountable process to ensure “meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implication” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” Under Executive Order 13132, the agencies may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by state and local government, or the agencies consult with state and local officials early in the process of developing the proposed regulation. The agencies also may not issue a regulation that has federalism implications and that preempts state law unless the agencies consult with state and local officials early in the process of developing the proposed regulation.

This proposed rule will not have substantial direct effects on the states, on the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely proposes to repeal a rule that was in effect in only a portion of the country for a short period of time, and does not alter the relationship or the distribution of power and responsibilities established in the CWA. The agencies are proposing to repeal the 2015 Rule in part because the 2015 Rule may have impermissibly and materially affected the states and the distribution of power and responsibilities among the various levels of government and therefore likely should have been characterized as having federalism implications when promulgated in 2015. Thus, the requirements of section 6 of the Executive Order do not apply to this proposed rule because it returns the federal-state relationship to the status quo.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled “Consultation and Coordination with

Indian Tribal Governments” (65 FR 67249, Nov. 9, 2000), requires the agencies to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” This proposed rule does not have tribal implications, as specified in Executive Order 13175. This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, because it merely preserves the status quo currently in effect today and in effect immediately before promulgation of the 2015 Rule. Thus, Executive Order 13175 does not apply to this proposed rule. Consistent with E.O. 13175, however, the agencies have and will continue to consult with tribal officials, as appropriate, as part of any future rulemaking to define “waters of the United States.”

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045, “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, Apr. 23, 1997), applies to any rule that: (1) Is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that an agency has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. This proposed rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act of 1995 requires federal agencies to evaluate existing technical standards when developing a new regulation. The proposed rule does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This proposed rule maintains the legal status quo. The agencies therefore believe that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, Feb. 16, 1994).

List of Subjects

33 CFR Part 328

Environmental protection, Administrative practice and procedure, Navigation (water), Water pollution control, Waterways.

40 CFR Part 110

Environmental protection, Oil pollution, Reporting and recordkeeping requirements.

40 CFR Part 112

Environmental protection, Oil pollution, Penalties, Reporting and recordkeeping requirements.

40 CFR Part 116

Environmental protection, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 117

Environmental protection, Hazardous substances, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 122

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 230

Environmental protection, Water pollution control.

40 CFR Part 232

Environmental protection, Intergovernmental relations, Water pollution control.

40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Occupational safety and health, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

40 CFR Part 302

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

40 CFR Part 401

Environmental protection, Waste treatment and disposal, Water pollution control.

■ For the reasons stated herein, the agencies propose to amend 33 CFR part 328 and 40 CFR parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401 of the Code of Federal Regulations to repeal the amendments that were promulgated in the 2015 Rule and reestablish the regulatory text that was in place immediately prior to promulgation of the 2015 Rule.

Dated: June 29, 2018.

E. Scott Pruitt,

Administrator, Environmental Protection Agency.

Dated: June 29, 2018.

R.D. James,

Assistant Secretary of the Army (Civil Works).

[FR Doc. 2018-14679 Filed 7-11-18; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2413-P]

RIN 0938-AT61

Medicaid Program; Reassignment of Medicaid Provider Claims

AGENCIES: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: This proposed rule would remove the regulatory text that allows a state to make payments to third parties on behalf of an individual provider for

benefits such as health insurance, skills training, and other benefits customary for employees. We are concerned that these provisions are overbroad, and insufficiently linked to the exceptions expressly permitted by the statute. As we noted in our prior rulemaking, section 1902(a)(32) of the Act provides for a number of exceptions to the direct payment requirement, but it does not authorize the agency to create new exceptions.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 13, 2018.

ADDRESSES: In commenting, please refer to file code CMS-2413-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2413-P, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2413-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

FOR FURTHER INFORMATION CONTACT: Christopher Thompson, (410) 786-4044.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

The Medicaid program was established by the Congress in 1965 to

provide health care services for low-income and disabled beneficiaries. Section 1902(a)(32) of the Social Security Act (the Act) requires direct payment to providers who render services to Medicaid beneficiaries. It states that no payment under the plan for care and services provided to an individual shall be made to anyone other than such individual or the person or institution providing such care or service, under an assignment or power of attorney or otherwise.

We codified § 447.10 implementing section 1902(a)(32) of the Act in the “Payment for Services” final rule published on September 29, 1978 (43 FR 45253). The statute provides several specific exceptions to the general principle of requiring that direct payment be made to the individual provider. The regulations implementing section 1902(a)(32) of the Act have generally tracked the plain statutory language and required direct payments absent a statutory exception.

In 2012, we proposed a new regulatory exception in the “Provider Payment Reassignment, and Setting Requirements for Community First Choice” proposed rule published on May 3, 2012 (77 FR 26361, 26406) for “a class of practitioners for which the Medicaid program is the primary source of service revenue” such as home health care providers. We recognized in the preamble to the proposed rule that section 1902(a)(32) of the Act does not authorize additional exceptions to the direct payment requirement (See 77 FR 26382).

We received a total of 7 comments on the proposed regulatory exception, all generally supportive of the proposed rule. This provision was finalized in the “Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community-Based Services (HCBS) Waivers” final rule published on January 16, 2014 (79 FR 2947, 3001) and authorized a state to make payments to third parties on behalf of the individual provider “for benefits such as health insurance, skills training, and other benefits customary for employees.”

We are concerned that § 447.10(g)(4) is overbroad, and insufficiently linked to the exceptions expressly permitted by the statute. As we noted in our prior rulemaking, section 1902(a)(32) of the Act provides for a number of exceptions to the direct payment requirement, but it does not authorize the agency to create new exceptions. Therefore, the regulatory provision grants permissions that Congress has foreclosed, so we are

proposing to remove the regulatory exception at § 447.10(g)(4).

II. Provisions of the Proposed Regulations

This proposal would remove § 447.10(g)(4), but leave in place the other provisions in § 447.10 including the exceptions at § 447.10(e), (f) and (g)(1) through (3). We seek comments regarding how we might provide further clarification on the types of payment arrangements that would be permissible assignments of Medicaid payments, such as arrangements where a state government withholds payments under a valid assignment. Specifically, we invite comments with examples of payment withholding arrangements between states and providers that we should address.

With regard to section 1915(c), 1915(i), 1915(j), and 1915(k) authority, this proposed rule will not impact a state’s ability to perform Financial Management Services (FMS) or secure FMS through a vendor arrangement. However, we also request comments on whether and how the proposed removal of § 447.10(g)(4) would impact self-directed service models, where the Medicaid beneficiary takes responsibility for retaining and managing his or her own services, and, in some cases, may be performing payroll and other employer-related duties. We are especially interested in comments that describe the additional flexibilities needed to support beneficiaries opting for self-directed service models, which may ensure stable, high-quality care for those beneficiaries.

III. Collection of Information Requirements

To the extent a state changes its payment as a result of this rule, the state would be required to notify entities of the pending change in payment and update its payment system. We believe the associated burden is exempt from the Paperwork Reduction Act (PRA) in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned requirement would be incurred by the state during the normal course of their activities and, therefore, should be considered usual and customary business practices.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and

time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

We are concerned that § 447.10(g)(4) is overbroad, and insufficiently linked to the exceptions expressly permitted by the statute. Therefore, the regulatory provision grants permissions that Congress has foreclosed. As we noted in our prior rulemaking published on January 16, 2014 (79 FR 2947, 3001), section 1902(a)(32) of the Act provides for a number of exceptions to the direct payment requirement, but the language does not explicitly authorize the agency to create new exceptions. Therefore, we are proposing to remove the regulatory exception at § 447.10(g)(4). To the extent a state increased reimbursement levels to reassign portions of a provider’s reimbursement to a third party, implementation of this rule may affect the rates that are set by the state in the future.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) create a serious

inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this proposed rule could be "economically significant" as it may have an annual effect on the economy in excess of the \$100 million threshold of Executive Order 12866, and hence that this proposed rule is also a major rule under the Congressional Review Act. However there is considerable uncertainty around this estimate and the Department invites public comments to help refine this analysis.

As discussed above, in the "Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community-Based Services (HCBS) Waivers" final rule published on January 16, 2014 (79 FR 2947, 3001), we authorized a state to make payments to third parties on behalf of the individual provider "for benefits such as health insurance, skills training, and other benefits customary for employees." We lack information with which to quantify the potential impacts of this policy on these types of payments as the Department does not formally track the amount of reimbursement that is being reassigned to third parties by states. To offer one example, one such potential impact of the proposed rulemaking would be that states stop reassigning homecare workers' dues to unions. We estimate that unions may currently collect as much as \$71 million from such assignments.¹ While we have not

similarly quantified the amount of other authorized reassignments, such as health insurance, skills training, or other benefits, we believe that the amount of payments made to third parties on behalf of individual providers for the variety of benefits within the scope of this rulemaking is likely in excess of \$100 million. We seek comment on this estimate, and particularly on the type and amount of payments currently being reassigned under the exceptions in § 447.10(g).

The potential direct financial impact to providers of this policy change could be affected by many factors, such as the nature and amounts of the types of payments currently being reassigned and decisions made by homecare providers after a final policy takes effect about whether or not to resume payments to third parties for these types of benefits. The Department is unable to quantify these direct financial impacts in the absence of specific information about the types and amount of payments being reassigned. Even where it may be possible to derive such estimates, such as with the example of union dues, the Department lacks information to reliably estimate the proportion of homecare providers likely to stop making payments versus those likely to continue making payments through alternative means. We request comments on the factors that might influence the direct financial impacts to providers and recipients of reassignments of this policy change for the varied types and amount of payments currently being reassigned under the exceptions in § 447.10(g).

Although states will no longer be able to withhold portions of a provider's payment, states may elect to maintain the same level of payment, thus affording the provider the opportunity to purchase the items that were previously funded through the reassignment of reimbursement. Conversely, states may elect to decrease payment levels because rescission of § 447.10(g)(4) will limit their ability to reassign payment to third parties. In other words, states may have previously factored their ability to reassign provider payments into their payment rates and might choose to revise their rates in response to this regulatory change. We request comments, particularly from states, on potential

potentially affected by this proposed rule. This transfer estimate could be over- or understated if other states pay home care workers different average wages than Pennsylvania and Illinois, if dues payments are collected at different rates, or if participation in Medicaid home care programs is not proportionate to total population.

state behavior under the proposed policy.

If a state elected to maintain the same level of payment, and if homecare providers opt to continue all voluntary payments presently being reassigned, then the rule may have no impacts. However, if a state elected to reduce payment levels and/or if homecare providers opt to discontinue all voluntary payments, then the impacts of the rule may be close to the full amount of current reassignments, thus making the rule economically significant.

While it is difficult for us to conduct a detailed quantitative analysis given this considerable uncertainty and lack of data, we believe that without this proposed rulemaking, states may apply the exceptions at § 447.10(g) in ways that do not comport with section 1902(a)(32) of the Act and we welcome comment with regard to the quantitative impact of the elimination of states' ability to reassign Medicaid payment for items such as health insurance, skills training and other benefits customary for employees. We also seek comments identifying impacts to states and the federal government as a result of this proposed rule, including on the assumption that the time, effort and financial resources necessary to comply with the proposed requirement would be incurred by states during the normal course of their activities and, therefore, does not impose incremental costs.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary proposes to certify, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment

¹ Dues payments potentially associated with policies of the type being proposed for revision have been reported to be \$8 million in Pennsylvania and \$10 million in Illinois (<https://www.fairnesscenter.org/cases/detail/protecting-the-vulnerable> and <https://www.washingtonexaminer.com/illinois-politicians-forced-home-care-workers-into-union-that-donates-heavily-to-them/article/2547368>). The total population is approximately 26 million in these two states and 102 million across the states that have been reported by the State Policy Network to have relevant third-party payment policies (California, Connecticut, Illinois, Maryland, Massachusetts, Minnesota, Missouri, New Jersey, Oregon, Vermont and Washington) (<https://www2.census.gov/programs-surveys/popest/tables/2010-2017/state/totals/nst-est2017-01.xlsx> and <https://spn.org/dues-skimming-faqs/>). Factoring the \$18 million (= \$8 million + \$10 million) proportionately by population yields a nationwide total of approximately \$71 million in union dues payments

regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary proposes to certify, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

D. Alternatives Considered

We considered issuing guidance to require states to formally document consent to reassign portions of a provider's payment. We also considered limiting the items for which provider reassignment could be made. However, we are concerned that § 447.10(g)(4) is

overbroad, and insufficiently linked to the exceptions expressly permitted by the statute. Therefore, we believe removing the regulatory exception is the best course of action.

E. Accounting Statement

As required by OMB Circular A-4 under Executive Order 12866 (available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>) in Table 1, we have prepared an accounting statement showing the classification of transfers associated with the provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis and omits categories of impacts for which partial quantification has not been possible.

TABLE 1—ACCOUNTING STATEMENT

Category	Low estimate	High estimate	Units		
			Year dollars	Discount rate (%)	Period covered
Transfers:					
Annualized Monetized \$ millions/year	0	\$71	2017	3	2019
	0	71	2017	7	2019
From whom to whom?	From third parties to home health providers.				

F. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This proposed rule is not expected to be subject to the requirements of E.O. 13771 because this proposed rule is expected to result in no more than *de minimis* costs.

G. Conclusion

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 447.10 [Amended]

■ 2. Section 447.10 is amended by removing paragraph (g)(4).

Dated: May 3, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 7, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–14786 Filed 7–10–18; 11:15 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 18–184; FCC 18–69]

New FM Radio Broadcast Class C4 and To Modify the Requirements for Designating Short-Spaced Assignments

AGENCY: Federal Communications Commission.

ACTION: Notice of inquiry.

SUMMARY: In this document, the Commission adopted a Notice of Inquiry (NOI), based on a petition for rulemaking filed by SSR Communications, Inc., in which the Commission sought comment on a proposal to create a new class of FM radio stations, Class C4, and to establish a procedure for designating certain FM stations.

DATES: Comments may be filed on or before August 13, 2018 and reply comments may be filed on or before September 10, 2018.

ADDRESSES: You may submit comments, identified by MB Docket No. 18–184, by any of the following methods:

- *Federal Communications*

Commission's Website: http://

www.fcc.gov/cgb/ecfs/. Follow the instructions for submitting comments.

- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- *People With Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov or phone: (202) 418-0530 or TTY: (202) 418-0432. For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Albert Shuldiner, Chief, Media Bureau, Audio Division, (202) 418-2721; James Bradshaw, Deputy Division Chief, Media Bureau, Audio Division, (202) 418-2739. Direct press inquiries to Janice Wise at (202) 418-8165.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Inquiry, FCC 18-69, adopted June 4, 2018, and released June 5, 2018. The full text of this document is available electronically via the FCC's Electronic Document Management System (EDOCS) website at <http://https://www.fcc.gov/edocs> or via the FCC's Electronic Comment Filing System (ECFS) website at <http://https://www.fcc.gov/ecfs/>. (Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.) This document is also available for public inspection and copying during regular business hours in the FCC Reference Information Center, which is located in Room CY-A257 at FCC Headquarters, 445 12th Street SW, Washington, DC 20554. The Reference Information Center is open to the public Monday through Thursday from 8:00 a.m. to 4:30 p.m. and Friday from 8:00 a.m. to 11:30 a.m. Alternative formats are available for people with disabilities (braille, large print, electronic files, audio format), by sending an email to fcc504@fcc.gov or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

Synopsis of Notice of Inquiry

1. *Introduction.* In this Notice of Inquiry (NOI), the Commission explores the possibility of amending part 73 of the Commission's Rules to create an intermediate class of FM broadcast

stations in Zone II between Class A and Class C3, to be designated Class C4. Commission staff estimates that 127 Class C3 stations, or 14 percent of the total number of Class C3 stations, are operating with facilities that are less than the proposed Class C3 minimums and thus could be subject to reclassification to Class C4. It also explores the possibility of establishing a procedure whereby an FM station in the non-reserved band (Channels 221-300), regardless of Zone or station class, could be designated as a Section 73.215 facility, resulting in such station receiving interference protection based on its actual authorized operating parameters rather than the maximum permitted parameters for its station class.

2. *Class C4 proposal.* This proceeding was initiated by a petition for rulemaking filed by SSR Communications, Inc. (SSR). SSR advocates the creation of a new Class C4 with an effective radiated power (ERP) that must exceed 6 kilowatts, a maximum ERP of 12 kilowatts, and a reference HAAT of 100 meters. The ERP that Class C3 stations must exceed would increase from 6 kilowatts to 12 kilowatts, but the maximum ERP would remain at 25 kilowatts. In addition, under the current rules, a station can operate below the minimum ERP for its class provided its HAAT allows it to exceed the class contour distance for the next lower class (for example, a Class C3 station must exceed the Class A contour distance of 28 kilometers). Under the SSR proposal, the next lower class for a Class C3 station would be Class C4, with a contour distance of 33 kilometers. SSR proposes amending Sections 73.207(b)(1), 73.210(a), 73.210(b), 73.211(a)(1), 73.211(b), and 73.215(e) of the Rules to implement these changes. SSR argues that a new Class C4 would provide upgrade opportunities for Class A facilities, particularly minority-owned stations, and create consistent ERP intervals between FM classes.

3. *Affected stations and their listeners.* Would the creation of a Class C4 materially benefit existing Class A stations by providing them with an opportunity to upgrade that is not possible today based on the current Class C3 parameters? Would Class A stations and their listeners, particularly in rural or underserved areas, benefit from the new Class C4? Is there a significant demand for the rule changes proposed by SSR? How many stations are likely to be affected by such a rule change? As suggested by SSR, would the creation of a Class C4 be particularly beneficial for minority-owned Class A

stations by providing them with an opportunity to upgrade? Would this action encourage diversity of ownership in the FM broadcast industry? Would there be a detrimental effect on existing stations and/or their listeners generally, either from increased interference or reclassification (upgrade or downgrade)?

4. *Secondary services.* How would a new Class C4 affect secondary services (FM translators and LPFM stations), as well as AM primary stations that rebroadcast on FM translator stations? Are there lawful ways to mitigate or eliminate the impact of this proposal on secondary services, and, if so, what measures would be effective or appropriate? To what extent, if any, does the Local Community Radio Act of 2010 (LCRA) impact the Commission's ability to protect existing FM translator and LPFM stations? In particular, would such protections be consistent with the LCRA directive that the "Federal Communications Commission, when licensing new FM translators, FM booster stations, and low-power FM stations . . . ensure . . . that . . . (3) [these stations] remain equal in status and secondary to existing and modified full-service FM stations"? In this respect, the Commission notes that it would be reluctant to adopt any proposal in this area that would have a significantly negative impact on FM translators and LPFM stations.

5. *Allocation goals.* Given the maturity of the FM service, would an increased density of signals resulting from Class A stations upgrading to Class C4 provide improved FM service coverage, or merely contribute to a higher "noise floor" overall while only modestly benefiting individual stations? Would upgrades to Class C4 increase the overall number of radio stations available to listeners or create interference that would degrade reception for stations in areas where there is currently a listenable signal, resulting in fewer listening choices for listeners? More generally, is there a "tipping point" at which increasingly granular station classifications are no longer conducive to efficient signal coverage and, if so, has that point been reached?

6. *Implementation procedures.* What is the appropriate balance of interests between the anticipated benefit of creating a new class of FM stations and the disruption entailed in the reclassification of existing stations? If a new class is created, should the Commission implement a blanket reclassification process, as it did in 1983 and 1989, by requiring existing Class C3 stations to file for modification to meet the proposed revised minimum facility

requirements for Class C3 stations within a set time frame or be reclassified based on their actual operating facilities? Should the mere filing for a modification be sufficient to avoid reclassification or should the Commission also require construction to be completed by a date certain? If a date certain is set for filing a modification or completing construction, what would be a reasonable amount of time for licensees to comply? Would a blanket reclassification provide more reliable and timely opportunities for upgrade than the show cause procedure outlined in the next paragraph?

7. Alternatively, should the Commission adopt a show cause procedure similar to that currently in use for Class C0, whereby a Class C3 station operating below the proposed revised minimum facility requirements for Class C3 stations would be reclassified only after the filing of a “triggering” application that requires it to be reclassified to Class C4? Should the affected Class C3 station have the opportunity to preserve its Class C3 status by filing a construction permit application to upgrade its facility to meet Class C3 minimums? The Commission notes that the Commission’s licensing staff has found that the Class C0 show cause procedure appears to incentivize delay and contention between the parties. Have licensees experienced delay or other difficulties using the Class C0 show cause procedure? Is the blanket reclassification process described in the preceding paragraph preferable for that reason? Are there other implementation approaches the Commission should consider that might address or avoid problems identified with this show cause procedure?

8. *Other issues.* To what extent, if any, does the LCRA impact the Commission’s creation of a new class of FM stations or reclassification of existing FM stations; in particular, the provision that the Commission “shall not amend its rules to reduce the minimum co-channel and first- and second-adjacent channel distance separation requirements in effect on [January 4, 2011] between—(A) low-power FM stations; and (B) full-service FM stations”? Are there specific rule changes that would be necessary or advisable to implement any of the foregoing proposals? The Commission also invites commenters to make suggestions as to how the Commission’s forms and databases should be modified to implement the above proposals.

9. *Section 73.215 proposal.* SSR argues that, by providing interference protection to a station’s contours based

on maximum class facilities, as opposed to the actual facilities, the Commission’s rules overprotect stations operating with facilities below their class maximum. Accordingly, SSR proposes an amendment to Section 73.3573 of the Rules that would require such “sub-maximum” stations to be designated as Section 73.215 facilities using a procedure similar to the existing Class C0 show cause and reclassification procedure. Designation as a Section 73.215 facility would result in the sub-maximum station receiving interference protection based on its actual authorized operating parameters rather than the maximum permitted parameters for its station class. Under SSR’s proposed procedure, stations not already authorized under Section 73.215 that, for ten years prior to the filing of a triggering application, have continuously operated with a HAAT or ERP below that of the class maximum (or equivalent class maximum HAAT and ERP combination in the case of station operating with a HAAT exceeding its reference HAAT) would be given an opportunity to upgrade to maximum class facilities or be subject to designation as a Section 73.215 facility.

10. SSR recommends a show cause procedure to implement its Section 73.215 proposal. Specifically, the procedure would be initiated by the filing of a “triggering” application that specifies facilities that require the designation of the affected sub-maximum station as a Section 73.215 facility. Triggering applications may utilize Section 73.215 and must certify that no alternative channel is available for the proposed service. Copies of a triggering application and related pleadings would be required to be served on the licensee of the affected sub-maximum station. If the staff concludes that a triggering application is acceptable for filing, it would issue an order to show cause why the affected sub-maximum station should not be designated as a Section 73.215 station. The order to show cause would provide the licensee of the sub-maximum station 30 days to express in writing an intention to seek authority to modify its technical facilities to its maximum class HAAT and ERP (or equivalent combination thereof) or to otherwise challenge the triggering application. If no such intention is expressed and the triggering application is not challenged, the affected sub-maximum station would be designated as a Section 73.215 station and processing of the triggering application would be completed. If such intention is expressed within the 30-day period, an additional 180-day period

would be provided during which the licensee of the sub-maximum station would be required to file an acceptable construction permit application to increase HAAT and/or ERP to its class maximum values (or equivalent combination thereof). Upon grant of such a construction permit application, the triggering application would be dismissed. As with Class C0 reclassifications, the licensee of the sub-maximum station would be required to serve on triggering applicants copies of any FAA submissions related to the application grant process. If the construction is not completed as authorized, the affected sub-maximum station would be automatically designated as a Section 73.215 facility. SSR’s proposal raises issues similar to those posed by the Class C4 proposal, and the Commission seeks comment generally on the costs and benefits of the proposal.

11. *Affected stations and their listeners.* Would the proposed Section 73.215 mechanism materially benefit stations seeking to upgrade and their listeners? What is the demand for such upgrades? Would there be a corresponding detrimental effect on listeners regarding loss of existing interference-free service provided by sub-maximum stations? The Commission has explained that its policy of protecting all stations as if they are operating at maximum permitted height or power for their class, even if they are in fact operating at or near the minimum permitted height and power for their class, “permits stations to improve technical facilities over time and provides a certain degree of flexibility for transmitter relocations.” To what extent would adoption of the Section 73.215 proposal undermine this policy? Is this policy still desirable in the mature FM service? What are the relevant factors that might affect the sub-maximum station’s ability to upgrade to the class maximums, and have those factors changed due to technological or other developments? If a station has operated below maximum facilities for a sufficient period of time, can the Commission conclude that the station is either unwilling or unable to operate at maximum facilities, thereby justifying protecting such station based on actual operating parameters and allowing for more efficient utilization of FM spectrum? Is ten years of continuous “sub-maximum” operation the appropriate period of time before a station would be subject to involuntary Section 73.215 designation, as suggested by SSR, or is another period of time

appropriate? To what extent should transfers of control or assignments of licensees impact the relevant time period? That is, should the time period apply per station or per licensee? For example, if the relevant time period is ten years and a station that has operated below class maximums for nine years is transferred or assigned to a third-party, should the new licensee have ten additional years to upgrade to class maximums free from potential designation as a Section 73.215 facility?

12. *Secondary services.* The Commission seeks comment on the likely impact of full service station upgrades using the proposed Section 73.215 procedure on nearby secondary services or AM primary stations that rebroadcast on FM translator stations. Are there lawful ways to mitigate or eliminate the impact of this proposal on secondary services, and, if so, what measures would be effective or appropriate?

13. *Allocation goals.* Would SSR's Section 73.215 proposal, if adopted, result in increased interference levels in the FM band? In particular, would the increased density of signals resulting from upgraded stations provide improved FM service coverage, or merely contribute to a higher "noise floor" overall while only modestly benefiting individual stations? Is this proposal in tension with the original purpose of Section 73.215 to afford applicants greater flexibility in the selection of transmitter sites? Should the Commission significantly expand the applicability of Section 73.215 as proposed by SSR, and what would be the policy and legal justifications for doing so? Does the Commission's long history of licensing thousands of stations in the reserved band—using a contour methodology based on stations' authorized facilities—show that expanding eligibility for Section 73.215 processing would result in increased or decreased services for listeners?

14. *Implementation procedures.* If the Section 73.215 proposal is adopted, should the Commission follow SSR's suggested procedures, which are based on those currently in use for Class C0? Should the triggering applicant be required to certify that no alternative channel is available for the proposed service? Should the Commission use a show cause procedure, and if so, what deadlines would be appropriate?

15. Alternatively, should the Commission adopt a more streamlined procedure whereby all sub-maximum stations would be provided a date certain by which they must file an upgrade application or automatically become subject to immediate

designation as a Section 73.215 facility upon the filing of an acceptable application from another licensee seeking to upgrade its facilities? What would be a reasonable amount of time to allow sub-maximum stations to file upgrade applications before becoming subject to automatic designation as a Section 73.215 facility? Would such a procedure avoid unnecessary delays in providing new FM service and incentivize more stations to upgrade to their class maximums? Would there be any disadvantages with this approach? Are there other streamlined implementation approaches the Commission should consider?

16. *Other issues.* The Commission invites comment on other details of SSR's Section 73.215 proposal. Which applicants should be permitted to use the proposed Section 73.215 procedure? Does "sub-maximum" include all stations operating at less than class maximums, or should the Commission establish a cutoff whereby a station would not be subject to designation as a Section 73.215 facility if it operates at a minimal distance below its class maximum contour distance, such as two kilometers? How would the proposal affect stations that are short-spaced under Section 73.213 of the Rules? Are there specific rule changes that would be necessary to implement the proposal? The Commission also invites commenters to make suggestions as to how its forms and databases should be modified to implement the Section 73.215 proposal.

17. *Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rule.* None.

Ex Parte Rules

18. *Permit But Disclose.* The proceeding this NOI initiates shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's ex parte rules. Ex parte presentations are permissible if disclosed in accordance with Commission rules, except during the Sunshine Agenda period when presentations, ex parte or otherwise, are generally prohibited. Persons making ex parte presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral ex parte presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the ex parte presentation was made, and (2)

summarize all data presented and arguments made during the presentation. Memoranda must contain a summary of the substance of the ex parte presentation and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during ex parte meetings are deemed to be written ex parte presentations and must be filed consistent with § 1.1206(b) of the rules. In proceedings governed by § 1.49(f) of the rules or for which the Commission has made available a method of electronic filing, written ex parte presentations and memoranda summarizing oral ex parte presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's ex parte rules.

Filing Procedures

19. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). Electronic Filers: Comments may be filed electronically using the internet by accessing the ECFS: <http://apps.fcc.gov/ecfs/>.

■ *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: <http://apps.fcc.gov/ecfs/>.

■ *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

■ Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or

overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

■ All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

■ Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

■ U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington DC 20554.

■ *People with Disabilities*: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

Ordering Clause

20. *It is further ordered* that, pursuant to the authority contained in Sections 1, 4(i), 4(j), 301, 303, 307, 308, 309, 316, and 319 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 301, 303, 307, 308, 309, 316, and 319, this Notice of Inquiry *is adopted*.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2018-14880 Filed 7-11-18; 8:45 am]

BILLING CODE 6712-01-P

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0032]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Animal Welfare

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the Animal Welfare Act regulations for the humane handling, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers.

DATES: We will consider all comments that we receive on or before September 10, 2018.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0032>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2018-0032, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0032> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room

hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the Animal Welfare Act regulations, contact Dr. Kay Carter-Corker, Director, National Policy Staff, Animal Care, APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737; (301) 851-3748. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

SUPPLEMENTARY INFORMATION:

Title: Animal Welfare.

OMB Control Number: 0579-0036.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Animal Welfare Act (AWA, 7 U.S.C. 2131 *et seq.*), the Secretary of Agriculture is authorized to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, exhibitors, operators of auction sales, research facilities, carriers and intermediate handlers. The Secretary has delegated responsibility for administering the AWA to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Animal Care.

Definitions, regulations, and standards established under the AWA are contained in 9 CFR parts 1, 2, and 3 (referred to below as the regulations). Part 1 contains definitions for terms used in parts 2 and 3. Part 2 provides administrative requirements and sets forth institutional responsibilities for regulated parties, including licensing requirements for dealers, exhibitors, and operators of auction sales. Dealers, exhibitors, and operators of auction sales are required to comply in all respects with the regulations and standards (9 CFR 2.100(a)) and to allow APHIS officials access to their place of business, facilities, animals, and records to inspect for compliance (9 CFR 2.126). Part 3 provides standards for the humane handling, care, treatment, and transportation of covered animals. Part 3 consists of subparts A through E, which contain specific standards for dogs and cats, guinea pigs and hamsters, rabbits, nonhuman primates, and

marine mammals, respectively, and subpart F, which sets forth general standards for warmblooded animals not otherwise specified in part 3.

Administering the AWA requires the use of several information collection activities such as license applications and renewals, which now include a request to identify whether the business mailing address is a personal residence or not a personal residence; registration applications and updates; annual reports; acknowledgement of regulations and standards; inspections; requests; notifications; agreements; plans; written program of veterinary care and health records; itineraries; applications and permits; records of acquisition, disposition, or transport of animals; official identification; variances; protocols; health certificates; complaints; marking requirements; and recordkeeping.

These information collection activity requirements provide APHIS with the data necessary for the review and evaluation of program compliance by regulated facilities, and they provide a workable enforcement system to carry out the requirements of the AWA and the intent of Congress without resorting to more detailed and stringent regulations and standards that could be more burdensome to regulated facilities.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

- (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

- (2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

- (3) Enhance the quality, utility, and clarity of the information to be collected; and

- (4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.31 hours per response.

Respondents: Individuals or households; businesses or other for-profit entities; not-for-profit institutions; farms; and State, local, and Tribal governments.

Estimated annual number of respondents: 9,112.

Estimated annual number of responses per respondent: 128.

Estimated annual number of responses: 1,164,553.

Estimated total annual burden on respondents: 366,021 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 9th day of July 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018-14945 Filed 7-11-18; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of New Fee Sites; Federal Lands Recreation Enhancement Act

AGENCY: Bitterroot National Forest, Forest Service, USDA.

ACTION: Notice of new fee sites.

SUMMARY: The Bitterroot National Forest is proposing to implement new fees at two campgrounds and one rental cabin. These fees are only proposed and will be determined upon further analysis and public comment.

DATES: Send any comments about these fee proposals by August 13, 2018 so comments can be compiled, analyzed, and shared with the Western Montana Bureau of Land Management Resource Advisory Committee. The effective date of implementation of proposed new fees will be no earlier than six months after publication of this notice.

ADDRESSES: Julie King, Forest Supervisor, Bitterroot National Forest, 1801 N First, Hamilton, MT 59840 or Email to jkking@fs.fed.us.

FOR FURTHER INFORMATION CONTACT: Erica Strayer, Recreation Program Manager, Darby Ranger District, at 406-821-4252 or estrayer@fs.fed.us. Information about proposed fee changes

can also be found at www.fs.usda.gov/goto/r1recfee.

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108-447) directed the Secretary of Agriculture to publish a six month advance notice in the **Federal Register** whenever new recreation fee areas are established. These new fees will be reviewed by the Western Montana Bureau of Land Management Resource Advisory Committee prior to a final decision and implementation.

The Forest proposes a \$50/night fee for Lost Horse Guard Station, which would open this site for public rental. The Forest also proposes a \$10/night fee for both Slate Creek and Sam Billings Memorial campgrounds. Lost Horse Guard Station was built in 1935 and listed on the National Register of Historic Places in 1989. It lies at the head of Lost Horse Creek, near the Montana/Idaho divide. It is near a variety of recreation opportunities such as hiking, camping, horseback riding, non-motorized water sports, hunting, backcountry skiing, and snowmobiling at Twin Lakes. The rustic guard station can sleep up to eight people.

Slate Creek Campground also has a new group gathering area and Sam Billings Memorial Campground has new horse camping sites. Reasonable fees, paid by users of these sites and services, will help ensure that the Forest can continue maintaining and improving the sites for future generations.

A business analysis of the proposed new fee sites listed has shown that people desire having a variety of recreation opportunities and experiences on the Bitterroot National Forest, such as group camping, cabin and lookout rentals and single family camping. A market analysis of surrounding recreation sites with similar amenities indicates that the proposed fees are comparable and reasonable.

Advance reservations for the Lost Horse Guard Station will be available through www.recreation.gov or by calling 1-877-444-6777. The National Recreation Reservation Service charges a \$10 fee for reservations.

Dated: May 17, 2018.

Glenn Casamassa,

Associate Deputy Chief, National Forest System.

[FR Doc. 2018-14910 Filed 7-11-18; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Proposed New Fee Site; Federal Lands Recreation Enhancement Act

AGENCY: Flathead National Forest, Forest Service, USDA.

ACTION: Notice of new fee site.

SUMMARY: The Flathead National Forest is proposing to charge a new fee at the Lindbergh Lake Campground. Funds generated at the site will be used for the operation and maintenance, upkeep of facilities, and improvements as feasible. This fee is only proposed and will be determined upon further analysis and public comment.

DATES: Send any comments about these fee proposals by August 13, 2018 so comments can be compiled, analyzed, and shared with the Western Montana Bureau of Land Management (BLM) Resource Advisory Council. The effective date of implementation of this fee would be no earlier than six months after publication of this notice.

ADDRESSES: Chip Weber, Forest Supervisor, Flathead National Forest, 650 Wolfpack Way, Kalispell, MT 59901 or Email to cweber@fs.fed.us.

FOR FURTHER INFORMATION CONTACT:

Chris Prew, Recreation Program Manager, Flathead National Forest, at 406-758-3538 or chrisprew@fs.fed.us. Information about proposed fee changes can also be found at www.fs.usda.gov/goto/r1recfee.

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108-447) directed the Secretary of Agriculture to publish a six month advance notice in the **Federal Register** whenever new recreation fee areas are established. This new fee will be reviewed by the Western Montana BLM Resource Advisory Council prior to a final decision and implementation.

The Flathead National Forest is proposing to charge a \$10 per night fee at Lindbergh Lake Campground. Lindbergh Lake Campground offers breathtaking views of the Mission and Swan Mountain Ranges and has a concrete boat ramp for ease of lake access and enjoyment. The lake offers boating, swimming, and fishing opportunities and is located in close proximity to the Mission Mountains Wilderness, which offers excellent hiking opportunities. The campground has 21 individual camp sites and features a new toilet facility and other site improvements.

A business analysis of the proposed new fee site has shown that people desire having a variety of recreation opportunities and experiences on the Flathead National Forest, such as lake-orientated developed campgrounds. A market analysis of surrounding recreation sites with similar amenities indicates that the proposed fee is comparable and reasonable.

Dated: July 5, 2018.

Glenn Casamassa,

Associate Deputy Chief, National Forest System.

[FR Doc. 2018-14911 Filed 7-11-18; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-18-2018]

Production Activity Not Authorized; Foreign-Trade Zone (FTZ) 26—Atlanta, Georgia; PBR, Inc. d/b/a SKAPS Industries (Non-Woven Geotextiles); Athens, Georgia

On March 9, 2018, PBR, Inc. d/b/a SKAPS Industries (SKAPS) submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 26—Site 29, in Athens, Georgia.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (83 FR 13473, March 29, 2018). On July 9, 2018 the applicant was notified of the FTZ Board's decision that further review of the activity is warranted. The production activity described in the notification was not authorized. If the applicant wishes to seek authorization for this activity, it will need to submit an application for production authority, pursuant to Section 400.23.

Dated: July 9, 2018.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2018-14928 Filed 7-11-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-122-854]

Supercalendered Paper From Canada: Notice of Rescission of Countervailing Duty Administrative Review; 2015 and 2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative reviews of the countervailing duty (CVD) order on supercalendered paper (SC paper) from Canada for the period of review August 3, 2015, through December 31, 2015, and the period of review January 1, 2016, through December 31, 2016.

DATES: Applicable July 12, 2018.

FOR FURTHER INFORMATION CONTACT: Emily Halle or Nicholas Czajkowski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482-0176 or (202) 482-1395, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 1, 2016, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the CVD order on SC paper from Canada for the period of review (POR) of August 3, 2015, through December 31, 2015.¹ Commerce received timely-filed requests from Verso Corporation (Verso); Catalyst Paper Corporation, Catalyst Pulp and Paper Sales Inc., and Catalyst Paper (USA) Inc. (collectively, Catalyst); Irving Paper Limited (Irving); Port Hawkesbury Paper LP (PHP); and Resolute FP Canada Inc and Resolute FP US Inc. (collectively, Resolute), in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), to conduct an administrative review of the CVD order.² Based upon this request, on

¹ See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 81 FR 86694 (December 1, 2016).

² See Letter from Verso, "Supercalendered Paper from Canada: Request for Administrative Review," January 3, 2017; see Letter from Catalyst, "Supercalendered Paper from Canada: Request for Administrative Review," December 9, 2016; see Letter from Irving, "Supercalendered Paper from Canada, Inv. No. C-122-854—Request for Administrative Review and Request for Expansion of Review Period," December 23, 2016; see Letter from PHP, "Supercalendered Paper from Canada: Request for Administrative Review," December 9,

February 13, 2017, in accordance with section 751(a) of the Act, Commerce published a notice of initiation.³

On December 4, 2017, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the CVD order on SC paper from Canada for the period of review (POR) of January 1, 2016, through December 31, 2016.⁴ Commerce received timely-filed requests from Verso Corporation, Irving Paper Limited, Port Hawkesbury Paper LP, and Resolute FP Canada Inc and Resolute FP US Inc., in accordance with section 751(a) of the Act, to conduct an administrative review of the CVD order.⁵ Based upon this request, on February 23, 2018, in accordance with section 751(a) of the Act, Commerce published a notice of initiation.⁶

On July 5, 2018, Commerce revoked the CVD order on SC paper.⁷

Rescission of Administrative Reviews

Pursuant to 19 CFR 351.222(g), Commerce revoked the CVD order on SC paper from Canada. The effective date of the revocation of the CVD order is August 3, 2015. As a result of the revocation, we instructed U.S. Customs and Border Protection (CBP) to discontinue the suspension of liquidation and the collection of cash deposits of estimated countervailing duties, to liquidate all unliquidated entries that were entered on or after August 3, 2015, without regard to countervailing duties, and to refund all CVD cash deposits on all such merchandise, with applicable interest. These administrative reviews cover the period August 3, 2015 through December 31, 2015, and the period January 1, 2016 through December 31,

2016; see Letter from Resolute, "Supercalendered Paper from Canada: Request for Administrative Review (8/3/15-12/31/15)," December 19, 2016.

³ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 82 FR 10457 (February 13, 2017).

⁴ See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 83 FR 57219 (December 4, 2017).

⁵ See Letter from Verso, "Supercalendered Paper from Canada: Request for Administrative Review," December 29, 2017; see Letter from Irving, "Supercalendered Paper from Canada, Inv. No. C-122-854—Request for Administrative Review," December 15, 2017; see Letter from PHP, "Supercalendered Paper from Canada: Request for Administrative Review," December 20, 2017; see Letter from Resolute, "Supercalendered Paper from Canada: Request for Administrative Review (1/1/2016-12/31/2016)," December 21, 2017.

⁶ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 83 FR 8058 (February 23, 2018).

⁷ See *Supercalendered Paper from Canada: Final Results of Changed Circumstances Review and Revocation of Countervailing Duty Order*, signed July 5, 2018.

2016. Because the revocation is retroactive to August 3, 2015, the periods covered by these ongoing administrative reviews are no longer subject to the CVD order, and there is no basis for conducting the administrative review. Therefore, Commerce is rescinding these administrative reviews.

Assessment

Because we ordered the liquidation of the entries subject to these administrative reviews, as a result of the revocation of the CVD order, there is no need to issue additional instructions to CBP.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with section 751 of the Act and 19 CFR 351.213(d)(4).

Dated: July 5, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018-14922 Filed 7-11-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-601]

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Preliminary Results and Intent To Rescind the Review in Part; 2016-2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review (AR) of the antidumping duty order on tapered roller bearings and parts thereof, finished and unfinished (TRBs), from the People's Republic of China (China). The AR covers 20 exporters, of which Commerce selected two exporters for

individual examination (*i.e.*, GGB Bearing Technology (Suzhou) Co., Ltd. (GGB); and Luoyang Bearing Corporation (Group) (Luoyang)). The period of review (POR) is June 1, 2016, through May 31, 2017. We preliminarily determine that sales of subject merchandise have been made below normal value (NV). Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 12, 2018.

FOR FURTHER INFORMATION CONTACT:

Andrew Medley, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-4987.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise covered by the order includes tapered roller bearings and parts thereof. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 8482.20.00, 8482.91.00.50, 8482.99.15, 8482.99.45, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.80, 8708.70.6060, 8708.99.2300, 8708.99.4850, 8708.99.6890, 8708.99.8115, and 8708.99.8180. The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of the order is dispositive.¹

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. For GGB, we calculated export prices in accordance with section 772 of the Act. Because China is a non-market economy (NME) within the meaning of section 771(18) of the Act, for GGB, NV was calculated in accordance with section 773(c) of the Act. We preliminarily find that Luoyang is ineligible for a separate rate and is part of the China-wide entity.

For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and

¹ For a complete description of the scope of the order, see Memorandum, "Decision Memorandum for the Preliminary Results of the 2016-2017 Antidumping Duty Administrative Review of Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China" (Preliminary Decision Memorandum), issued concurrently with and hereby adopted by this notice.

Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>, and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at <http://enforcement.trade.gov/frn/>. The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content. A list of the topics discussed in the Preliminary Decision Memorandum is attached as the Appendix to this notice.

Rate for Non-Examined Companies Which Are Eligible for a Separate Rate

As indicated in the "Preliminary Results of Review" section below, we preliminarily determine that a weighted-average dumping margin of 6.87 percent applies to the six firms not selected for individual review which are eligible for a separate rate. For further information, see the Preliminary Decision Memorandum at "Separate Rate Assigned to Non-Selected Companies."

Preliminary Results of Review

Twelve companies involved in the administrative review did not demonstrate that they are entitled to a separate rate.² Therefore, we preliminarily finds these companies to be part of the China-wide entity.³ The rate previously established for the China-wide entity is 92.84 percent. One additional company, Hangzhou Xiaoshan Dingli Machinery Co., Ltd. (Dingli), could not demonstrate that it had a suspended entry during the POR;

² These companies are: (1) Apex Maritime Shanghai Co., Ltd.; (2) Crossroads Global Trading Co., Ltd.; (3) Honour Lane Shipping Ltd.; (4) Kinetsu World Express China Co., Ltd.; (5) Luoyang; (6) Pacific Link Intl Freight Forwarding Co., Ltd.; (7) Shanghai Dizhao Industrial Trading Co., Ltd.; (8) Thi Group Shanghai Ltd.; (9) Weifang Haoxin-Commet Mechanical Products Co., Ltd.; (10) Yantai Huilong Machinery Parts Co.; Ltd.; (11) Zhejiang Machinery Import & Export Corp.; and (12) Zhejiang Zhaofeng Mechanical & Electronic Co., Ltd.

³ See Preliminary Decision Memorandum, at 8. Pursuant to Commerce's change in practice, Commerce no longer considers the NME entity as an exporter conditionally subject to administrative reviews. See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963, 65970 (November 4, 2013). Under this practice, the NME entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the entity, the entity is not under review and the entity's rate is not subject to change.

thus, we intend to rescind the review with respect to Dingli.

We preliminarily determine that the following weighted-average dumping

margins exist for the period June 1, 2016, through May 31, 2017:

Exporter	Weighted-average dumping margin (percent)
GGB Bearing Technology (Suzhou) Co., Ltd	6.87
CNH Industrial Italia SpA *	6.87
GSP Automotive Group Wenzhou Co. Ltd *	6.87
Hangzhou Hanji Auto Parts Co., Ltd *	6.87
Hangzhou Radical Energy-Saving Technology Co., Ltd *	6.87
Ningbo Xinglun Bearings Import & Export Co., Ltd *	6.87
Zhejiang Sihe Machine Co., Ltd *	6.87

* This company was not selected as a mandatory respondent but is subject to this administrative review and demonstrated that it qualified for a separate rate during the POR.

Disclosure and Public Comment

Commerce will disclose calculations performed for these preliminary results to the parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.⁴ Rebuttals to case briefs may be filed no later than five days after case briefs are filed and all rebuttal briefs must be limited to comments raised in the case briefs.⁵ Parties who submit comments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.⁶

Any interested party may request a hearing within 30 days of publication of this notice.⁷ Hearing requests should contain the following information: (1) The party’s name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs.⁸ If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.⁹

All submissions, with limited exceptions, must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by 5 p.m. Eastern Time (ET) on the due date.¹⁰ Documents excepted from the electronic submission requirements must be filed manually (i.e., in paper form) with the APO/ Dockets Unit in Room 18022 and

stamped with the date and time of receipt by 5 p.m. ET on the due date.¹¹

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results of the administrative review, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.¹² For each examined respondent which is eligible for a separate rate and which has a weighted-average dumping margin which is not zero or *de minimis* (i.e., less than 0.5 percent), we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer’s examined sales to the total entered value of those sales, in accordance with 19 CFR 351.212(b)(1).

Pursuant to Commerce’s assessment practice, for entries that were not reported in the U.S. sales data submitted by an examined respondent, we will instruct CBP to liquidate such entries at the China-wide rate. Additionally, if we determine that an exporter had no shipments of the subject merchandise, any suspended entries that entered under that exporter’s case number (i.e., at that exporter’s cash deposit rate) will be liquidated at the China-wide rate.¹³

¹¹ See 19 CFR 351.303(b) and “ACCESS Handbook on Electronic Filing Procedures Enforcement and Compliance International Trade Administration U.S. Department of Commerce,” dated October 24, 2017, available at https://access.trade.gov/help/Handbook_on_Electronic_Filing_Procedures.pdf.

¹² See 19 CFR 351.212(b)(1).

¹³ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011).

For the respondents which were not selected for individual examination in this administrative review and which qualified for a separate rate, the assessment rate will be equal to the weighted-average dumping margin determined for the non-examined respondents in the final results of this administrative review. For the final results, if we continue to treat the 12 exporters preliminarily found not to qualify for separate rates as part of the China-wide entity, we will instruct CBP to apply an *ad valorem* assessment rate of 92.84 percent, the current rate established for the China-wide entity, to all entries of subject merchandise during the POR which were exported by those companies. In addition, if Commerce continues to find that Dingli had no suspended entries during the POR, we will rescind the review for that company.¹⁴

We intend to issue assessment instructions to CBP 15 days after the publication of the final results of these reviews.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above which have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review (except, if the rate is zero or *de minimis*, then a cash deposit rate of zero will be established for that company); (2) for previously

¹⁴ For a full discussion of this practice, see *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011).

⁴ See 19 CFR 351.309(c)(1)(ii).

⁵ See 19 CFR 351.309(d).

⁶ See 19 CFR 351.309(c)(2).

⁷ See 19 CFR 351.310(c).

⁸ *Id.*

⁹ See 19 CFR 351.310(d).

¹⁰ See 19 CFR 351.103(c).

investigated or reviewed Chinese and non-Chinese exporters not listed above that have separate rates, the cash deposit rate will continue to be equal to the exporter-specific weighted-average dumping margin published for the most recently completed segment of this proceeding; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the cash deposit rate established for the China-wide entity, 92.84 percent; and (4) for all exporters of subject merchandise which are not located in China and which are not eligible for a separate rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1), 751(a)(2)(B) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 3, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of the Methodology
 - a. Non-Market Economy Country Status
 - b. Separate Rates
 - i. Separate Rates Applicants with No Evidence of Suspended Entries
 - ii. Separate Rate Recipients
 1. Wholly Foreign-Owned Companies
 2. Wholly China-Owned Companies and Joint Ventures
 - a. Absence of *De Jure* Control
 - b. Absence of *De Facto* Control
 3. Companies Not Receiving a Separate Rate

- c. Separate Rate Assigned to Non-Selected Companies
- d. The China-Wide Entity
- e. Application of Facts Available and Use of Adverse Interferences
- f. Application of Partial AFA for GGB
- g. Surrogate Country
- h. Date of Sale
- i. Normal Value Comparisons
- j. Determination of Comparison Method
- k. Constructed Export Price
 - i. Irrecoverable Value-Added Tax (VAT)
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 1. Normal Value
 - i. Factor Valuations
 - ii. Currency Conversion
5. Recommendation

[FR Doc. 2018–14924 Filed 7–11–18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–874]

Certain Steel Nails From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Daejin Steel Co. (Daejin), Koram Inc. (Koram), and Korea Wire Co., Ltd. (Kowire), producers/exporters of merchandise subject to this administrative review, made sales of subject merchandise at less than normal value. The period of review (POR) is July 1, 2016, through June 30, 2017.

DATES: Applicable July 12, 2018.

FOR FURTHER INFORMATION CONTACT: Robert Galantucci (Kowire), Maliha Khan (Daejin), or Trisha Tran (Koram), AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2923, (202) 482–0895, or (202) 482–4852, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 3, 2017, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty (AD) order on certain steel nails (steel nails)

from Korea.¹ On July 31, 2017, Daejin² and Kowire³ each requested an administrative review, and Mid Continent Steel & Wire, Inc.⁴ (the petitioner) requested an administrative review of 206 producers and/or exporters, including Daejin, Koram, Koram Steel Co. Ltd., and Kowire. On September 28, 2017, the petitioner withdrew its administrative review request with respect to 202 of the 206 companies identified as producers/exporters in the petitioner's July 31, 2017 letter. The petitioner maintained its administrative review request with respect to: Daejin, Koram, Koram Steel Co. Ltd., and Kowire. As such, Commerce issued its AD questionnaire to these companies on October 10, 2017.⁵

Partial Rescission of Administrative Review

Commerce received timely requests to conduct an administrative review of certain exporters covering the POR. Because the petitioner timely withdrew its request for review of all of the companies listed in the *Initiation Notice*, with the exception of Daejin, Koram, Koram Steel Co. Ltd., and Kowire, we are rescinding this administrative review with respect to the remaining companies on which we initiated a review pursuant to 19 CFR 351.213(d)(1). For a list of the companies for which we are rescinding this review, see Appendix II to this notice.

As discussed in the Preliminary Decision Memorandum, we preliminarily determine that Koram is the successor-in-interest to Koram Steel Co. Ltd.; therefore, we will not calculate a separate dumping margin for Koram Steel Co., Ltd.⁶ Accordingly, the three companies subject to the instant review are: Daejin, Koram, and Kowire.

¹ See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation: Opportunity to Request Administrative Review*, 82 FR 30833 (July 3, 2017).

² See Letter from Daejin, "Administrative Review of the Antidumping Duty Order on Certain Steel Nails from Korea—Request for Review," dated July 31, 2017.

³ See Letter from Kowire, "Steel Nails from the Republic of Korea—Request for Administrative Review," dated July 31, 2017.

⁴ See Letter from the petitioner, "Certain Steel Nails from Korea: Request for Administrative Reviews," dated July 31, 2017.

⁵ See Commerce's Letter, "Administrative Review of Certain Steel Nails from Korea: Antidumping Duty Questionnaire," dated October 10, 2017.

⁶ See Memorandum, "Decision Memorandum for Preliminary Results of the 2016–2017 Antidumping Duty Administrative Review of Certain Steel Nails from the Republic of Korea," dated concurrently with, and hereby adopted by this notice (Preliminary Decision Memorandum) at 2.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov> and available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at <http://enforcement.trade.gov/frn/>. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The merchandise covered by this order is certain steel nails having a nominal shaft length not exceeding 12 inches.⁷ Merchandise covered by the order is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this order also may be classified under HTSUS subheadings 7907.00.60.00, 8206.00.00.00 or other HTSUS subheadings. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive. For a full description of the scope of the order, see the Preliminary Decision Memorandum.⁸

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum.⁹ A list of topics included in the Preliminary Decision

Memorandum is included as Appendix I to this notice.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following weighted-average dumping margins for the period July 1, 2016, through June 30, 2017:

Exporter and/or producer	Weighted-average dumping margin (percent)
Daejin Steel Co	3.02
Koram Inc	10.59
Korea Wire Co., Ltd	1.10

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of this review.

For any individually examined respondents whose weighted-average dumping margin is above *de minimis* (i.e., 0.50 percent), we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).¹⁰ For entries of subject merchandise during the POR produced by each respondent for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate un-reviewed entries at the all-others rate if there is no rate for the intermediate company involved in the transaction.¹¹ We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis*. Where either the respondent's weighted-average dumping margin is zero or *de minimis*, or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to

liquidate the appropriate entries without regard to antidumping duties.

For the 202 companies for which this review is rescinded, antidumping duties will be assessed at rates equal to the cash deposit of estimated antidumping duties in effect at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Cash Deposit Requirement

The following deposit requirements will be effective upon publication of the notice of the final results of administrative review for all shipments of steel nails from Korea entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis*, no cash deposit will be required); (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 11.80 percent *ad valorem*, the all-others rate established in the less-than-fair value investigation.¹²

Disclosure and Public Comment

Commerce intends to disclose the calculations used in our analysis to interested parties in this review within five days of the date of publication of this notice in accordance with 19 CFR

⁷ The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

⁸ See Preliminary Decision Memorandum.

⁹ *Id.*

¹⁰ In these preliminary results, Commerce applied the assessment rate calculation methodology adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101 (February 14, 2012).

¹¹ See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

¹² See *Certain Steel Nails from the Republic of Korea: Final Determination of Sales at Less Than Fair Value*, 80 FR 28955 (May 20, 2015).

351.224(b). Interested parties are invited to comment on the preliminary results of this review. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the time limit for filing case briefs.¹³ Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each brief: (1) A statement of the issues, (2) a brief summary of the argument, and (3) a table of authorities.¹⁴ Executive summaries should be limited to five pages total, including footnotes.¹⁵ Case and rebuttal briefs should be filed using ACCESS.¹⁶

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register**. If a hearing is requested, Commerce will notify interested parties of the hearing schedule. Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically *via* ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.

We intend to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, unless otherwise extended.¹⁷

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: July 5, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Rescission of Review, In Part
- V. Affiliation
- VI. Duty Absorption Inquiry
- VII. Discussion of the Methodology
 - A. Comparisons to Normal Value
 - B. Product Comparisons
 - C. Date of Sale
 - D. Level of Trade
 - E. Export Price
 - F. Normal Value
 - G. Successor-In-Interest Determination—Koram
- VIII. Currency Conversions
- IX. Recommendation

Appendix II

Airlift Trans Oceanic Pvt. Ltd.
 Aironware Enterprise (China) Ltd.
 AM Global Shipping Lines
 Ansing Rich Tech & Trade Co. Ltd.
 Apex Maritime Co., Ltd.
 Apex Shipping Co. Ltd.
 Astrotech Steels Private Limited
 Baoding Jiebooshun Trading Corp. Ltd.
 Beijing Jin Heung Co. Ltd.
 Beijing Kang Jie Kong Int'l Cargo Co. Ltd.
 Beijing Qin Li Jeff Trading Co., Ltd.
 Bestbond International Limited
 Bipex Co., Ltd.
 Bollore Logistics Co. Ltd.
 Bolung International Trading Co., Ltd.
 Bon Voyage Logistics Inc.
 Bonuts Hardware Logistics Co. Ltd.
 Brilliant Group Logistics Corp.
 C&D International Freight Forwarding
 C.H. Robinson Freight Services Ltd.
 Caesar International Logistics Co. Ltd.
 Cana (Rizhao) Hardware Co. Ltd.
 Cangzhou Xinqiao Int'l Trade Co. Ltd.
 Capital Freight Management Inc.
 Cargo Services Co. Ltd.
 Caribbean International Co. Ltd.
 Casia Global Logistics Co Ltd
 China Container Line Northern Ltd.
 China Dinghao Co., Ltd.
 China International Freight Co., Ltd.
 China Staple Enterprise Co. Ltd
 Chinatrans International Limited
 Chongqing Welluck Trading Co. Ltd.
 Chosun Shipping Co. Ltd.
 CJ Korea Express Corp.
 CKX Co. Ltd.
 Cohesion Freight (HK) Ltd.
 Consolidated Shipping Services L.L.C.
 Crelux International Co. Ltd.

Dahnay Logistics Private Ltd.
 Dalian Sunny International Logistics
 DCS Dah Star Logistics Co., Ltd.
 De Well Container Shipping Inc.
 Dezhou Hualude Hardware Products Co., Ltd.
 Dong E Fuqiang Metal Products Co. Ltd.
 DT Logistics Hong Kong Ltd
 Duo-Fast Korea Co., Ltd.
 Dynamic Network Container Line Limited
 E&E Transport International Co., Ltd.
 ECI Taiwan Co., Ltd.
 Eco Steel Co., Ltd.
 Ejem Brothers Limited
 Eumex Line Shenzhen Limited
 Eunsan Shipping & Aircargo Co., Ltd.
 Euroline Global Co., Ltd.
 Expeditors Korea Ltd.
 Faithful Engineering Products Co. Ltd.
 Fastgrow International Co.
 Fastic Transportation Co., Ltd.
 Flyjac Logistics Pvt. Ltd.
 G Link Express Logistics (Korea) Ltd
 GCL Logistics Co., Ltd.
 Global Container Line, Inc.
 Globelink Weststar Shipping
 Glovis America
 Grandee Logistics Ltd.
 Hanbit Logistics Co., Ltd.
 Hanjin Logistics India Private Ltd.
 Hanmi Staple Co., Ltd.
 Hanon Systems
 Hebei Minmetals Co., Ltd.
 Hebei Tuohua Metal Products Co., Ltd.
 Hecny Shipping Ltd.
 Hecny Transportation Ltd.
 Hengtuo Metal Products Co Ltd
 High Link Line Inc.
 Hong Kong Hong Xing Da Trading Co. Ltd.
 Hongyi Hardware Products Co., Ltd.
 Honour Lane Logistics Company
 Honour Lane Shipping Limited
 Huanghua Yingjin Hardware Products Co., Ltd.
 Hyundai Logistics Co. Ltd.
 Inmax Industries Sdn. Bhd.
 Integral Building Products Inc.
 International Maritime and Aviation LLC
 JAS Forwarding Co. Ltd.
 Je-il Wire Production Co., Ltd.
 Jeil Tacker Co. Ltd.
 Jiangsu Soho Honry Import Export Co. Ltd.
 Jiaying Silk Import & Export Co., Ltd.
 Jinhai Hardware Co., Ltd.
 Jinheung Steel Corporation
 Jinkaiyi International Industry Co.
 Jinsco International Corp.
 Joo Sung Sea Air Co., Ltd.
 K Logistics Corp.
 K Logistics Inc.
 Kasy Logistics (Tianjin) Co., Ltd.
 King Shipping Company
 Korchina International Logistics Co. Ltd.
 Korea Total Logistics Co. Ltd.
 Kousa International Logistics Co. Ltd.
 Kuehne Nagel Ltd.
 LF Logistics Co. Ltd.
 Linyi Flying Arrow Imp. & Exp. Ltd.
 MR Forwarding China Ltd.
 Maxspeed International Transport Co. Ltd.
 Mingguang Ruifeng Hardware Products Co., Ltd.
 Nailtech Co. Ltd.
 Nanjing Caiqing Hardware Co., Ltd.
 Nauri Logistics Co. Ltd.
 NCL Container Lines Co. Ltd.
 Neo Gls

¹³ See 19 CFR 351.309(d)(1).

¹⁴ See 19 CFR 351.309(c)(2) and (d)(2).

¹⁵ *Id.*

¹⁶ See 19 CFR 351.303.

¹⁷ See section 751(a)(3)(A) of the Act.

Neptune Shipping Limited
 Nexen L&C Corp.
 OEC Freight Worldwide Korea Co. Ltd.
 OEC Logistics Co., Ltd.
 OEC World Wide Korea Co. Ltd.
 Oman Fasteners LLC
 Orient Express Container Co., Ltd.
 Oriental Power Logistics Co. Ltd.
 Overseas Distribution Services Inc.
 Overseas International Steel Industry
 Panalpina World Transport (PRC) Ltd.
 Paslode Fasteners (Shanghai) Co. Ltd.
 Promising Way (Hong Kong) Limited
 Pudong Prime International Logistics, Inc.
 Qingdao Chesire Trading Co. Ltd.
 Qingdao D&L Group Ltd.
 Qingdao Hongyuan Nail Industry Co. Ltd.
 Qingdao Master Metal Products Co. Ltd.
 Qingdao Meijialucky Industry and Commerce
 Co., Ltd.
 Qingdao Mst Industry and Commerce Co.,
 Ltd.
 Qingdao Tiger Hardware Co., Ltd.
 Ramses Logistics Company Limited
 Regency Global Logistics Co., Ltd.
 Ricoh Logistics System Co., Ltd.
 Rise Time Industrial Co. Ltd.
 Sam Un Co. Ltd.
 Scanwell Container Line Ltd.
 Schenker
 Schenker & CO AG
 SDC International Australia PTY Ltd
 Seamaster Global Forwarding
 Seamaster Logistics Sdn Bhd
 Sejung (China) Sea & Air Co., Ltd.
 Shandong Dinglong Imp. & Exp. Co. Ltd.
 Shandong Liaocheng Minghua Metal PR
 Shandong Oriental Cherry Hardware Group
 Co. Ltd.
 Shanghai Haoray International Trade Co. Ltd.
 Shanghai Jade Shuttle Hardware Tools Co.,
 Ltd.
 Shanghai Line Feng Int'l Transportation Co.
 Ltd.
 Shanghai Pinnacle International Trading Co.,
 Ltd.
 Shanghai Pudong International
 Transportation
 Shanxi Pioneer Hardware Industry Co., Ltd.
 Shanxi Tianli Industries Co., Ltd.
 Shijiazhuang Shuangjian Tools Co. Ltd.
 Shipping Imperial Co., Ltd.
 Sino Connections Logistics Inc.
 S-Mart (Tianjin) Technology Development
 Co., Ltd.
 Sparx Logistics China Limited
 Speedmark International Ltd.
 Suntec Industries Co., Ltd.
 Swift Freight (India) Pvt Ltd.
 T.H.I. Group Ltd.
 The Stanley Works (Langfang) Fastening
 System Co., Ltd.
 Tianjin Bluekin Industries Limited
 Tianjin Coways Metal Products Co.
 Tianjin Free Trade Service Co. Ltd.
 Tianjin Fulida Supply Co. Ltd.
 Tianjin Huixinshangmao Co. Ltd.
 Tianjin Hweschun Fasteners Manufacturing
 Co. Ltd.
 Tianjin Jinchi Metal Products Co., Ltd.
 Tianjin Long Sheng Tai
 Tianjin M&C Electronics Co., Ltd.
 Tianjin Wonderful International Trading
 Tianjin Zehui Hardware Co. Ltd.
 Tianjin Zhonglian Metals Ware Co. Ltd.
 Tianjin Zhonglian Times Technology

Toll Global Forwarding Ltd.
 Top Logistics Korea Ltd.
 Top Ocean Consolidated Service Ltd.
 Toyo Boeki Co. Ltd.
 Trans Knights, Inc.
 Translink Shipping, Inc.
 Transwell Logistics Co. Ltd.
 Transworld Transportation Co. Ltd.
 Trim International Inc.
 TTI Freight Forwarder Co. Ltd.
 Unicorn (Tianjin) Fasteners Co., Ltd.
 UPS SCS (China) Limited
 Vanguard Logistics Services
 W&K Corporation Limited
 Weida Freight System Co. Ltd.
 Woowon Sea & Air Co. Ltd.
 Xi'an Metals and Minerals Imp. Exp. Co.
 Xinjiayuan International Trade Co.
 Xinjiayuan Trading Co., Limited
 Youngwoo Fasteners Co., Ltd.
 You-One Fastening Systems
 Yumark Enterprises Corp.
 Zhaoqing Harvest Nails Co. Ltd.

[FR Doc. 2018-14920 Filed 7-11-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-122-854]

Supercalendered Paper From Canada: Final Results of Changed Circumstances Review and Revocation of Countervailing Duty Order

AGENCY: Enforcement and Compliance,
 International Trade Administration,
 Department of Commerce.

SUMMARY: The Department of Commerce
 (Commerce) is revoking the
 countervailing duty (CVD) order on
 supercalendered paper (SC paper) from
 Canada.

DATES: Applicable August 3, 2015.

FOR FURTHER INFORMATION CONTACT:
 Emily Halle or Nicholas Czajkowski,
 AD/CVD Operations, Enforcement and
 Compliance, International Trade
 Administration, U.S. Department of
 Commerce, 1401 Constitution Avenue
 NW, Washington, DC 20230; telephone
 (202) 482-0176 or (202) 482-1395,
 respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 10, 2015, Commerce
 published the *CVD Order* on SC paper
 from Canada.¹ On March 21, 2018,
 Verso Corporation (Verso) (*i.e.*, the
 petitioner) requested that Commerce
 conduct a changed circumstances
 review (CCR), pursuant to section
 782(h)(2) of the Tariff Act of 1930, as
 amended (the Act) and 19 CFR

351.222(g)(l)(i). Verso expressed a lack
 of interest in the enforcement or
 existence of the *CVD Order*, and
 requested the retroactive revocation of
 the *CVD Order*, effective August 3,
 2015.² Commerce published the
 initiation of this CCR on May 14, 2018.³
 The parties to this proceeding provided
 comments on May 21, 2018.⁴ On June
 21, 2018, pursuant to 19 CFR
 351.302(b), Commerce extended the
 time limit for completing this CCR.⁵

Final Results of Changed Circumstances Review, and Revocation of the Order

Pursuant to section 751(d)(1) of the
 Act, and 19 CFR 351.222(g), Commerce
 may revoke an antidumping duty or
 CVD order, in whole or in part, based on
 a review under section 751(b) of the Act
 (*i.e.*, a CCR). Section 751(b)(1) of the Act
 requires a CCR to be conducted upon
 receipt of a request which shows
 changed circumstances sufficient to
 warrant a review. Section 782(h)(2) of
 the Act gives Commerce the authority to
 revoke an order if producers accounting
 for substantially all of the production of
 the domestic like product have
 expressed a lack of interest in the order.
 Section 351.222(g) of Commerce's
 regulations provides that Commerce
 will conduct a CCR under 19 CFR
 351.216, and may revoke an order (in
 whole or in part), if it concludes that: (i)
 Producers accounting for substantially
 all of the production of the domestic
 like product to which the order pertains
 have expressed a lack of interest in the
 relief provided by the order, in whole or
 in part; or (ii) if other changed
 circumstances sufficient to warrant
 revocation exist. Both the Act and
 Commerce's regulations require that
 "substantially all" domestic producers
 express a lack of interest in the order for
 Commerce to revoke the order, in whole
 or in part.⁶ Commerce has interpreted
 "substantially all" to represent
 producers accounting for at least 85
 percent of U.S. production of the
 domestic like product.⁷ In the *Initiation*

² See Letter from Verso, "Supercalendered Paper
 from Canada/Request for Changed Circumstances
 Review," March 21, 2018 (Verso Request).

³ See *Supercalendered Paper from Canada:
 Initiation of Changed Circumstances Review*, 83 FR
 22249 (May 14, 2018) (*Initiation Notice*).

⁴ See Letter from Verso, *et. al.*, "Supercalendered
 Paper from Canada (C-122-854): Joint Comments
 on Initiation of Changed Circumstances Review,"
 May 21, 2018.

⁵ See Letter to Verso Corporation, "Countervailing
 Duty Order on Supercalendered Paper from Canada:
 Changed Circumstances Review; Extension of
 Deadline for Final Results," dated June 21, 2018.

⁶ See section 782(h) of the Act and 19 CFR
 351.222(g).

⁷ See *Honey from Argentina; Antidumping and
 Countervailing Duty Changed Circumstances*

¹ See *Supercalendered Paper from Canada:
 Countervailing Duty Order*, 80 FR 76668 (December
 10, 2015) (*CVD Order*).

Notice, we stated that Verso's request indicated it accounts for at least 85 percent of domestic production.⁸ We received no comments concerning Verso's claim regarding its production or otherwise indicating a lack of industry support with respect to this CCR.

As noted in the *Initiation Notice*, Verso requested the revocation of this *CVD Order* because it is no longer interested in maintaining the *CVD Order* or in the imposition of duties on the subject merchandise as of August 3, 2015.⁹ We conclude that producers accounting for substantially all of the production of the domestic like product, to which this *CVD Order* pertains, lack interest in the relief provided by the *CVD Order*. We find that the petitioner's affirmative statement of no interest in the *CVD Order* constitutes good cause for the conduct of this review.

On May 21, 2018, Commerce received comments from Verso, the Government of Canada, the Government of New Brunswick, the Government of Nova Scotia, the Government of Ontario, the Government of Quebec, Irving Paper Limited, Port Hawkesbury Paper L.P., Resolute FP Canada Inc., and Resolute FP US Inc. In a joint filing, these parties, who represent all of the interested parties to this proceeding, stated their agreement with the outcome proposed in the *Initiation Notice*. Moreover, the parties cited to 19 CFR 351.216(e), which provides that, when all parties agree to the outcome, Commerce will issue its final results of CCR within 45 days of the initiation.

Accordingly, we are notifying the public that we are revoking the *CVD Order*, in whole. Based on Verso's request that revocation be retroactive to August 3, 2015, and because we have not completed any administrative reviews of the *CVD Order*, we will instruct U.S. Customs and Border Protection (CBP) to discontinue the suspension of liquidation and the collection of cash deposits of estimated countervailing duties, to liquidate all unliquidated entries that were entered on or after August 3, 2015, without regard to countervailing duties, and to refund all CVD cash deposits on all such merchandise, with applicable interest.

Reviews; Preliminary Intent to Revoke Antidumping and Countervailing Duty Orders, 77 FR 67790, 67791 (November 14, 2012), unchanged in *Honey from Argentina; Final Results of Antidumping and Countervailing Duty Changed Circumstances Reviews; Revocation of Antidumping and Countervailing Duty Orders*, 77 FR 77029 (December 31, 2012).

⁸ See *Initiation Notice*, 83 FR at 22249.

⁹ *Id.*

Scope of the Order

The product covered by the order is SC paper. SC paper is uncoated paper that has undergone a calendaring process in which the base sheet, made of pulp and filler (typically, but not limited to, clay, talc, or other mineral additive), is processed through a set of supercalenders, a supercalender, or a soft nip calender operation.¹⁰

The scope of this order covers all SC paper regardless of basis weight, brightness, opacity, smoothness, or grade, and whether in rolls or in sheets. Further, the scope covers all SC paper that meets the scope definition regardless of the type of pulp fiber or filler material used to produce the paper.

Specifically excluded from the scope are imports of paper printed with final content of printed text or graphics.

Subject merchandise primarily enters under Harmonized Tariff Schedule of the United States (HTSUS) subheading 4802.61.3035, but may also enter under subheadings 4802.61.3010, 4802.62.3000, 4802.62.6020, and 4802.69.3000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Instructions to U.S. Customs and Border Protection

Because we determine that there are changed circumstances that warrant the revocation of the *CVD Order*, in whole, we will instruct CBP to discontinue the suspension of liquidation and the collection of cash deposits of estimated countervailing duties, to liquidate all unliquidated entries that were entered on or after August 3, 2015, without regard to countervailing duties, and to refund all CVD cash deposits on all such merchandise, with applicable interest.

Notification to Interested Parties

This notice serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply

¹⁰ Supercalendering and soft nip calendering processing, in conjunction with the mineral filler contained in the base paper, are performed to enhance the surface characteristics of the paper by imparting a smooth and glossy printing surface. Supercalendering and soft nip calendering also increase the density of the base paper.

with the regulations and terms of an APO is a sanctionable violation.

We are issuing and publishing these final results and revocation, in whole, and notice in accordance with sections 751(b) and 777(i) of the Act and 19 CFR 351.216, 19 CFR 351.221(c)(3), and 19 CFR 351.222.

Dated: July 5, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018-14921 Filed 7-11-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-904]

Certain Activated Carbon From the People's Republic of China: Continuation of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC) that revocation of the antidumping duty order on certain activated carbon from the People's Republic of China (China) would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, Commerce is publishing a notice of continuation of the antidumping duty order.

DATES: Applicable July 12, 2018.

FOR FURTHER INFORMATION CONTACT: Robert Palmer, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-9068.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 2007, Commerce published in the **Federal Register** notice of the antidumping duty order on certain activated carbon from China.¹ On February 1, 2018, Commerce published the notice of initiation of the second five-year (sunset) review of the antidumping duty order on certain

¹ See *Notice of Antidumping Duty Order: Certain Activated Carbon from the People's Republic of China*, 72 FR 20988 (April 27, 2007).

activated carbon from China, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).²

Commerce conducted this sunset review on an expedited basis, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), because it received a complete, timely, and adequate response from a domestic interested party but no substantive responses from respondent interested parties. As a result of its review, Commerce determined in accordance with section 751(c) of the Act that revocation of the antidumping duty order would likely lead to a continuation or recurrence of dumping.³ Commerce, therefore, notified the ITC of the magnitude of the margins likely to prevail should the antidumping duty order be revoked. On July 6, 2018, the ITC published notice of its determination, pursuant to section 751(c) of the Act, that revocation of the antidumping duty order on certain activated carbon from China would likely lead to a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.⁴

Scope of the Order

The merchandise subject to the order is certain activated carbon. Certain activated carbon is a powdered, granular, or pelletized carbon product obtained by “activating” with heat and steam various materials containing carbon, including but not limited to coal (including bituminous, lignite, and anthracite), wood, coconut shells, olive stones, and peat. The thermal and steam treatments remove organic materials and create an internal pore structure in the carbon material. The producer can also use carbon dioxide gas (CO₂) in place of steam in this process. The vast majority of the internal porosity developed during the high temperature steam (or CO₂ gas) activated process is a direct result of oxidation of a portion of the solid carbon atoms in the raw material, converting them into a gaseous form of carbon.

The scope of the order covers all forms of activated carbon that are activated by steam or CO₂, regardless of

the raw material, grade, mixture, additives, further washing or post-activation chemical treatment (chemical or water washing, chemical impregnation or other treatment), or product form. Unless specifically excluded, the scope of the order covers all physical forms of certain activated carbon, including powdered activated carbon (PAC), granular activated carbon (GAC), and pelletized activated carbon.

Excluded from the scope of the order are chemically activated carbons. The carbon-based raw material used in the chemical activation process is treated with a strong chemical agent, including but not limited to phosphoric acid, zinc chloride, sulfuric acid, or potassium hydroxide that dehydrates molecules in the raw material, and results in the formation of water that is removed from the raw material by moderate heat treatment. The activated carbon created by chemical activation has internal porosity developed primarily due to the action of the chemical dehydration agent. Chemically activated carbons are typically used to activate raw materials with a lignocellulosic component such as cellulose, including wood, sawdust, paper mill waste and peat.

To the extent that an imported activated carbon product is a blend of steam and chemically activated carbons, products containing 50 percent or more steam (or CO₂ gas) activated carbons are within the scope, and those containing more than 50 percent chemically activated carbons are outside the scope. This exclusion language regarding blended material applies only to mixtures of steam and chemically activated carbons.

Also excluded from the scope are reactivated carbons. Reactivated carbons are previously used activated carbons that have had adsorbed materials removed from their pore structure after use through the application of heat, steam and/or chemicals.

Also excluded from the scope is activated carbon cloth. Activated carbon cloth is a woven textile fabric made of or containing activated carbon fibers. It is used in masks and filters and clothing of various types where a woven format is required.

Any activated carbon meeting the physical description of subject merchandise provided above that is not expressly excluded from the scope is included within the scope. The products subject to the order are currently classifiable under the HTSUS subheading 3802.10.00. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Continuation of the Order

As a result of the determinations by Commerce and the ITC that revocation of the antidumping duty order would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the antidumping duty order on certain activated carbon from China. U.S. Customs and Border Protection will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of the order will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, Commerce intends to initiate the next sunset review of the order not later than 30 days prior to the fifth anniversary of the effective date of continuation.

This sunset review and this notice are in accordance with section 751(c) and 751(d)(2) of the Act and published pursuant to section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: July 6, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–15014 Filed 7–11–18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with May anniversary dates. In accordance with Commerce’s regulations, we are initiating those administrative reviews.

DATES: Applicable July 12, 2018.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401

² See *Initiation of Five-Year (Sunset) Reviews*, 83 FR 4681 (February 1, 2018).

³ See *Certain Activated Carbon from the People’s Republic of China: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order*, 83 FR 26949 (June 11, 2018) (*Final Results*) and accompanying Issues and Decision Memorandum.

⁴ See *Certain Activated Carbon from China: Investigation No. 731-TA-1103 (Second Review)*, USITC Publication 4776 (June 2018); see also *Certain Activated Carbon from China: Determination*, 83 FR 31568 (July 6, 2018).

Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482-4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with May anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify Commerce within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at <http://access.trade.gov> in accordance with 19 CFR 351.303.¹ Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on Commerce's service list.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 30 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments five days after the deadline for the initial comments.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce has found that determinations concerning whether particular companies should be "collapsed" (e.g., treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (e.g., investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Respondent Selection—Aluminum Extrusions From the People's Republic of China

In the event Commerce limits the number of respondents for individual examination in the administrative review of the antidumping duty order on aluminum extrusions from the People's Republic of China ("China"), Commerce intends to select respondents based on volume data contained in responses to Q&V questionnaires. Further, Commerce intends to limit the number of Q&V questionnaires issued in the review based on CBP data for U.S. imports of aluminum extrusions from the China. The extremely wide variety of individual types of aluminum

extrusion products included in the scope of the order on aluminum extrusions would preclude meaningful results in attempting to determine the largest China exporters of subject merchandise by volume. Therefore, Commerce will limit the number of Q&V questionnaires issued based on the import values in CBP data which will serve as a proxy for imported quantities. Parties subject to the review to which Commerce does not send a Q&V questionnaire may file a response to the Q&V questionnaire by the applicable deadline if they desire to be included in the pool of companies from which Commerce will select mandatory respondents. The Q&V questionnaire will be available on Commerce's website at <http://trade.gov/enforcement/news.asp> on the date of publication of this notice in the **Federal Register**. The responses to the Q&V questionnaire must be received by Commerce within 14 days of publication of this notice. Please be advised that due to the time constraints imposed by the statutory and regulatory deadlines for antidumping duty administrative reviews, Commerce does not intend to grant any extensions for the submission of responses to the Q&V questionnaire. Parties will be given the opportunity to comment on the CBP data used by Commerce to limit the number of Q&V questionnaires issued. We intend to release the CBP data under APO to all parties having an APO within seven days of publication of this notice in the **Federal Register**. Commerce invites comments regarding CBP data and respondent selection within five days of placement of the CBP data on the record.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is Commerce's policy to assign all exporters of merchandise subject to an administrative review in an NME

¹ See *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011).

country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce’s website at [http://enforcement.trade.gov/nme/nme-](http://enforcement.trade.gov/nme/nme-sep-rate.html)

[sep-rate.html](http://enforcement.trade.gov/nme/nme-sep-rate.html) on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the “Instructions for Filing the Certification” in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding² should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,³ should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Status Application will be available on Commerce’s website at

<http://enforcement.trade.gov/nme/nme-sep-rate.html> on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to Commerce no later than 30 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than May 31, 2019.

	Period to be reviewed
Antidumping Duty Proceedings	
AUSTRIA: Carbon and Alloy Steel Cut-to-Length Plate, A-433-812 Bohler Edelstahl GmbH & Co KG Bohler Bleche GmbH & Co KG	11/14/16-4/30/18
BELGIUM: Carbon and Alloy Steel Cut-to-Length Plate, A-423-812 Henegehoef Concrete Joints NV Industeel Belgium S.A. NLMK Clabecq S.A./NLMK Plate Sales S.A./NLMK Sales Europe S.A./NLMK Manage Steel Center S.A./NLMK La Louviere S.A. Sarens NV Thyssenkrupp Materials Belgium N.V. Universal Eisen und Stahl GmbH Valvan Baling Systems Voestalpine Belgium NV.	11/14/16-4/30/18
CANADA: Citric Acid and Citrate Salt, A-122-853 Jungbunzlauer Canada Inc.	5/1/17-4/30/18
CANADA: Polyethylene Terephthalate Resin, A-122-855 Compagnie Selenis Canada	5/1/17-4/30/18
FRANCE: Carbon and Alloy Steel Cut-To-Length Plate, A-427-828 Industeel France S.A.S.	11/14/16-4/30/18
GERMANY: Carbon and Alloy Steel Cut-To-Length Plate, A-428-844 AG der Dillinger Huttenwerke Ilseburger Grobblech GmbH Perficon Steel GmbH Reiner Brach GmbH & Co. KG Rudolf Rafflenbeul Stahlwarenfabrik GmbH & Co. Salzgitter Mannesmann Grobblech GmbH Salaigitter Flachstahl GmbH Salzgitter Mannesmann International GmbH	11/14/16-4/30/18

² Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (e.g., an ongoing administrative review, new

shipper review, etc.) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

³ Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

	Period to be reviewed
Tenova (TAKRAF GmbH Lauchhammer) ThyssenKrupp Steel Europe AG ThyssenKrupp Schulte GmbH UPC Universal Piping GmbH VETTER Umformtechnik GmbH	
INDIA: Certain Frozen Warmwater Shrimp, ⁴ A-533-840	2/1/17-1/31/18
INDIA: Certain Welded Carbon Steel Standard Pipes and Tubes, A-533-502	5/1/17-4/30/18
Apl Apollo Tubes Ltd. Asian Contec Ltd. Bhandari Foils & Tubes Ltd. Bhushan Steel Ltd. Blue Moon Logistics Pvt. Ltd. CH Robinson Worldwide Ess-Kay Engineers, Manushi Enterprise & Nishi Boring Corporation Fiber Tech Composite Pvt. Ltd. Garg Tube Export LLP GCL Private Limited Goodluck India Ltd. GVN Fuels Ltd. Hydromatik Jindal Quality Tubular Ltd. KLT Automatic & Tubular Products Ltd. Lloyds Line Pipes Ltd. MARINetrans India Private Ltd. Patton International Ltd. SAR Transport Systems Pvt. Ltd. Surya Global Steel Tubes Ltd. Surya Roshni Ltd. Welspun India Ltd. Zenith Birla (India) Ltd. Zenith Birla Steels Private Ltd. Zenith Dyeintermediates Ltd.	
ITALY: Carbon and Alloy Steel Cut-To-Length Plate, A-475-834	11/14/16-4/30/18
Euroflex SpA Evarz Palini e Bertoil SpA Ilva SpA Metalcam SpA Modelleria di Modini Renato NLMK Verona SpA Officine Tecnosider srl Ondulit Italiana SpA Padana Tubi e Profilati Acciaio SpA Riva Fire SpA	
JAPAN: Diffusion-Annealed Nickel-Plated Flat-Rolled Steel Products, A-588-869	5/1/17-4/30/18
Nippon Steel & Sumitomo Metals Corporation Toyo Kohan Co., Ltd.	
OMAN: Polyethylene Terephthalate Resin, A-523-810	5/1/17-4/30/18
Octal Saoc FZC	
REPUBLIC OF KOREA: Carbon and Alloy Steel Cut-To-Length Plate, A-580-887	11/14/16-4/30/18
Buma Ce Co., Ltd. Dong Yang Steel Pipe Co., Ltd. Dongkuk Steel Mill Co., Ltd. Expeditors Korea Ltd. Haem Co., Ltd. Hyundai Glovis Co., Ltd. Hyundia Steel Company J.I. Sea & Air Express Co., Ltd. Maxpeed Co., Ltd. POSCO POSCO Daewoo Corporation POSCO Processing & Service Co., Ltd. Rames Logistics Co., Ltd. Sumitomo Corp. Korea Ltd.	
REPUBLIC OF KOREA: Polyester Staple Fiber, A-580-839	5/1/17-4/30/18
Huvis Corporation Toray Chemical Korea, Inc.	
TAIWAN: Carbon and Alloy Steel Cut-To-Length Plate, A-583-858	11/14/16-4/30/18
Broad Hand Enterprise Co., Ltd. C.H. Robinson Freight Services China Steel Corporation Chun Chi Grating Co., Ltd. Eci Taiwan Co., Ltd. Locksure Inc. Nan Hoang Traffic Instrument Co.	

	Period to be reviewed
New Marine Consolidator Co., Ltd. North America Mining Group Co., Ltd.. Oriental Power Logistics Co., Ltd. Product Depot International Corp. Scanwell Logistics (Taiwan) Shang Chen Steel Co., Ltd. Shin Yang Steel Co., Ltd. Shye Yao Steel Co., Ltd. Speedmark Consolidation Sumeeko Industries Co., Ltd. Triple Merits Ltd. UKI Enterprise Co., Ltd.	
TAIWAN: Certain Circular Welded Carbon Steel Pipes and Tubes, A-583-008	5/1/17-4/30/18
Chung Hung Steel Corp. Far East Machinery Co., Ltd. Far East Machinery Group Fine Blanking & Tool Co., Ltd. Hou Lih Co., Ltd. Kao Hsing Chang Iron & Steel Corp. Lang Hwang Corp. Locksure Inc. New Chance Products Co., Ltd. Pat & Jeff Enterprise Co., Ltd. Pin Tai Metal Inc. Shang Jouch Industrial Co., Ltd. Shengyu Steel Co., Ltd. Shin Yang Steel Co., Ltd. Shuan Hwa Industrial Co., Ltd. Tension Steel Industries Co., Ltd. Titan Fastech Ltd. Yeong Shien Industrial Co., Ltd. Yieh Hsing Enterprise Co., Ltd. Yousing Precision Industry Co., Ltd.	
TAIWAN: Stilbenic Optical Brightening Agents, A-583-848	5/1/17-4/30/18
Teh Fong Min International Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: 1-Hydroxyethylidene-1,1-Diphosphonic Acid (Hedp), A-570-045	11/14/16-4/30/18
Henan Qingshuiyuan Technology Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Aluminum Extrusions, A-570-967	5/1/17-4/30/18
Acro Import and Export Co. Activa International Inc. Activa Leisure Inc. Allied Maker Limited Alnan Aluminum Co., Ltd. Alnan Aluminum Ltd. Aluminicaste Fundicion de Mexico AMC Ltd. AMC Limited Anji Chang Hong Chain Manufacturing Anshan Zhongjda Industry Co., Ltd. Aoda Aluminium (Hong Kong) Co., Limited AsiaAlum GroupAtlas Integrated Manufacturing Ltd. Belton (Asia) Development Limited Belton (Asia) Development Ltd. Birchwoods (Lin'an) Leisure Products Co., Ltd. Bolnar Hong Kong Ltd. Bracalente Metal Products (Suzhou) Co., Ltd. Brilliance General Equipment Co., Ltd. Changshu Changshen Aluminum Products Co., Ltd. Changshu Changsheng Aluminum Products Co., Ltd. Changzhou Changzhen Evaporator Co., Ltd. Changzhou Changzheng Evaporator Co., Ltd. Changzhou Tenglong Auto Accessories Manufacturing Co. Ltd Changzhou Tenglong Auto Parts Co., Ltd. Changzhou Tenglong Auto Parts Co. Ltd. China Square China Square Industrial Co. China Square Industrial Ltd. China Zhongwang Holdings, Ltd. Chiping One Stop Industrial & Trade Co., Ltd. Classic & Contemporary Inc. Clear Sky Inc. Cosco (J.M.) Aluminum Co., Ltd. Cosco (JM) Aluminum Development Co. Ltd. Dalian Huacheng Aquatic Products	

	Period to be reviewed
<p> Dalian Liwang Trade Co., Ltd. Danfoss Micro Channel Heat Exchanger (Jia Xing) Co., Ltd. Daya Hardware Co. Ltd. Dongguan Dazhan Metal Co., Ltd. Dongguang Aoda Aluminum Co., Ltd. Dongguan Golden Tiger Hardware Industrial Co., Ltd. Dragonlux Limited Dynabright International Group (HK) Ltd. Dynamic Technologies China ETLA Technology (Wuxi) Co. Ltd. Ever Extend Ent. Ltd. Fenghua Metal Product Factory First Union Property Limited FookShing Metal & Plastic Co. Ltd. Foreign Trade Co. of Suzhou New & High-Tech Industrial Development Zone Foshan City Nanhai Hongjia Aluminum Alloy Co., Ltd. Foshan Golden Source Aluminum Products Co., Ltd. Foshan Guangcheng Aluminium Co., Ltd. Foshan Jinlan Aluminum Co. Ltd. Foshan JinLan Aluminum Co., Ltd. Foshan JMA Aluminum Company Limited Foshan Nanhai Niu Yuan Hardware Product Co., Ltd. Foshan Shanshui Fenglu Aluminum Co., Ltd. Foshan Shunde Aoneng Electrical Appliances Co., Ltd. Foshan Yong Li Jian Aluminum Co., Ltd. Fujian Sanchuan Aluminum Co., Ltd. Fukang Aluminum & Plastic Import and Export Co., Ltd. Fuzhou Sunmodo New Energy Equipment Gaotang Xinhai Economy & Trade Co., Ltd. Genimex Shanghai, Ltd. Global Hi-Tek Precision Co. Ltd. Global PMX Dongguan Co., Ltd. Global Point Technology (Far East) Limited Gold Mountain International Development, Ltd. Golden Dragon Precise Copper Tube Group, Inc. Gran Cabrio Capital Pte. Ltd. Gree Electric Appliances GT88 Capital Pte. Ltd. Guang Ya Aluminium Industries Co. Ltd. Guang Ya Aluminum Industries Company Ltd Guang Ya Aluminium Industries (HK) Ltd. Guangcheng Aluminum Co., Ltd. Guangdong Hao Mei Aluminum Co., Ltd. Guangdong Jianmei Aluminum Profile Company Limited Guangdong JMA Aluminum Profile Factory (Group) Co., Ltd. Guangdong Midea Guangdong Midea Microwave and Electrical Appliances Guangdong Nanhai Foodstuffs Imp. & Exp. Co., Ltd. Guangdong Weiye Aluminum Factory Co., Ltd. Guangdong Whirlpool Electrical Appliances Co., Ltd. Guangdong Xingfa Aluminum Co., Ltd. Guangdong Xin Wei Aluminum Products Co., Ltd. Guangdong Yonglijian Aluminum Co., Ltd. Guangdong Zhongya Aluminum Company Ltd. Guangzhou Jangho Curtain Wall System Engineering Co., Ltd. Guangzhou Mingcan Die-Casting Hardware Products Co., Ltd. Hangzhou Xingyi Metal Products Co., Ltd. Hanwood Enterprises Limited Hanyung Alcoba Co., Ltd. Hanyung Alcobis Co., Ltd. Hanyung Metal (Suzhou) Co., Ltd. Hao Mei Aluminum Co., Ltd. Hao Mei Aluminum International Co., Ltd. Hebei Xusen Wire Mesh Products Co., Ltd. Henan New Kelong Electrical Appliances Co., Ltd. Henan Zhongduo Aluminum Magnesium New Material Co, Ltd. Hong Kong Gree Electric Appliances Sales Limited Hong Kong Modern Non-Ferrous Metal Honsense Development Company Houztek Architectural Products Co., Ltd. Hui Mei Gao Aluminum Foshan Co., Ltd. Huixin Aluminum IDEX Dinglee Technology (Tianjin) Co., Ltd. IDEX Health </p>	

	Period to be reviewed
<p> IDEX Technology Suzhou Co., Ltd. Innovative Aluminum (Hong Kong) Limited iSource Asia Jackson Travel Products Co., Ltd. Jangho Curtain Wall Hong Kong Ltd. Jiangmen Jianghai District Foreign Economic Enterprise Corp. Ltd. Jiangmen Jianghai Foreign Ent. Gen. Jiangmen Qunxing Hardware Diecasting Co., Ltd. Jiangsu Changfa Refrigeration Co. Jiangyin Suncitygaylin Jiangyin Trust International Inc. Jiangyin Xinhong Doors and Windows Co., Ltd. Jiaxing Jackson Travel Products Co., Ltd. Jiaxing Taixin Metal Products Co., Ltd. Jiuyan Co., Ltd. JMA (HK) Company Limited Johnson Precision Engineering (Suzhou) Co., Ltd. Justhere Co., Ltd. Kam Kiu Aluminum Products Sdn Bhd Kanal Precision Aluminum Product Co., Ltd. Karlton Aluminum Company Ltd. Kong Ah International Company Limited Kromet International Inc. Kromet Intl Inc. Kromet International Kunshan Giant Light Metal Technology Co., Ltd. Liaoning Zhong Da Industrial Aluminum Co., Ltd. Liaoning Zhongwang Group Co., Ltd. Liaoyang Zhongwang Aluminum Profile Co. Ltd. Longkou Donghai Trade Co., Ltd. Metal Tech Co. Ltd. Metaltek Group Co., Ltd. Metaltek Metal Industry Co., Ltd. Midea Air Conditioning Equipment Co., Ltd. Midea Electric Trading Co., Pte Ltd. Midea International Trading Co., Ltd. Midea International Training Co., Ltd. Miland Luck Limited Nanhai Textiles Import & Export Co., Ltd. New Asia Aluminum & Stainless Steel Product Co., Ltd. New Zhongya Aluminum Factory Nidec Sankyo (Zhejiang) Corporation Nidec Sankyo Zhejiang Corporation Nidec Sankyo Singapore Pte. Ltd. Ningbo Coaster International Co., Ltd. Ningbo Hi Tech Reliable Manufacturing Company Ningbo Innopower Tengda Machinery Ningbo Ivy Daily Commodity Co., Ltd. Ningbo Yili Import and Export Co., Ltd. North China Aluminum Co., Ltd. North Fenghua Aluminum Ltd. Northern States Metals PanAsia Aluminum (China) Limited Pengcheng Aluminum Enterprise Inc. Permasteelisa Hong Kong Limited Permasteelisa South China Factory Pingguo Aluminum Company Limited Pingguo Asia Aluminum Co., Ltd. Popular Plastics Company Limited Precision Metal Works Ltd. Press Metal International Ltd. Samuel, Son & Co., Ltd. Sanchuan Aluminum Co., Ltd. Sanhua (Hangzhou) Micro Channel Heat Exchanger Co., Ltd. Shandong Fukang Aluminum & Plastic Co. LTD. Shandong Huajian Aluminum Group Shangdong Huasheng Pesticide Machinery Co. Shangdong Nanshan Aluminum Co., Ltd. Shanghai Automobile Air-Conditioner Accessories Co. Ltd. Shanghai Automobile Air Conditioner Accessories Ltd. Shanghai Canghai Aluminum Tube Packaging Co., Ltd. Shanghai Dofiberone Composites Co. Ltd. Shanghai Dongsheng Metal Shanghai Shen Hang Imp & Exp Co., Ltd. </p>	

	Period to be reviewed
Shanghai Tongtai Precise Aluminum Alloy Manufacturing Co. Ltd. Shanghai Top-Ranking Aluminum Products Co., LTD. Shanghai Top-Ranking New Materials Co., Ltd. Shenyang Yuanda Aluminum Industry Engineering Co. Ltd. Shenzhen Hudson Technology Development Co. Shenzhen Jiuyuan Co., Ltd. Sihui Shi Guo Yao Aluminum Co., Ltd. Sincere Profit Limited Skyline Exhibit Systems (Shanghai) Co. Ltd. Southwest Aluminum (Group) Co., Ltd. Summit Heat Sinks Metal Co., Ltd. Summit Plastics Nanjing Co. Ltd. Suzhou JRP Import & Export Co., Ltd. Suzhou New Hongji Precision Part Co. Tai-Ao Aluminum (Taishan) Co. Ltd. Taishan City Kam Kiu Aluminium Extrusion Co., Ltd. Taizhou Lifeng Manufacturing Co., Ltd. Taitoh Machinery Shanghai Co. Ltd. Taizhou United Imp. & Exp. Co., Ltd. tenKsolar (Shanghai) Co., Ltd. Tianjin Ganglv Nonferrous Metal Materials Co., Ltd. Tianjin Jinmao Import & Export Corp., Ltd. Tianjin Ruxin Electric Heat Transmission Technology Co., Ltd. Tianjin Xiandai Plastic & Aluminum Products Co., Ltd. Tiazhou Lifeng Manufacturing Corporation Top-Wok Metal Co., Ltd. Traffic Brick Network, LLC Union Aluminum (SIP) Co. Union Industry (Asia) Co., Ltd. USA Worldwide Door Components (Pinghu) Co., Ltd. Wenzhou Shengbo Decoration & Hardware Wenzhou Yongtai Electric Co., Ltd. Whirlpool (Guangdong) Whirlpool Canada L.P. Whirlpool Microwave Products Development Ltd. Worldwide Door Components, Inc. WTI Building Products, Ltd. Wuxi Lutong Fiberglass Doors Co., Ltd. Xin Wei Aluminum Co. Xin Wei Aluminum Company Limited Xinya Aluminum & Stainless Steel Product Co., Ltd. Yuyao Haoshen Import & Export Yuyao Fanshun Import & Export Co., Ltd. Zhaqing China Square Industry Limited Zhaqing Asia Aluminum Factory Company Ltd. Zhaqing China Square Industry Limited Zhaqing China Square Industrial Ltd. Zhaqing New Zhongya Aluminum Co., Ltd. Zhejiang Anji Xinxiang Aluminum Co., Ltd. Zhejiang Lilies Industrial and Commercial Co. Zhejiang Yili Automobile Air Condition Co., Ltd. Zhejiang Yongkang Listar Aluminum Industry Co., Ltd. Zhejiang Zhengte Group Co., Ltd. Zhenjiang Xinlong Group Co., Ltd. Zhongshan Daya Hardware Co., Ltd. Zhongshan Gold Mountain Aluminum Factory Ltd. Zhongya Shaped Aluminum (HK) Holding Limited Zhuhai Runxingtai Electrical Equipment Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Oil Country Tubular Goods, A-570-943	5/1/17-4/30/18
Baoshan Iron & Steel Hengyang Steel Tube Group International Trading Inc. Hubei Xinyegang Steel Co., Ltd. Hubei Xin Yegang Special Tube	
THE PEOPLE'S REPUBLIC OF CHINA: Pure Magnesium, A-570-832	5/1/17-4/30/18
Tianjin Magnesium International Co., Ltd. Tianjin Magnesium Metal Co., Ltd.	
TURKEY: Circular Welded Carbon Steel Pipes and Tubes, A-489-501	5/1/17-4/30/18
Borusan Birlesik Boru Fabrikalari San ve Tic. Borusan Gemlik Boru Tesisleri A.S. Borusan Holding Borusan Ihracat Ithalat ve Dagitim A.S. Borusan Istikbal Ticaret T.A.S. Borusan Ithicat ve Dagitim A.S. Borusan Mannesmann Boru Sanayi ve Ticaret A.S.	

	Period to be reviewed
Borusan Mannesmann Yatirim Holding Cayirova Boru Sanayi ve Ticaret A.S. Cinar Boru Profil San. Ve Tic. As Erbosan Erciyas Boru Sanayi ve Ticaret A.S. Kale Baglanti Teknolojileri San. ve Tic. Noksel Celik Boru Sanayi A.S. Toscelik Metal Ticaret A.S. Toscelik Profil ve Sac Endustrisi A.S. Tosyali Dis Ticaret A.S. Tubeco Pipe and Steel Corporation Yucel Boru ve Profil Endustrisi A.S. Yucelboru Ihracat Ithalat ve Pazarlama A.S.	
TURKEY: Light-Walled Rectangular Pipe and Tube, A-489-815	5/1/17-4/30/18
Noksel Celik Boru Sanayi A.S.	
Countervailing Duty Proceedings	
REPUBLIC OF KOREA: Carbon and Alloy Steel Cut-To-Length Plate, C-580-888	9/14/16- 12/31/17
BDP International Blue Track Equipment Boxco Bukook Steel Co., Ltd. Buma CE Co., Ltd. Daelim Industrial Co., Ltd. Daesam Industrial Co., Ltd. Daesin Lighting Co., Ltd. Daewoo International Corp. Dong Yang Steel Pipe Dongkuk Industries Co., Ltd. Dongkuk Steel Mill Co., Ltd. Dongbu Steel Co., Ltd. EAE Automotive Equipment EEW KHPC Co., Ltd. Eplus Expo Inc. GS Global Corp. Haem Co., Ltd. Han Young Industries Hyosung Corp. Hyundai Steel Co. Jinmyung Frictech Co., Ltd. Korean Iron and Steel Co., Ltd. Kyoungil Precision Co., Ltd. POSCO Samsun C&T Corp. SK Netwoks Co., Ltd. Steel N People Ltd. Summit Industry Sungjin Co., Ltd. Young Sun Steel	
THE PEOPLE'S REPUBLIC OF CHINA: 1-Hydroxyethylidene-1,1-Diphosphonic Acid (Hedp), C-570-046	9/8/16-12/31/17
Changzhou Kewei Fine Chemicals Co., Ltd. Changzhou Yao's Tongde Chemical Co., Ltd. Hebei Longke Water Treatment Co., Ltd. Henan Qinshuiyuan Technology Co., Ltd. Jinghai Environmental Protection Co., Ltd. (Jianghai) Nanjing University of Chemical Technology Changzhou Wujin Water Quality Stabilizer Factory Nantong Uniphos Chemicals Co., Ltd. Shandong Huayou Chemistry Co., Ltd. Shandong Taihe Chemicals Co., Ltd. Shandong Taihe Water Treatment Technologies Co., Ltd. Shandong Xintai Water Treatment Technology Wujin Fine Chemical Factory Co., Ltd. Zaozhuang Fuxing Water Treatment Technology Zaozhuang YouBang Chemicals Co., Ltd. Zouping Dongfang Chemical Industry Co., Ltd.	
THE PEOPLE'S REPUBLIC OF CHINA: Aluminum Extrusions, C-570-968	1/1/17-12/31/17
Acro Import and Export Co. Activa International Inc. Activa Leisure Inc. Allied Maker Limited Alnan Aluminum Co., Ltd. Alnan Aluminum Ltd. Aluminicaste Fundicion de Mexico AMC Ltd.	

	Period to be reviewed
<p> AMC Limited Anji Chang Hong Chain Manufacturing Anshan Zhongjda Industry Co., Ltd. Aoda Aluminium (Hong Kong) Co., Limited AsiaAlum Group Atlas Integrated Manufacturing Ltd. Belton (Asia) Development Limited Belton (Asia) Development Ltd. Birchwoods (Lin'an) Leisure Products Co., Ltd. Bolnar Hong Kong Ltd. Bracalente Metal Products (Suzhou) Co., Ltd. Brilliance General Equipment Co., Ltd. Changshu Changshen Aluminum Products Co., Ltd. Changshu Changsheng Aluminum Products Co., Ltd. Changzhou Changzhen Evaporator Co., Ltd. Changzhou Changzheng Evaporator Co., Ltd. Changzhou Tenglong Auto Accessories Manufacturing Co. Ltd Changzhou Tenglong Auto Parts Co., Ltd. Changzhou Tenglong Auto Parts Co Ltd China Square China Square Industrial Co. China Square Industrial Ltd. China Zhongwang Holdings, Ltd. Chiping One Stop Industrial & Trade Co., Ltd. Classic & Contemporary Inc. Clear Sky Inc. Cosco (J.M.) Aluminum Co., Ltd. Cosco (JM) Aluminum Development Co. Ltd Dalian Huacheng Aquatic Products Dalian Liwang Trade Co., Ltd. Danfoss Micro Channel Heat Exchanger (Jia Xing) Co., Ltd. Daya Hardware Co. Ltd. Dongguan Dazhan Metal Co., Ltd. Dongguang Aoda Aluminum Co., Ltd. Dongguan Golden Tiger Hardware Industrial Co., Ltd. Dragonlux Limited Dynabright International Group (HK) Ltd. Dynamic Technologies China ETLA Technology (Wuxi) Co. Ltd. Ever Extend Ent. Ltd. Fenghua Metal Product Factory First Union Property Limited FookShing Metal & Plastic Co. Ltd. Foreign Trade Co. of Suzhou New & High-Tech Industrial Development Zone Foshan City Nanhai Hongjia Aluminum Alloy Co., Ltd. Foshan Golden Source Aluminum Products Co., Ltd. Foshan Guangcheng Aluminium Co., Ltd Foshan Jinlan Aluminum Co. Ltd. Foshan JinLan Aluminum Co., Ltd. Foshan JMA Aluminum Company Limited Foshan Nanhai Niu Yuan Hardware Product Co., Ltd. Foshan Shanshui Fenglu Aluminum Co., Ltd. Foshan Shunde Aoneng Electrical Appliances Co., Ltd Foshan Yong Li Jian Aluminum Co., Ltd. Fujian Sanchuan Aluminum Co., Ltd. Fukang Aluminum & Plastic Import and Export Co., Ltd. Fuzhou Sunmodo New Energy Equipment Gaotang Xinhai Economy & Trade Co., Ltd. Genimex Shanghai, Ltd. Global Hi-Tek Precision Co. Ltd Global PMX Dongguan Co., Ltd. Global Point Technology (Far East) Limited Gold Mountain International Development, Ltd. Golden Dragon Precise Copper Tube Group, Inc. Gran Cabrio Capital Pte. Ltd. Gree Electric Appliances GT88 Capital Pte. Ltd. Guang Ya Aluminium Industries Co. Ltd. Guang Ya Aluminum Industries Company Ltd Guang Ya Aluminium Industries (HK) Ltd. Guangcheng Aluminum Co., Ltd. Guangdong Hao Mei Aluminum Co., Ltd. Guangdong Jianmei Aluminum Profile Company Limited Guangdong JMA Aluminum Profile Factory (Group) Co., Ltd. </p>	

	Period to be reviewed
<p>Guangdong Midea Guangdong Midea Microwave and Electrical Appliances Guangdong Nanhai Foodstuffs Imp. & Exp. Co., Ltd. Guangdong Weiye Aluminum Factory Co., Ltd. Guangdong Whirlpool Electrical Appliances Co., Ltd. Guangdong Xingfa Aluminum Co., Ltd. Guangdong Xin Wei Aluminum Products Co., Ltd. Guangdong Yonglijian Aluminum Co., Ltd. Guangdong Zhongya Aluminum Company Ltd. Guangzhou Jangho Curtain Wall System Engineering Co., Ltd. Guangzhou Mingcan Die-Casting Hardware Products Co., Ltd. Hangzhou Xingyi Metal Products Co., Ltd. Hanwood Enterprises Limited Hanyung Alcoba Co., Ltd. Hanyung Alcobis Co., Ltd. Hanyung Metal (Suzhou) Co., Ltd. Hao Mei Aluminum Co., Ltd. Hao Mei Aluminum International Co., Ltd. Hebei Xusen Wire Mesh Products Co., Ltd. Henan New Kelong Electrical Appliances Co., Ltd. Henan Zhongduo Aluminum Magnesium New Material Co., Ltd. Hong Kong Gree Electric Appliances Sales Limited Hong Kong Modern Non-Ferrous Metal Honsense Development Company Houzteck Architectural Products Co., Ltd. Hui Mei Gao Aluminum Foshan Co., Ltd. Huixin Aluminum IDEX Dinglee Technology (Tianjin) Co., Ltd. IDEX Health IDEX Technology Suzhou Co., Ltd. Innovative Aluminum (Hong Kong) Limited iSource Asia Jackson Travel Products Co., Ltd. Jangho Curtain Wall Hong Kong Ltd. Jiangmen Jianghai District Foreign Economic Enterprise Corp. Ltd. Jiangmen Jianghai Foreign Ent. Gen. Jiangmen Qunxing Hardware Diecasting Co., Ltd. Jiangsu Changfa Refrigeration Co. Jiangyin Suncitygaylin Jiangyin Trust International Inc. Jiangyin Xinhong Doors and Windows Co., Ltd. Jiaxing Jackson Travel Products Co., Ltd. Jiaxing Taixin Metal Products Co., Ltd. Jiuyan Co., Ltd. JMA (HK) Company Limited Johnson Precision Engineering (Suzhou) Co., Ltd. Justhere Co., Ltd. Kam Kiu Aluminum Products Sdn Bhd Kanal Precision Aluminum Product Co., Ltd. Karlton Aluminum Company Ltd. Kong Ah International Company Limited Kromet International Inc. Kromet Intl Inc. Kromet International Kunshan Giant Light Metal Technology Co., Ltd. Liaoning Zhong Da Industrial Aluminum Co., Ltd. Liaoning Zhongwang Group Co., Ltd. Liaoyang Zhongwang Aluminum Profile Co. Ltd. Longkou Donghai Trade Co., Ltd. Metal Tech Co Ltd. Metaltek Group Co., Ltd. Metaltek Metal Industry Co., Ltd. Midea Air Conditioning Equipment Co., Ltd. Midea Electric Trading Co., Pte Ltd. Midea International Trading Co., Ltd. Midea International Training Co., Ltd. Miland Luck Limited Nanhai Textiles Import & Export Co., Ltd. New Asia Aluminum & Stainless Steel Product Co., Ltd. New Zhongya Aluminum Factory Nidec Sankyo (Zhejiang) Corporation Nidec Sankyo Zhejiang Corporation Nidec Sankyo Singapore Pte. Ltd. Ningbo Coaster International Co., Ltd.</p>	

	Period to be reviewed
<p> Ningbo Hi Tech Reliable Manufacturing Company Ningbo Innopower Tengda Machinery Ningbo Ivy Daily Commodity Co., Ltd. Ningbo Yili Import and Export Co., Ltd. North China Aluminum Co., Ltd. North Fenghua Aluminum Ltd. Northern States Metals PanAsia Aluminum (China) Limited Pengcheng Aluminum Enterprise Inc. Permasteelisa Hong Kong Limited Permasteelisa South China Factory Pingguo Aluminum Company Limited Pingguo Asia Aluminum Co., Ltd. Popular Plastics Company Limited Precision Metal Works Ltd. Press Metal International Ltd. Samuel, Son & Co., Ltd. Sanchuan Aluminum Co., Ltd. Sanhua (Hangzhou) Micro Channel Heat Exchanger Co., Ltd. Shandong Fukang Aluminum & Plastic Co. LTD. Shandong Huajian Aluminum Group Shandong Huasheng Pesticide Machinery Co. Shandong Nanshan Aluminum Co., Ltd. Shanghai Automobile Air-Conditioner Accessories Co Ltd. Shanghai Automobile Air Conditioner Accessories Ltd. Shanghai Canghai Aluminum Tube Packaging Co., Ltd. Shanghai Dofiberone Composites Co. Ltd. Shanghai Dongsheng Metal Shanghai Shen Hang Imp & Exp Co., Ltd. Shanghai Tongtai Precise Aluminum Alloy Manufacturing Co. Ltd. Shanghai Top-Ranking Aluminum Products Co., LTD. Shanghai Top-Ranking New Materials Co., Ltd. Shenyang Yuanda Aluminum Industry Engineering Co. Ltd. Shenzhen Hudson Technology Development Co. Shenzhen Jiuyuan Co., Ltd. Sihui Shi Guo Yao Aluminum Co., Ltd. Sincere Profit Limited Skyline Exhibit Systems (Shanghai) Co. Ltd. Southwest Aluminum (Group) Co., Ltd. Summit Heat Sinks Metal Co., Ltd. Summit Plastics Nanjing Co. Ltd. Suzhou JRP Import & Export Co., Ltd. Suzhou New Hongji Precision Part Co. Tai-Ao Aluminum (Taishan) Co. Ltd. Taishan City Kam Kiu Aluminium Extrusion Co., Ltd. Taitoh Machinery Shanghai Co. Ltd. Taizhou Lifeng Manufacturing Co., Ltd. Tiazhou Lifeng Manufacturing Corporation Taizhou United Imp. & Exp. Co., Ltd. tenKsolar (Shanghai) Co., Ltd. Tianjin Ganglv Nonferrous Metal Materials Co., Ltd. Tianjin Jinmao Import & Export Corp., Ltd. Tianjin Ruxin Electric Heat Transmission Technology Co., Ltd. Tianjin Xiandai Plastic & Aluminum Products Co., Ltd. Top-Wok Metal Co., Ltd. Traffic Brick Network, LLC Union Aluminum (SIP) Co. Union Industry (Asia) Co., Ltd. USA Worldwide Door Components (Pinghu) Co., Ltd. Wenzhou Shengbo Decoration & Hardware Wenzhou Yongtai Electric Co., Ltd. Whirlpool (Guangdong) Whirlpool Canada L.P. Whirlpool Microwave Products Development Ltd. Worldwide Door Components, Inc. WTI Building Products, Ltd. Wuxi Lutong Fiberglass Doors Co., Ltd. Xin Wei Aluminum Co. Xin Wei Aluminum Company Limited Xinya Aluminum & Stainless Steel Product Co., Ltd. Yuyao Fanshun Import & Export Co., Ltd. Yuyao Haoshen Import & Export Zhaqing China Square Industry Limited Zhaqing Asia Aluminum Factory Company Ltd. </p>	

	Period to be reviewed
Zhaoqing China Square Industrial Ltd. Zhaoqing China Square Industry Limited Zhaoqing New Zhongya Aluminum Co., Ltd. Zhejiang Anji Xinxiang Aluminum Co., Ltd. Zhejiang Lilies Industrial and Commercial Co. Zhejiang Yili Automobile Air Condition Co., Ltd. Zhejiang Yongkang Listar Aluminum Industry Co., Ltd. Zhejiang Zhenqte Group Co., Ltd. Zhenjiang Xinlong Group Co., Ltd. Zhongshan Daya Hardware Co., Ltd. Zhongshan Gold Mountain Aluminum Factory Ltd. Zhongya Shaped Aluminum (HK) Holding Limited Zhuhai Runxingtai Electrical Equipment Co., Ltd.	

Suspension Agreements

None.

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

⁴ On April 16, 2018, Commerce initiated the 2017–2018 administrative review of Certain Frozen Warmwater Shrimp from India. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 83 FR 16298, 16300–16304. In the notice of initiation, Commerce inadvertently made the following errors: (1) We included Premier Marine Products Private Limited twice; (2) we made typographical errors in the names of two companies (*i.e.*, Triveni Fisheries P Ltd. and U & Company Marine Exports, listed as Triveni Fisheries P Ltd.U & Company Marine Exports); and (3) we failed to limit the review for Devi Sea Foods to shrimp produced in India where Devi Sea Foods acted as either the manufacturer or exporter (but not both), because shrimp produced and exported by this company is not covered by the antidumping duty order. See *Certain Frozen Warmwater Shrimp from India: Final Results of Antidumping Duty Administrative Review, Partial Rescission of Review, and Notice of Revocation of Order in Part*, 75 FR 41813, 41814 (July 19, 2010). Accordingly, we are initiating this administrative review for: (1) Premier Marine Products Private Limited only once; (2) Triveni Fisheries P Ltd. and U & Company Marine Exports (instead of Triveni Fisheries P Ltd.U & Company Marine Exports); and (3) Devi Sea Foods, but only with respect to shrimp for which Devi Sea Foods is either the manufacturer or exporter, but not both.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures “gap” period, of the order, if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in Commerce’s regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.*, the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce’s regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on

the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the final rule, available at <http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt>, prior to submitting factual information in this segment.

Any party submitting factual information in an antidumping duty or countervailing duty proceeding must certify to the accuracy and completeness of that information.⁵ Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives. All segments of any antidumping duty or countervailing duty proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule*.⁶ Commerce intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable revised certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by the Secretary. See 19 CFR 351.302. In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are

⁵ See section 782(b) of the Act.

⁶ See *Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings*, 78 FR 42678 (July 17, 2013) (*Final Rule*); see also the frequently asked questions regarding the *Final Rule*, available at http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07122013.pdf.

not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning U.S. Customs and Border Protection data; and (5) quantity and value questionnaires. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Please review the final rule, available at <http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm>, prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: July 6, 2018.

Wendy J. Frankel,

Director, Customs and Border Protection Liaison Unit, Antidumping and Countervailing Duty Operations, Enforcement and Compliance.

[FR Doc. 2018-14923 Filed 7-11-18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG310

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of final determination and discussion of underlying biological

and environmental analyses; notice of availability of Finding of No Significant Impact.

SUMMARY: NMFS has evaluated the joint resource management plan (RMP) submitted to NMFS by the Sauk-Suiattle Indian Tribe, Swinomish Indian Tribal Community, Upper Skagit Indian Tribe, the Skagit River System Cooperative, and the Washington Department of Fish and Wildlife, pursuant to the limitation on take prohibitions for actions conducted under Limit 6 of the 4(d) Rule for salmon and steelhead promulgated under the Endangered Species Act (ESA). The RMP specifies harvest of ESA-listed, Skagit River steelhead in Treaty Indian fisheries and non-treaty recreational fisheries in the Skagit River terminal area of Washington State. This document serves to notify the public that NMFS, by delegated authority from the Secretary of Commerce, had determined pursuant to Limit 6 of the 4(d) rule for salmon and steelhead that implementing and enforcing the RMP will not appreciably reduce the likelihood of survival and recovery of Puget Sound steelhead. In compliance with the National Environmental Policy Act (NEPA), NMFS also announces the availability of its Finding of No Significant Impact for the Skagit River steelhead fisheries determination.

DATES: The final determination of take prohibition limitation under the ESA was made on April 12, 2018. The Finding of No Significant Impact was signed on April 12, 2018.

ADDRESSES: Requests for copies of the decision documents or any of the other associated documents should be directed to NOAA's National Marine Fisheries Service, West Coast Region, Sustainable Fisheries Division, 510 Desmond Drive, Suite 103, Lacey, WA 98503. The documents are also available online at www.westcoast.fisheries.noaa.gov.

FOR FURTHER INFORMATION CONTACT: James Dixon at (360) 534-9329 or by email at james.dixon@noaa.gov.

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Steelhead (*Oncorhynchus mykiss*): threatened, naturally produced and artificially propagated Puget Sound.

Chinook salmon (*O. tshawytscha*): threatened, naturally produced and artificially propagated Puget Sound.

Background

The Sauk-Suiattle Indian Tribe, Swinomish Indian Tribal Community,

Upper Skagit Indian Tribe, and the Skagit River System Cooperative and the Washington Department of Fish and Wildlife have jointly submitted a steelhead fishery RMP to NMFS pursuant to the limitation on take prohibitions for actions conducted under Limit 6 of the 4(d) Rule for salmon and steelhead promulgated under the Endangered Species Act (ESA). The plan was submitted in November of 2016, pursuant to limit 6 of the 4(d) Rule for ESA-listed salmon and steelhead. The RMP would manage the harvest of Skagit River natural-origin steelhead in the Skagit River and in the terminal marine area of the Skagit River. As required, NMFS took public comments on its recommended determination for how the plans address the criteria in § 223.203(b)(5) prior to making its final determination.

Discussion of the Biological Analysis Underlying the Determination

The goal of the Skagit RMP is to provide steelhead fishing opportunities for the Skagit River Treaty Tribes and for recreational fishers, in a manner that is conservative at higher run sizes and increasingly so at lower run sizes. For a period of five years, the Skagit RMP will implement annual steelhead fisheries in the Skagit terminal management area consistent with the impact limits, management framework, enforcement, and monitoring requirements, as described in the RMP. The Skagit RMP utilizes an abundance-based, stepped harvest regime to determine annual harvest rates, based on the annual forecasted run size. These stepped harvest rates range from a 4 percent total allowable harvest rate at low run sizes (<4,001 adults) to 25 percent for runs greater than 8,001 adults.

NMFS has analyzed the Skagit RMP's proposed abundance-based, stepped harvest regime, along with the conservation measures proposed in the plan. We have concluded that the Skagit RMP would provide effective protection to the Skagit River steelhead populations based on parameters defining a viable salmonid population; in terms of overall abundance and productivity, as well as the diversity and spatial structure of the individual populations within the Skagit River basin. The Skagit RMP will provide for the proposed harvest opportunities while not appreciably slowing the population's achievement of viable function.

NMFS' determination on the Skagit RMP depends upon implementation of all of the monitoring, evaluation, reporting tasks or assignments, and

enforcement activities included in the RMP. Reporting and inclusion of new information derived from research, monitoring, and evaluation activities described in the plan provide assurance that performance standards will be achieved in future seasons.

Summary of Comments Received in the Response to the Proposed Evaluation and Pending Determination

NMFS published notice of its Proposed Evaluation and Pending Determination (PEPD) on the plan for public review and comment on December 7, 2017 (82 FR 57729). The PEPD was available for public review and comment for 30 days.

During the public comment period, 121 comments were received, all by email. These came in the form of: Individual, unique comments; individuals who submitted form-letter communications, some with added comments; and letters from fish conservation organizations. NMFS thoroughly reviewed and considered all of the substantive comments received from the public and the additional literature and studies submitted. This review of new information and data informed NMFS' subsequent analysis, in its biological opinion, but did not lead to any changes to the Skagit RMP, as submitted, or to NMFS' determination that the plan adequately addresses the 4(d), Limit 6 criteria. A section summarizing and responding to the substantive comments received during the public comment period on the PEPD is included as part of the final evaluation document, available on the West Coast Region website. Based on its evaluation and recommended determination and taking into account the public comments, NMFS issued its final determination on the joint state-tribal plan.

Authority

Under section 4 of the ESA, the Secretary of Commerce is required to adopt such regulations as he deems necessary and advisable for the conservation of species listed as threatened. The ESA salmon and steelhead 4(d) rule (50 CFR 223.203(b)) specifies categories of activities that contribute to the conservation of listed salmonids and sets out the criteria for such activities. The rule further provides that the prohibitions of paragraph (a) of the rule do not apply to actions undertaken in compliance with a plan developed jointly by a state and a tribe and determined by NMFS to be in accordance with the salmon and

steelhead 4(d) rule (65 FR 42422, July 10, 2000).

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018-14950 Filed 7-11-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: National Oceanic and Atmospheric Administration's Papahānaumokuākea Marine National Monument and University of Hawaii Research Internship Program.

OMB Control Number: 0648-0719.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 80.

Average Hours per Response: 1 hour or less, for each application, reference letter and support letter.

Burden Hours: 80.

Needs and Uses: This request is for extension of a currently approved information collection.

The National Oceanic and Atmospheric Administration's (NOAA's) Papahānaumokuākea Marine National Monument (PMNM) would like to collect student data and information for the purposes of selecting candidates for its research internship program in partnership with the University of Hawaii. The application package would contain: (1) A form requesting information on academic background and professional experiences, (2) reference forms in support of the internship application by two educational or professional references, and (3) a support letter from one academic professor or advisor.

Affected Public: Individuals or households.

Frequency: One time.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of

Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA_Submission@omb.eop.gov or fax to (202) 395-5806.

Dated: July 8, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018-14889 Filed 7-11-18; 8:45 am]

BILLING CODE 3510-NK-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: NOAA Marine Debris Program Performance Progress Report and Data Collection Form.

OMB Control Number: 0648-0718.

Form Number(s): None.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 70.

Average Hours per Response: 1.400.

Burden Hours: 1,400.

Needs and Uses: This request is for revision and extension of an existing information collection.

The NOAA Marine Debris Program (MDP) supports national and international efforts to research, prevent, and reduce the impacts of marine debris. The MDP is a centralized office within NOAA that coordinates and supports activities, both within the bureau and with other federal agencies, which address marine debris and its impacts. In addition to inter-agency coordination, the MDP uses partnerships with state and local agencies, tribes, non-governmental organizations, academia, and industry to investigate and solve the problems that stem from marine debris through research, prevention, and reduction activities, in order to protect and conserve our nation's marine environment and ensure navigation safety.

The Marine Debris Research, Prevention, and Reduction Act (33

U.S.C. 1951 *et seq.*) as amended by the Marine Debris Act Amendments of 2012 (Pub. L. 112–213, Title VI, Sec. 603, 126 Stat. 1576, December 20, 2012) outlines three central program components for the MDP to undertake: (1) Mapping, identification, impact assessment, removal, and prevention; (2) reducing and preventing fishing gear loss; and (3) outreach to stakeholders and the general public. To address these components, the Marine Debris Act authorized the MDP to establish several competitive grant programs on marine debris research, prevention and removal that provide federal funding to non-federal applicants throughout the coastal United States and territories.

The terms and conditions of the financial assistance awarded through these grant programs require regular progress reporting and communication of project accomplishments to MDP. Progress reports contain information related to, among other things, the overall short and long-term goals of the project, project methods and monitoring techniques, actual accomplishments (such as pounds of debris removed from an ecosystem, numbers of volunteers participating in a cleanup project, etc.), status of approved activities, challenges or potential roadblocks to future progress, and lessons learned. This information collection enables MDP to monitor and evaluate the activities supported by federal funds to ensure accountability to the public and to ensure that funds are used consistent with the purpose for which they were appropriated. It also ensures that reported information is standardized in such a way that allows for it to be meaningfully synthesized across a diverse set of projects and project types. MDP uses the information collected in a variety of ways to communicate with federal and non-federal partners and stakeholders on individual project and general program accomplishments.

Revision: A section has been added to the report form, but there is no change to burden.

Affected Public: Not-for-profit institutions; business or other for-profit organizations; state, local or tribal government.

Frequency: Semiannual.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to OIRA_Submission@omb.eop.gov or fax to (202) 395–5806.

Dated: July 8, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–14888 Filed 7–11–18; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Highly Migratory Species

Dealer, Importer, and Exporter

Reporting Family of Forms.

OMB Control Number: 0648–0040.

Form Number(s): None.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 10,391.

Average Hours per Response: 15 minutes for catch document/statistical document/re-export certificate validation by government official; 120 minutes for authorization of non-governmental catch document/statistical document/re-export certificate validation; 2 minutes for daily Atlantic bluefin tuna landing reports; 3 minutes for daily Atlantic bluefin tuna landing reports from pelagic longline and purse seine vessels; 1 minute for Atlantic bluefin tuna tagging; 15 minutes for biweekly Atlantic bluefin tuna dealer landing reports; 15 minutes for HMS international trade biweekly reports; 15 minutes for weekly electronic HMS dealer landing reports (*e-dealer*); 5 minutes for negative weekly electronic HMS dealer landing reports (*e-dealer*); 15 minutes for voluntary fishing vessel and catch forms; 2 minutes for provision of HMS dealer email address.

Burden Hours: 18,552.

Needs and Uses: This request is for revision and extension of a currently approved information collection.

Under the provisions of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), the National Marine Fisheries Service (NMFS) is responsible for management of the Nation's marine fisheries. NMFS must also promulgate

regulations, as necessary and appropriate, to carry out obligations the United States (U.S.) undertakes internationally regarding tuna management through the Atlantic Tunas Convention Act (ATCA, 16 U.S.C. 971 *et seq.*).

This collection serves as a family of forms for Atlantic highly migratory species (HMS) dealer reporting, including purchases of HMS from domestic fishermen, and the import, export, and/or re-export of HMS, including federally managed tunas, sharks, and swordfish.

Transactions covered under this collection include purchases of Atlantic HMS from domestic fishermen; and the import/export of all bluefin tuna, frozen bigeye tuna, southern bluefin tuna or swordfish under the HMS International Trade Program, regardless of geographic area of origin. This information is used to monitor the harvest of domestic fisheries, and/or track international trade of internationally managed species.

The domestic dealer reporting covered by this collection includes weekly electronic landing reports and negative reports (*i.e.*, reports of no activity) of Atlantic swordfish, sharks, bigeye tuna, albacore, yellowfin, and skipjack tunas (collectively referred to as BAYS tunas), and biweekly and electronic daily landing reports for bluefin tuna, including tagging of individual fish. Because of the recent development of an individual bluefin quota (IBQ) management system (RIN 0648–BC09), electronic entry of IBQ-related landing data is required for Atlantic bluefin tuna purchased from Longline and Purse seine category vessels. NMFS intends to consider integrating the electronic dealer reporting for bluefin tuna and electronic reporting for the IBQ system; however, at this time, dealers must submit limited bluefin tuna landings data to both NMFS systems for purse seine and pelagic longline vessels.

International trade tracking programs are required by both the International Commission for the Conservation of Atlantic Tunas (ICCAT) and the Inter-American Tropical Tuna Commission (IATTC) to account for all international trade of covered species. The U.S. is a member of ICCAT and IATTC and required by ATCA and the Tunas Convention Act (16 U.S.C. 951 *et. seq.*, consecutively) to promulgate regulations as necessary and appropriate to implement ICCAT and IATTC recommendations. These programs require that a statistical document or catch document accompany each export from and import to a member nation,

and that a re-export certificate accompany each re-export. The international trade reporting requirements covered by this collection include implementation of catch document, statistical document, and re-export certificate trade tracking programs for bluefin tuna, frozen bigeye tuna, and swordfish. An electronic catch document program for bluefin tuna (EBCD) was recommended by ICCAT and implemented by the United States in 2016 (0648-BF17). U.S. regulations implementing ICCAT statistical document and catch document programs require statistical documents and catch documents for international transactions of the covered species from all ocean areas, so Pacific imports and exports must also be accompanied by statistical documents and catch documents. Since there are statistical document programs in place under other international conventions (e.g., the Indian Ocean Tuna Commission), a statistical document or catch document from another program may be used to satisfy the statistical document requirement for imports into the United States. *Revision: These statistical and catch documents are now covered under OMB Control No. 0648-0732, but their validation is still part of this information collection.*

Dealers who internationally trade Southern bluefin tuna are required to participate in a trade tracking program to ensure that imported Atlantic and Pacific bluefin tuna will not be intentionally mislabeled as “southern bluefin” to circumvent reporting requirements. This action is authorized under ATCA, which provides for the promulgation of regulations as may be necessary and appropriate to carry out ICCAT recommendations.

In addition to statistical document, catch document, and re-export certificate requirements, this collection includes biweekly reports to complement trade tracking statistical documents by summarizing statistical document data and collecting additional economic information.

Affected Public: Business or other for-profit organizations.

Frequency: Weekly and biweekly.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA_Submission@omb.eop.gov or fax to (202) 395-5806.

Dated: July 8, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018-14887 Filed 7-11-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2018-OS-0043]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Office of the Deputy Assistant Secretary of Defense for Military Personnel Policy announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 10, 2018.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350-1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any

personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Deputy Assistant Secretary of Defense for Military Personnel Policy, ATTN: Accession Policy (3D1066), 1500 Defense Pentagon, Washington, DC 20301-1500, or call 703-695-5525.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Police Records Check; DD Form 369; OMB Control Number 0704-0007.

Needs and Uses: The information collection requirement is necessary, per Sections 504, 505 Title 10 U.S.C, to identify persons who may be undesirable for military service. Applicants for enlistment must be screened to identify any discreditable involvement with police or other law enforcement agencies. The DD Form 369, “Police Records Check,” is forwarded to law enforcement agencies to identify if an applicant has a criminal record.

Affected Public: State, Local or Tribal Government.

Annual Burden Hours: 78,750.

Number of Respondents: 175,000.

Responses per Respondent: 1.

Annual Responses: 175,000.

Average Burden per Response: 27 minutes.

Frequency: On occasion.

Dated: July 9, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018-14933 Filed 7-11-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2018-OS-0041]

Notice of Availability of an Environmental Assessment Addressing Hazardous Materials Warehouses and Gas Cylinder Sheds at Naval Station Norfolk and Naval Support Activity Norfolk Naval Shipyard, Virginia

AGENCY: Defense Logistics Agency (DLA), Department of Defense.

ACTION: Notice of availability (NOA).

SUMMARY: DLA announces the availability of an Environmental Assessment (EA) documenting the

potential environmental effects associated with the proposed action to construct and operate hazardous materials warehouses and gas cylinder sheds at Naval Station Norfolk and Naval Support Activity Norfolk Naval Shipyard, Virginia. The EA has been prepared as required under the National Environmental Policy Act (NEPA) and DLA Regulation, Environmental Considerations in Defense Logistics Agency Actions.

DATES: The public comment period will end on August 13, 2018.

ADDRESSES: You may submit comments, identified by DOD-2018-OS-0041, to one of the following:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350-1700.

FOR FURTHER INFORMATION CONTACT: Ira Silverberg at 571-767-0705 during normal business hours Monday through Friday, from 8:00 a.m. to 4:30 p.m. (EDT) or by email: ira.silverberg@dla.mil.

Dated: July 9, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018-14926 Filed 7-11-18; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD-2018-OS-0042]

Notice of Availability for an Environmental Assessment Addressing Upgrade of the Main Gate Access Control Point at Defense Distribution Depot, San Joaquin, California, and Surrounding Area

AGENCY: Defense Logistics Agency (DLA), Department of Defense.

ACTION: Notice of availability (NOA).

SUMMARY: DLA announces the availability of an Environmental Assessment (EA) documenting the potential environmental effects associated with the proposed action to upgrade the main gate access control point at Defense Distribution Depot, San Joaquin, California, and surrounding area.

DATES: The public comment period will end on August 13, 2018.

ADDRESSES: You may submit comments, identified by DOD-2018-OS-0042, to one of the following:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350-1700.

FOR FURTHER INFORMATION CONTACT: Ira Silverberg at 571-767-0705 during normal business hours Monday through Friday, from 8:00 a.m. to 4:30 p.m. (EDT) or by email: ira.silverberg@dla.mil.

SUPPLEMENTARY INFORMATION: The EA has been prepared as required under the National Environmental Policy Act (NEPA) and DLA Regulation 1000.22, Environmental Considerations in Defense Logistics Agency Actions.

The EA posted to the docket provides additional information about the proposed action.

The EA is available in hardcopy at the Tracy Branch Library, 20 East Eaton Avenue, Tracy, CA 95376.

Dated: July 9, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018-14927 Filed 7-11-18; 8:45 am]

BILLING CODE 5001-06-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-1048]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the

information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before September 10, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to PRA@fcc.gov and to Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418-2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-1048.

Title: Section 1.929(c)(1), Composite Interference Contour (CIC).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents and Responses: 50 respondents; 50 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 309(j).

Total Annual Burden: 100 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management

and Budget (OMB) for approval of an extension request.

Under 47 CFR 1.929(c)(1) of the Commission's rules, any increase in the composite interference contour (CIC) of a site-based licensee in the Paging and Radiotelephone Service, Rural Radiotelephone Service, or 800 MHz Specialized Mobile Radio Service is a major modification of a license that requires prior Commission approval.

However, in February 2005, the Commission adopted and released final rules which amended section 1.929(c)(1) to specify that expansion of a composite interference contour (CIC) of a site-based licensee in the Paging and Radiotelephone Service—as well as the Rural Radiotelephone Service and 800 MHz Specialized Mobile Radio Service—over water on a secondary, non-interference basis should be classified as a minor (rather than major) modification of a license. Such reclassification has eliminated the filing requirements associated with these license modifications, but requires site-based licensees to provide the geographic area licensee (on the same frequency) with the technical and engineering information necessary to evaluate the site-based licensee's operations over water.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018-14860 Filed 7-11-18; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0009, OMB 3060-0594, OMB 3060-0601 and OMB 3060-0609]

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the

Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before August 13, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418-2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0009.

Title: Application for Consent to Assignment of Broadcast Station Construction Permit or License or Transfer of Control of Corporation Holding Broadcast Station Construction Permit or License, FCC Form 316.

Form Number: FCC Form 316.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or tribal government.

Number of Respondents and Responses: 750 respondents, 750 responses.

Estimated Time per Response: 1.5-4.5 hours.

Frequency of Response: On occasion reporting requirement.

Obligation To Respond: Required to obtain benefits. Statutory authority for this collection of information is contained in Sections 154(i) and 310(d) of the Communications Act of 1934, as amended.

Total Annual Burden: 1,231 hours.

Total Annual Cost: \$711,150.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Confidentiality is not required with this collection of information.

Needs and Uses: FCC Form 316 is required when applying for authority for assignment of a broadcast station construction permit or license, or for consent to transfer control of a corporation holding a broadcast station construction permit or license where there is little change in the relative interest or disposition of its interests; where transfer of interest is not a controlling one; there is no substantial change in the beneficial ownership of the corporation; where the assignment is less than a controlling interest in a partnership; where there is an appointment of an entity qualified to succeed to the interest of a deceased or legally incapacitated individual permittee, licensee or controlling stockholder; and, in the case of LPFM stations, where there is a voluntary transfer of a controlling interest in the licensee or permittee entity. In addition, the applicant must notify the Commission when an approved transfer of control of a broadcast station construction permit or license has been consummated.

OMB Control Number: 3060-0594.

Title: Cost of Service Filing for Regulated Cable Services, FCC Form 1220.

Form Number: FCC Form 1220.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; State, Local, or Tribal Government.

Number of Respondents and Responses: 20 respondents; 10 responses.

Estimated Hours per Response: 4-80 hours.

Frequency of Response: On occasion and annual reporting requirements; Third party disclosure requirement.

Total Annual Burden: 1,220 hours.

Total Annual Cost: \$100,000.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 154(i) and 623 of the Communications Act of 1934, as amended.

Nature and Extent Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The Cable Television Consumer Protection and Competition Act of 1992 required the Commission to prescribe rules and regulations for

determining reasonable rates for basic tier cable service and to establish criteria for identifying unreasonable rates for cable programming services and associated equipment.

OMB Control Number: 3060–0601.

Title: Setting Maximum Initiated Permitted Rates for Regulated Cable Services, FCC Form 1200.

Form Number: FCC Form 1200.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; State, Local, or Tribal Government.

Number of Respondents and Responses: 100 respondents; 50 responses.

Estimated Hours per Response: 2–10 hours.

Frequency of Response: One time and annual reporting requirements; Third party disclosure requirement.

Total Annual Burden: 800 hours.

Total Annual Cost: \$62,500.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 623 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Cable operators and local franchise authorities file FCC Form

1200 to justify the reasonableness of rates in effect on or after May 15, 1994. The FCC uses the data to evaluate cable rates the first time they are reviewed on or after May 15, 1994, so that maximum permitted rates for regulated cable service can be determined.

OMB Control Number: 3060–0609.

Title: Section 76.934(e), Petitions for Extension of Time.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; and State, local, or tribal governments.

Number of Respondents and Responses: 20 respondents; 10 responses.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Estimated Time per Response: 4 hours.

Total Annual Burden: 80 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Obligation to Respond: Required to obtain or retain benefits. The statutory authority is contained in Sections 4(i) and 623 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The information collection requirements contained under 47 CFR 76.934(e) states that small cable systems may obtain an extension of time to establish compliance with rate regulations provided that they can demonstrate that timely compliance would result in severe economic hardship. Requests for the extension of time should be addressed to the local franchising authorities (“LFAs”) concerning rates for basic service tiers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018–14858 Filed 7–11–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Open Commission Meeting, Thursday, July 12, 2018

July 5, 2018.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, July 12, 2018 which is scheduled to commence at 10:30a.m. in Room TW–C305, at 445 12th Street SW, Washington, DC.

Item No.	Bureau	Subject
1	WIRELESS TELE-COMMUNICATIONS, INTERNATIONAL AND OFFICE OF ENGINEERING & TECHNOLOGY.	<p><i>Title:</i> Expanding Flexible Use of the 3.7 to 4.2 GHz Band (GN Docket No. 18–122); Expanding Flexible Use in Mid-Band Spectrum Between 3.7 and 24 GHz (GN Docket No. 17–183); Petition for Rulemaking to Amend and Modernize Parts 25 and 101 of the Commission’s Rules to Authorize and Facilitate the Deployment of Licensed Point-to-Multipoint Fixed Wireless Broadband Service in the 3.7–4.2 GHz Band (RM–11791); Fixed Wireless Communications Coalition, Inc., Request for Modified Coordination Procedures in Band Shared Between the Fixed Service and the Fixed Satellite Service (RM–11778)</p> <p><i>Summary:</i> The Commission will consider an Order and Notice of Proposed Rulemaking that would continue the Commission’s efforts to make mid-band spectrum in the 3.7–4.2 GHz band available for expanded flexible use, primarily by seeking comment on mechanisms for clearing for mobile use and whether to allow point-to-multipoint use on a shared basis in portions of the band. To inform the Commission’s decision-making on the future of the band, it would also collect information about FSS earth stations and space stations to provide a clear understanding of the operations of current users.</p>
2	WIRELESS TELE-COMMUNICATIONS ..	<p><i>Title:</i> Amendment of Parts 1 and 22 of the Commission’s Rules with Regard to the Cellular Service, Including Changes in Licensing of Unserved Area (WT Docket No. 12–40); Amendment of the Commission’s Rules with Regard to Relocation of Part 24 to Part 27; Interim Restrictions and Procedures for Cellular Service Applications (RM–11510); Amendment of Parts 0, 1, and 22 of the Commission’s Rules with Regard to Frequency Coordination for the Cellular Service; Amendment of Part 22 of the Commission’s Rules Regarding Certain Administrative and Filing Requirements; Amendment of the Commission’s Rules Governing Radiated Power Limits for the Cellular Service (RM–11660); Amendment of Parts 1, 22, 24, 27, 74, 80, 90, 95, and 101 to Establish Uniform License Renewal, Discontinuance of Operation, and Geographic Partitioning and Spectrum Disaggregation Rules and Policies for Certain Wireless Radio Services (WT Docket No. 10–112); 2016 Biennial Review of Telecommunications Regulations (WT Docket No. 16–138)</p> <p><i>Summary:</i>The Commission will consider a Report and Order eliminating unnecessary rules that apply to cellular service and other licensees.</p>

Item No.	Bureau	Subject
3	MEDIA	<i>Title:</i> Children’s Television Programming Rules (MB Docket No. 18–202); Modernization of Media Regulation Initiative (MB Docket No. 17–105) <i>Summary:</i> The Commission will consider a Notice of Proposed Rulemaking seeking comment on proposed revisions to the children’s television programming rules to provide broadcasters greater flexibility in meeting their children’s programming obligations.
4	PUBLIC SAFETY & HOMELAND SECURITY.	<i>Title:</i> Amendment of Part 11 of the Commission’s Rules Regarding the Emergency Alert System (PS Docket No. 15–94); Wireless Emergency Alerts (PS Docket No. 15–91) <i>Summary:</i> The Commission will consider a Report and Order and Further Notice of Proposed Rulemaking to improve emergency alerting, including facilitating more effective EAS tests and preventing false alerts.
5	WIRELINE COMPETITION	<i>Title:</i> Nationwide Number Portability (WC Docket No. 17–244); Numbering Policies for Modern Communications (WC Docket No. 13–97) <i>Summary:</i> The Commission will consider a Report and Order that forbears from legacy requirements and amends rules to facilitate the move toward complete nationwide number portability to promote competition between all service providers and increase network routing efficiencies.
6	ENFORCEMENT	<i>Title:</i> Amendment of Procedural Rules Governing Formal Complaint Proceedings Delegated to the Enforcement Bureau (EB Docket No. 17–245) <i>Summary:</i> The Commission will consider a Report and Order that consolidates and streamlines the rules governing formal complaint proceedings delegated to the Enforcement Bureau.

* * * * *

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the internet from the FCC Live web page at www.fcc.gov/live.

For a fee this meeting can be viewed live over George Mason University’s Capitol Connection. The Capitol Connection also will carry the meeting live via the internet. To purchase these services, call (703) 993–3100 or go to www.capitolconnection.gmu.edu.

Federal Communications Commission.

Marlene Dortch,
Secretary.

[FR Doc. 2018–14861 Filed 7–11–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request (OMB No. 3064–0109; 0124; and 0162)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of existing information collections, as required by the Paperwork Reduction Act of 1995. The FDIC published notices of its intent to renew the information collections described below in the **Federal Register** and requested comment for 60 days. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of these collections, and again invites comment on the renewal.

DATES: Comments must be submitted on or before August 13, 2018.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- <https://www.FDIC.gov/regulations/laws/federal>.

- *Email:* comments@fdic.gov. Include the name and number of the collection in the subject line of the message.

- *Mail:* Manny Cabeza, Counsel, Room MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Counsel, 202–898–3767, mcabeza@FDIC.gov, MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collections of information:

1. *Title:* Notice of Branch Closure.
OMB Number: 3064–0109.
Form Number: None.
Affected Public: Insured depository institutions.
Burden Estimate:

SUMMARY OF ANNUAL BURDEN

	Type of burden	Obligation to respond	Estimated number of respondents	Estimated time per response (hours)	Frequency of response	Average total annual estimated burden (hours)
Adoption of Closure Policy	Recordkeeping	Mandatory	23	8	One time	184
Notice of Closure	Disclosure	Mandatory	683	2	On occasion	1,366
Total Estimated Annual Burden	1,550

General Description of Collection:
Section 42 of the Federal Deposit Insurance Act mandates that an insured depository institution closing a branch notify its primary federal regulator not later than 90 days prior to the closing. The statute also provides that a notice be posted on the premises of the branch for the 30-day period immediately prior to the closing and that the customers be notified in a mailing at least 90 days prior to the closing. Each insured depository institution that has one or more branches is required to adopt a written policy for branch closings.

Burden Estimate Methodology and Assumptions:

There are no changes in the methodology or substance of this information collection. FDIC believes that the existing estimate of the time required to develop a written branch closure policy and to provide the

required branch closure notices is accurate. The number of branch closure notifications is closely related to the number of branches closed, while the number of closure policy adoptions equals the number newly chartered branch banking institutions and the number of existing banking institutions that transition from having no branches to having at least one branch. To derive an estimate of average annual branch closure notifications, FDIC Risk Management Supervision (RMS) staff counted the number of full-service standalone and in-store branches that closed between 2015 and 2017. In addition, FDIC staff count the number of newly chartered branch banking institutions and the number of institutions that transitioned from having no branches to having at least one branch. To derive an estimate of average annual branch closure

notifications, FDIC Risk Management Supervision (RMS) staff counted the number of full-service standalone and in-store branches that closed between 2015 and 2017. In addition, FDIC staff counted the number of newly chartered branch banking institutions and the number of institutions that transitioned from having no branches to having at least one branch. FDIC records reflect that there were 683 branch closures, on average, each year between 2015 and 2017. FDIC estimates that an average of 23 institutions each year will transition from having no branches to having at least one branch.

2. *Title:* Notification of Change of Insured Status.

OMB Number: 3064-0124.

Form Number: None.

Affected Public: Insured depository institutions.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

	Type of burden	Obligation to respond	Estimated number of respondents	Estimated time per response (hours)	Frequency of response	Average total annual estimated burden (hours)
Certification	Reporting	Mandatory	150	.25	On Occasion	37.5
Notification	Disclosure	Mandatory	2	1	On Occasion	2
Total Estimated Annual Burden	39.5

General Description of Collection:
This information collection consists of two parts: (1) A certification that insured depository institutions provide the FDIC when all deposit liabilities from one insured depository institution are assumed from another insured depository institution, with the latter institution responsible for providing the certification, and (2) a notification that an insured depository institution provides to its depositors when it seeks to voluntarily terminate its insured status. The certification is necessary to implement the provisions of section 8(q) of the Federal Deposit Insurance Act, 12 U.S.C. 1818(q), regarding termination of the insured status of the transferring institution and termination of the separate deposit insurance coverage

provided on deposit accounts assumed by the assuming institution. The depositor notification is required by section 8(a) (6) of the Federal Deposit Insurance Act, 12 U.S.C. 1818(a) (6). This provision ensures that the institution's depositors receive appropriate information regarding the institution's intent to terminate its insured status and that, prior to the termination of the institution's insured status, depositors receive appropriate information concerning federal deposit insurance coverage of their accounts once the institution's insured status is terminated.

There is no change in the methodology or substance of this information collection. The number of certifications submitted under this

information collection is closely related to the number of insured depository institutions that are acquired by another depository institution through mergers or as a result of the closing of the institution by its chartering authority. The number of depositor notifications is driven by the number of institutions that elect to voluntarily terminate its insured status without having its deposits assumed by another insured depository institution. The change in burden is due to economic fluctuation reflected in a lower number of certifications following mergers or closures and a reduction in the number of notifications due to voluntary terminations of insured status.

3. *Title:* Large Bank Deposit Insurance Program.

OMB Number: 3064–0162.
 Form Number: None.
 Affected Public: Insured depository institutions having at least \$2 billion in

deposits and at least either: (a) 250,000 Deposit accounts; or (b) \$20 billion in total assets, regardless of the number of

deposit accounts (a “covered institution”).
 Burden Estimate:

SUMMARY OF ANNUAL BURDEN

	Type of burden	Obligation to respond	Average estimated number of respondents	Estimated time per response (hours)	Frequency of response	Average total annual estimated burden (hours)
Implementation						
Posting and removing provisional holds—360.9(c)(1) and (2).	Recordkeeping	Mandatory	8	150	One time	1,200
Providing standard data format for deposit account and customer information—360.9(d)(1).	Recordkeeping	Mandatory	8	110	One time	880
Notification of identity of person responsible for producing standard data downloads—360.9(c)(3).	Reporting	Mandatory	8	8	One time	64
Request for exemption from provisional hold requirements—360.9(c)(9).	Reporting	Voluntary	1	20	On occasion	20
Provide deposit account and customer information in required standard format—360.9(d)(3).	Reporting	Mandatory	8	40	On occasion	320
Request for extension of compliance deadline—360.9(e)(7).	Reporting	Voluntary	1	20	On occasion	20
Request for exemption—360.9(f)	Reporting	Voluntary	1	20	On occasion	20
Total Implementation Burden						2,524
Ongoing						
Notification of identity of person responsible for producing standard data downloads—360.9(c)(3).	Reporting	Mandatory	153	8	On occasion	1,224
Request for exemption from provisional hold requirements—360.9(c)(9).	Reporting	Voluntary	1	20	On occasion	20
Request for exemption—360.9(f)	Reporting	Voluntary	1	20	On occasion	20
Test compliance with 360.9(c)–(d) pursuant to 360.9(h)	Reporting	Mandatory	81	80	On occasion	6,480
Total Ongoing Burden						7,744
Total Estimated Annual Burden						10,268

General Description of Collection:
 Upon the failure of an FDIC-insured depository institution, the FDIC is required to pay insured deposits as soon as possible.¹ To do so, the FDIC must be able to quickly determine the total insured amount for each depositor. To make this determination, the FDIC must ascertain the balances of all deposit accounts owned by the same depositor in the same ownership capacity at a failed institution as of the day of failure. The FDIC issued a regulation (12 CFR 360.9) to modernize the process of determining the insurance status of each depositor in the event of failure of a covered institution. The regulation requires covered institutions to adopt mechanisms that would, in the event of the institution’s failure (1) provide the FDIC with standard deposit account and other customer information, and (2) allow the placement and release of holds on liability accounts, including deposits. The regulation applies only to covered institutions and imposes the

following recordkeeping and reporting requirements:

Recordkeeping

360.9(c)(1) and (2)—*Posting and Removing Provisional Holds.* Covered institutions must have an automatic process for placing a provisional hold on deposit accounts within timeframes specified in FDIC regulations.

360.9(d)(1) and (2)—*Providing Standard Data Format for Deposit Account and Customer Information.* Covered institutions must produce information in the specified standard data format.

Reporting

360.9(c)(3)—Covered institutions must notify the FDIC of the person(s) responsible for producing required standard data downloads and for administering provisional holds.

360.9(c)(9)—A covered institution may request an exemption from the provisional hold requirements for certain account systems servicing a relatively small number of accounts where manual application of provisional holds is feasible.

360.9(d)(3)—Upon request by the FDIC, a covered institution must submit the data required by 360.9(d)(1) .

360.9(e)(7)—A covered institution may request an extension of the deadline to comply with provisional hold and standard data format requirements.

360.9(f)—A covered institution may request an exemption from the provisional hold and standard data format requirements due to high concentration of deposits incidental to credit card operations.

360.9(h)—A covered institution’s compliance with the recordkeeping and reporting requirements set forth in the rule will be tested by the FDIC.

Burden Estimate Methodology and Assumptions:

The FDIC is revising its burden estimate because the number of covered institutions has decreased due to economic fluctuations and most covered institutions have already implemented the requirements of the regulation and will only face reduced ongoing compliance burdens. Based on FDIC Call Report data,² the regulation currently applies to 145 institutions.

¹ The FDIC can meet its obligation to pay insured deposits either by payment in cash or by making available to each depositor a transferred deposit in a another insured depository institution. 12 U.S.C § 1821(f)(1).

² FDIC Call Report, September 30, 2017.

The FDIC has determined that in the past, between 1 and 3 new institutions per quarter have become covered under the regulation. FDIC estimates that on

average, 2 new institutions per quarter (8 new institutions per year) will become covered and be subject to initial implementation burden. The following

table reflects the FDCI's estimate of the breakdown of covered institutions facing implementation and ongoing burden during the next three years:

NUMBER OF INSTITUTIONS

	Year 1	Year 2	Year 3	Average
Implementation	8	8	8	8
Ongoing	145	153	161	153
Total	153	161	169	161

All covered institutions will be required to comply with the requirements of 360.9(h). FDIC estimates that half of the covered institutions will be tested for compliance each year. As a result, it is estimated that an average of 81 covered institutions will be affected by this reporting burden annually. No institutions have requested an extension under section 360.9(e)(7), or exemptions under sections 360.9(c)(9) or 360.9(f). The "Summary of Annual Burden" table above lists a respondent count of 1 for these requests as placeholders to preserve the burden estimates for these activities.

Request for Comment: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, on July 6, 2018.
Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. 2018-14864 Filed 7-11-18; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, July 17, 2018 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

Contact Person for More Information: Judith Ingram, Press Officer, Telephone: (202) 694-1220.

Laura E. Sinram,
Deputy Secretary of the Commission.

[FR Doc. 2018-15024 Filed 7-10-18; 4:15 pm]

BILLING CODE 6715-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 6, 2018.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Platte Valley Financial Service Companies, Inc., Scottsbluff, Nebraska;* to acquire 100 percent of the voting shares of The American Bank of Sidney, Sidney, Nebraska.

Board of Governors of the Federal Reserve System, July 9, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018-14931 Filed 7-11-18; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. 182 3100]

ReadyTech Corporation; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 1, 2018.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: "ReadyTech Corporation" on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/readytechconsent> by following the

instructions on the web-based form. If you prefer to file your comment on paper, write “ReadyTech; File No. 1823100” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580; or deliver your comment to: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT:

Monique Einhorn (202-326-2575), Bureau of Consumer Protection, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 2, 2018), on the World Wide Web, at <https://www.ftc.gov/news-events/commission-actions>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 1, 2018. Write “ReadyTech; File No. 1823100” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission website, at <https://www.ftc.gov/policy/public-comments>.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublishcommentworks.com/ftc/readytechconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that website.

If you prefer to file your comment on paper, write “ReadyTech; File No.

1823100” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC website at <https://www.ftc.gov>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the

requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 1, 2018. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, a consent agreement applicable to ReadyTech Corporation (“ReadyTech”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

This matter concerns alleged false or misleading representations that ReadyTech made to consumers concerning its participation in the Privacy Shield framework agreed upon by the U.S. and the European Union (“EU”). The Privacy Shield framework allows U.S. companies to transfer data outside the EU consistent with EU law. To join the EU-U.S. Privacy Shield framework, a company must self-certify to the U.S. Department of Commerce (“Commerce”) that it complies with a set of principles and related requirements that have been deemed by the European Commission as providing “adequate” privacy protection. These principles include notice; choice; accountability for onward transfer; security; data integrity and purpose limitation; access; and recourse, enforcement, and liability. Commerce maintains a public website, <https://www.privacyshield.gov/list>, where it posts the names of companies that have self-certified to the EU-U.S. Privacy Shield framework. The listing of companies indicates whether their self-certification is current. Companies are required to re-certify every year in order to retain their status as current members

of the EU-U.S. Privacy Shield framework.

ReadyTech provides online and instructor-led training. According to the Commission's complaint, ReadyTech has set forth on its website, www.readytech.com/policies/privacy-policy/, privacy policies and statements about its practices, including statements related to the status of its participation in the EU-U.S. Privacy Shield framework.

The Commission's complaint alleges that ReadyTech deceptively represented that it was actively in the process of certifying compliance with the EU-U.S. Privacy Shield framework when, in fact, ReadyTech never completed the necessary steps to finalize its application, and was not certified to participate in the EU-U.S. Privacy Shield framework.

Part I of the proposed order prohibits ReadyTech from making misrepresentations about its membership in any privacy or security program sponsored by the government or any other self-regulatory or standard-setting organization, including, but not limited to, the EU-U.S. Privacy Shield framework and the Swiss-U.S. Privacy Shield framework.

Parts II through VI of the proposed order are reporting and compliance provisions. Part II requires acknowledgement of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part III ensures notification to the FTC of changes in corporate status and mandates that ReadyTech submit an initial compliance report to the FTC. Part IV requires ReadyTech to retain documents relating to its compliance with the order for a five-year period.

Part V mandates that ReadyTech make available to the FTC information or subsequent compliance reports, as requested. Part VI is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed complaint or order or to modify the order's terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2018-14865 Filed 7-11-18; 8:45 am]

BILLING CODE 6750-01-P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0080; Docket No. 2018-0001; Sequence No. 3]

Submission for OMB Review; General Services Administration Acquisition Regulation; Contract Financing Final Payment (GSA Form 1142 Release of Claims)

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement and the reinstatement of GSA Form 1142, Release of Claims, regarding final payment under construction and building services contract. GSA Contracting Officers have used this form to achieve uniformity and consistency in the release of claims process.

DATES: Submit comments on or before: August 13, 2018.

FOR FURTHER INFORMATION CONTACT:

Leah Price, Procurement Analyst, General Services Acquisition Policy Division, GSA, by phone at 202-714-9482 or by email at leah.price@gsa.gov.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for Information Collection 3090-0080. Select the link "Comment Now" that corresponds with "Information Collection 3090-0080, Contract Financing Final Payment; GSA Form 1142, Release of Claims". Follow the instructions on the screen. Please include your name, company name (if any), and "Information Collection 3090-0080, Contract Financing Final Payment; GSA Form 1142, Release of Claims" on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms.

Mandell/IC 3090-0080, Contract Financing Final Payment; GSA Form 1142, Release of Claims.

Instructions: Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two-to-three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration Acquisition Regulation (GSAR) clause 552.232-72 requires construction and building services contractors to submit a release of claims before final payment is made to ensure contractors are paid in accordance with their contract requirements and for work performed. GSA Form 1142, Release of Claims is used to achieve uniformity and consistency in the release of claims process.

B. Annual Reporting Burden

Respondents: 7,500.

Responses per Respondent: 1.

Annual Responses: 7,500.

Hours per Response: .10.

Total Burden Hours: 750.

C. Public Comments

A notice published in the **Federal Register** at 83 FR 13280 on March 28, 2018. No comments were received. Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 3090-0080, Contract Financing Final Payment; GSA Form 1142, Release of Claims, in all correspondence.

Dated: July 2, 2018.

Jeffrey A. Koses,

Director, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2018-14885 Filed 7-11-18; 8:45 am]

BILLING CODE 6820-61-P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0205; Docket No. 2018–0001; Sequence No. 12]

General Services Administration Acquisition Regulation (GSAR); Information Collection; Environmental Conservation, Occupational Safety, and Drug-Free Workplace

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding the extension of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding Environmental Conservation, Occupational Safety, and Drug-Free Workplace.

DATES: Submit comments on or before: September 10, 2018.

ADDRESSES: Submit comments identified by Information Collection 3090–0205 by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link “Comment Now” that corresponds with “Information Collection 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace”. Follow the instructions provided on the screen. Please include your name, company name (if any), and “Information Collection 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace” on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace.

Instructions: Please submit comments only and cite Information Collection 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace, in all correspondence related to this collection. Comments received generally will be posted without change to *regulations.gov*, including any personal and/or business confidential information provided. To confirm

receipt of your comment(s), please check *regulations.gov*, approximately two-to-three business days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Johnnie McDowell, Procurement Analyst, General Services Acquisition Policy Division, GSA, at telephone 202–718–6112, or via email to johnnie.mcdowell@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The Federal Hazardous Substance Act and Hazardous Material Transportation Act prescribe standards for packaging of hazardous substances. To meet the requirements of the Acts, the General Services Administration Regulation prescribes provision 552.223–72, Hazardous Material Information, to be inserted in solicitations and contracts that provides for delivery of hazardous materials on a Free On Board (FOB) origin basis.

This information collection will be accomplished by means of the provision which requires the contractor to identify for each National Stock Number (NSN), the DOT Shipping Name, Department of Transportation (DOT) Hazards Class, and whether the item requires a DOT label. Contracting Officers and technical personnel use the information to monitor and ensure contract requirements based on law and regulation.

Properly identified and labeled items of hazardous material allows for appropriate handling of such items throughout GSA’s supply chain system. The information is used by GSA, stored in an NSN database and provided to GSA customers. Non-Collection and/or a less frequently conducted collection of the information resulting from GSAR provision 552.223–72 would prevent the Government from being properly notified. Government activities may be hindered from apprising their employees of; (1) All hazards to which they may be exposed; (2) Relative symptoms and appropriate emergency treatment; and (3) Proper conditions and precautions for safe use and exposure.

B. Annual Reporting Burden

Respondents: 563.
Responses per Respondent: 3.
Total Responses: 1689.
Hours per Response: .67.
Total Burden Hours: 1111.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will

have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division, 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0205, Environmental Conservation, Occupational Safety, and Drug-Free Workplace, in all correspondence.

Dated: July 9, 2018.

Jeffrey Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2018–14937 Filed 7–11–18; 8:45 am]

BILLING CODE 6820–61–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0287; Docket No. 2018–0001; Sequence No. 10]

Information Collection; Background Investigations for Child Care Workers

AGENCY: Office of Mission Assurance, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an existing OMB information collection.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a previously approved information collection requirement regarding the collection of personal data for background investigations for child care workers accessing GSA owned and leased controlled facilities

DATES: Submit comments on or before: September 10, 2018.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503.

Additionally, submit a copy to GSA by any of the following methods:

- *Regulations.gov*: <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link “Submit a Comment” that corresponds with “Information Collection 3090–0287, Background Investigations for Child Care Workers”. Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “Information Collection 3090–0287, Background Investigations for Child Care Workers” on your attached document.

- *Mail*: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 3090–0287, Background Investigations for Child Care Workers.

Instructions: Please submit comments only and cite Information Collection 3090–0287, Background Investigations for Child Care Workers, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Phil Ahn, Security Officer, Office of Mission Assurance, GSA, by telephone at XXX–XXX–XXXX or email phillip.ahn@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

Homeland Security Presidential Directive (HSPD) 12 “Policy for a Common Identification Standard for Federal Employees and Contractors” requires the implementation of a governmentwide standard for secure and reliable forms of identification for Federal employees and contractors. OMB’s implementing instructions requires all contract employees requiring routine access to federally controlled facilities for greater than six (6) months to receive a background investigation. The minimum background investigation is Tier 1 and the Office of Personnel Management offers a Tier 1C for child care.

However, there is no requirement in the law or HSPD–12 that requires child care employees to be subject to the Tier 1C since employees of child care

providers are neither government employees nor government contractors. The child care providers are required to complete the criminal history background checks mandated in the Crime Control Act of 1990, Public Law 101–647, dated November 29, 1990, as amended by Public Law 102–190, dated December 5, 1991. These statutes require that each employee of a child care center located in a Federal building or in leased space must undergo a background check.

According to GSA policy, child care workers (as described above) will need to submit the following:

1. An original signed copy of a *Basic National Agency Check Criminal History*, GSA Form 176; and
2. Two sets of fingerprints on FBI Fingerprint Cards, for SF–87 and/or electronic prints from an enrollment center.
3. Electronically submit the e-qip (SF85) application for completion of the Tier 1C.

This is not a request to collect new information; this is a request to change the form that is currently being used to collect this information.

B. Annual Reporting Burden

Respondents: 1,200.

Responses per Respondent: 1.

Hours per Response: 1.

Total Burden Hours: 1,200.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite Background Investigations for Child Care Workers, in all correspondence.

Dated: July 2, 2018.

David A. Shive,
Chief Information Officer.

[FR Doc. 2018–14882 Filed 7–11–18; 8:45 am]

BILLING CODE 6820–23–P

**GENERAL SERVICES
ADMINISTRATION**

[OMB Control No. 3090–0007; Docket No. 2018–0001; Sequence No. 1]

Submission for OMB Review; General Services Administration Acquisition Regulation; Contractor’s Qualifications and Financial Information (GSA Form 527)

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding Contractor’s Qualifications and Financial Information (GSA Form 527).

DATES: Submit comments on or before: August 13, 2018.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC, 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov*: <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal searching Information Collection 3090–0007. Select the link “Comment Now” that corresponds with “Information Collection 3090–0007, Contractor’s Qualifications and Financial Information”. Follow the instructions provided on the screen. Please include your name, company name (if any), and “Information Collection 3090–0007, Contractor’s Qualifications and Financial Information” on your attached document.

- *Mail*: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 3090–0007, Contractor’s Qualifications and Financial Information.

Instructions: Please submit comments only and cite Information Collection 3090–0007, Contractor’s Qualifications and Financial Information, in all correspondence related to this collection. Comments received generally will be posted without change to

regulations.gov, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *regulations.gov*, approximately two-to-three business days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Johnnie McDowell, Policy Analyst, Office of Governmentwide Policy, at 202-718-6112, or via email at johnnie.mcdowell@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration will be requesting that OMB extend information collection 3090-0007, concerning GSA Form 527, Contractor's Qualifications and Financial Information. This form is used to determine the financial capability of prospective contractors as to whether they meet the financial responsibility standards in accordance with the Federal Acquisition Regulation (FAR) 9.103(a) and 9.104-1 and also the General Services Administration Acquisition Manual (GSAM) 509.105-1(a).

B. Annual Reporting Burden

Respondents: 2,542.

Responses per Respondent: 1.2.

Total Responses: 3,050.

Hours per Response: 1.5.

Total Burden Hours: 4,575.

The estimated annual burden has decreased since GSA's 2014 submission from 5,292 to 4,575 burden hours to reflect the continued use of the widespread option for potential contractors to submit financial statements and balance sheets in lieu of completing the applicable fields on GSA Form 527. The alternate submission of financial statements and balance sheets significantly reduces the burden on prospective contractors, as these documents are generally readily available. The average estimated hours to complete a response remained at the optimal rate of 1.5 hours.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected. A request for public comments was issued in the **Federal Register** at 83 FR 7184, on

February 20, 2018. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202-501-4755.

Please cite OMB Control No. 3090-0007, Contractor's Qualifications and Financial Information (GSA Form 527), in all correspondence.

Dated: July 2, 2018.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2018-14879 Filed 7-11-18; 8:45 am]

BILLING CODE 6820-61-P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-XXXX; Docket No. 2018-0001; Sequence No. 17]

Information Collection; CDP Supply Chain Climate Change Information Request

AGENCY: Office of Government-Wide Policy (OGP), General Services Administration.

ACTION: Notice of request for comments regarding a new request for an Office of Management and Budget (OMB) clearance.

SUMMARY: The Office of Governmentwide Policy, General Services Administration (GSA) will submit a request to the Office of Management and Budget (OMB) for review and clearance for the CDP Supply Chain Climate Change Information Request. As required by the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before September 10, 2018.

ADDRESSES: Submit comments identified by Information Collection 3090-XXXX; CDP Supply Chain Climate Change Information Request, by any of the following methods:

ADDRESSES: Submit comments on this collection by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for "Information Collection 3090-XXXX; CDP Supply Chain Climate Change Information Request." Select the link "Submit a Comment" that corresponds with "Information Collection 3090-XXXX; CDP Supply Chain Climate Change Information

Request." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 3090-XXXX; CDP Supply Chain Climate Change Information Request" on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 3090-XXXX; CDP Supply Chain Climate Change Information Request.

Instructions: Please submit comments only and cite Information Collection 3090-XXXX; CDP Supply Chain Climate Change Information Request, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

SUPPLEMENTARY INFORMATION:

A. Purpose

The CDP Supply Chain Climate Change Information Request is an electronic questionnaire designed to collect information pertinent to organizations' exposure to energy market and environmental risks. The questionnaire is administered by CDP North America, Inc., a 501(c)(3) nonprofit organization ("CDP"). CDP administers the questionnaire annually to companies on behalf of over 650 institutional investors and over 100 major purchasing corporations and governmental purchasing organizations. In accordance with 31 U.S. Code § 3512(c)(1)(b), GSA will use the information collected via this questionnaire to inform and develop purchasing policies and contract requirements necessary to safeguard Federal assets against waste, loss, and misappropriation resulting from unmitigated exposure to energy market and environmental risks.

B. Annual Burden Hours

Frequency: Annual.

Affected Public: Federal contractors.

Number of Respondents: 250.

Responses per Respondent: 1.

Total Annual Responses: 250.

Estimated Time per Respondent: 4.8 hrs.

Total Burden Hours: 1,210.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Dated: July 2, 2018.

David A. Shive,

Chief Information Officer.

[FR Doc. 2018-14884 Filed 7-11-18; 8:45 am]

BILLING CODE 6820-61-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC, announces the following meeting of the Advisory Board on Radiation and Worker Health (ABRWH). This meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 150 people and the audio conference line has 150 ports for callers. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference (information below).

DATES: The meeting will be held on August 22, 2018 from 8:30 a.m. to 5:00 p.m., EDT, and August 23, 2018, 8:30 a.m. to 12:00 p.m., EDT. A public comment session will be held on August 22, 2018 at 5:00 p.m. and conclude at 6:00 p.m. or following the final call for public comment, whichever comes first.

ADDRESSES: Hilton Providence, 21 Atwells Avenue, Providence, RI 02903; Phone: (401)–831–3900, Fax: (401)–274–1562 and audio conference call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701. Web conference by Skype: meeting CONNECTION: <https://webconf.cdc.gov/zab6/yzdq02pl?sl=1>.

FOR FURTHER INFORMATION CONTACT:

Theodore Katz, MPA, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email ocas@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered under Executive Order 13811 on February 12, 2018, and will terminate on September 30, 2019.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such

radiation doses may have endangered the health of members of this class.

Matters to be Considered: The agenda will include discussions on the following: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; SEC Petitions Update; possible discussion of a site profile review (dose reconstruction methods for Feed Materials Production Center (Fernald, Ohio); SEC Petitions for: Sandia National Laboratory (Albuquerque, New Mexico), Metals and Controls Corporation (Attleboro, Massachusetts, Idaho National Laboratory (Scoville, Idaho), and DeSoto Facility (Los Angeles, California); continued review of dose reconstruction methods associated with estimating skin doses; and a Board Work Session. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018-14929 Filed 7-11-18; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Healthcare Infection Control Practices Advisory Committee (HICPAC). This meeting is open to the public, limited only by audio phone lines available. The public is also welcome to listen to the meeting by dialing 888-790-3409, passcode: 3250534. A total of 200 lines will be available. To register for this call, please go to www.cdc.gov/hicpac.

DATES: The meeting will be held on August 29, 2018, 3:00 p.m. to 5:00 p.m., EDT.

ADDRESSES: Teleconference Number: 1–888–790–3409, passcode: 3250534.

FOR FURTHER INFORMATION CONTACT: Erin Stone, M.A., HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, 1600 Clifton Road NE, Mailstop A–31, Atlanta, Georgia 30333; Telephone (404) 639–4045, Email: HICPAC@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The Committee is charged with providing advice and guidance to the Director, Division of Healthcare Quality Promotion (DHQP), the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the Director, CDC, the Secretary, Health and Human Services regarding (1) the practice of healthcare infection prevention and control; (2) strategies for surveillance, prevention, and control of infections, antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of CDC guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters to be Considered: The agenda will include discussions on updates from the guidelines for infection prevention in healthcare personnel workgroup and the guidelines for infection prevention in patients of neonatal intensive care units workgroup. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018–14930 Filed 7–11–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval Washington Medicaid State Plan Amendment (SPA) 17–0027

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing; Reconsideration of disapproval.

SUMMARY: This notice announces an administrative hearing to be held on August 9, 2018, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid & Children’s Health, Seattle Regional Office, 701 Fifth Avenue, Suite 1600, Seattle, WA 98104 to reconsider CMS’ decision to disapprove Washington’s Medicaid SPA 17–0027.

DATES: *Closing Date:* Requests to participate in the hearing as a party must be received by the presiding officer by July 27, 2018.

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244, Telephone: (410) 786–3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS’ decision to disapprove Washington’s Medicaid state plan amendment (SPA) 17–0027, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on August 22, 2017 and disapproved on May 14, 2018. This SPA requested CMS approval to add coverage and reimbursement of services provided by Dental Health Aide Therapists (DHATs) under the Other Licensed Practitioner (OLP) benefit. Specifically, SPA 17–0027 proposed the coverage and reimbursement of services provided by DHATs only when furnished in a practice setting within the boundaries of a tribal reservation and only when operated by an Indian health program, and proposed to make coverage of DHAT services available only to members of a federally recognized tribe or those otherwise eligible for services under Indian Health Service criteria. Washington would, therefore, not permit Medicaid beneficiaries to receive Medicaid coverage for DHAT services if they are not members of a federally recognized tribe or otherwise eligible for services under Indian Health Service criteria.

The issues to be considered at the hearing are whether Washington SPA 17–0027 is inconsistent with the requirements of:

- Section 1902(a)(23) of the Social Security Act (the Act) because it would restrict access to services provided by a DHAT to a limited group of beneficiaries, and it would also prevent beneficiaries from receiving DHAT services from similarly qualified dental services providers that provide services outside the boundaries of a tribal reservation or that are not Indian health programs.
- Section 1902(a)(10)(A) of the Act because it was unclear whether DHATs

must be supervised by a licensed professional consistent with the requirements of the OLP benefit, and because CMS was therefore unable to determine whether DHAT services are “medical assistance” consistent with 1902(a)(10)(A) and 1905 of the Act.

Section 1116 of the Act and federal regulations at 42 CFR part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. CMS is required to publish in the **Federal Register** a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the state Medicaid agency of additional issues that will be considered at the hearing, we will also publish that notice in the **Federal Register**.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Washington announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. MaryAnne Lindeblad
Director
State of Washington, Health Care Authority
626 8th Avenue PO Box 45502
Olympia, WA 98504–5050

Dear Ms. Lindeblad:

I am responding to your June 8, 2018 request for reconsideration of the decision to disapprove Washington’s State Plan amendment (SPA) 17–0027. Washington SPA 17–0027 was submitted to the Centers for Medicare & Medicaid Services (CMS) on August 22, 2017, and disapproved on May 14, 2018. I am scheduling a hearing on your request for reconsideration to be held on August 9, 2018, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid & Children’s Health, Seattle Regional Office, 701 Fifth Avenue, Suite 1600, Seattle, WA 98104.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786–3169. In order to facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to

indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR Part 430.

This SPA requested CMS approval to add coverage and reimbursement of services provided by Dental Health Aide Therapists (DHATs) under the Other Licensed Practitioner (OLP) benefit. Specifically, SPA 17-0027 proposed the coverage and reimbursement of services provided by DHATs only when furnished in a practice setting within the boundaries of a tribal reservation and only when operated by an Indian health program, and proposed to make coverage of DHAT services available only to members of a federally recognized tribe or those otherwise eligible for services under Indian Health Service criteria. Washington would, therefore, not permit Medicaid beneficiaries to receive Medicaid coverage for DHAT services if they are not members of a federally recognized tribe or otherwise eligible for services under Indian Health Service criteria.

The issues to be considered at the hearing are whether Washington SPA 17-0027 is inconsistent with the requirements of:

- Section 1902(a)(23) of the Social Security Act (the Act) because it would restrict access to services provided by a DHAT to a limited group of beneficiaries, and it would also prevent beneficiaries from receiving DHAT services from similarly qualified dental services providers that provide services outside the boundaries of a tribal reservation or that are not Indian health programs.

- Section 1902(a)(10)(A) of the Act because it was unclear whether DHATs must be supervised by a licensed professional consistent with the requirements of the OLP benefit, and because CMS was therefore unable to determine whether DHAT services are “medical assistance” consistent with 1902(a)(10)(A) and 1905 of the Act.

In the event that CMS and the State come to agreement on resolution of the issues which formed the basis for disapproval, this SPA may be moved to approval prior to the scheduled hearing.

Sincerely,

Seema Verma

Administrator

Section 1116 of the Social Security Act (42 U.S.C. section 1316; 42 CFR section 430.18) (Catalog of Federal Domestic Assistance program No. 13.714. Medicaid Assistance Program.)

Dated: July 6, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018-14876 Filed 7-6-18; 4:15 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2642]

Advisory Committee; Science Advisory Board to the National Center for Toxicological Research; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Science Advisory Board (the Board) to the National Center for Toxicological Research (NCTR) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Board to the NCTR for an additional 2 years beyond the charter expiration date. The new charter will be in effect until June 2, 2020.

DATES: Authority for the Board to the NCTR expired on June 2, 2018; however, the Commissioner formally determined that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Donna L. Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993-0002, 301-796-8892, donna.mendrick@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Board to the NCTR. The Board is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Board to the NCTR advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility. The Board advises the NCTR Director in establishing, implementing, and evaluating the research programs that assist the Commissioner in fulfilling regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

The Board shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or

designee from among authorities knowledgeable in the fields of toxicological research. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this Board serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ToxicologicalResearch/ucm148166.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: July 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14943 Filed 7-11-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2565]

Advisory Committee; Psychopharmacologic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Psychopharmacologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Psychopharmacologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until June 4, 2020.

DATES: Authority for the Psychopharmacologic Drugs Advisory Committee will expire on June 4, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, email: PDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Psychopharmacologic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugs>

[AdvisoryCommittee/default.htm](https://www.fda.gov/AdvisoryCommittees/default.htm) or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: July 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14934 Filed 7-11-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2236]

Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry.” The draft guidance provides recommendations to stakeholders developing human gene therapy (GT) products for retinal disorders affecting adult and pediatric patients. The draft guidance focuses on issues specific to GT products for retinal disorders and provides recommendations related to product development, preclinical testing, and clinical trial design for such GT products.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for Written/Paper Submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-D-2236 for “Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Angela Moy, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry.” The draft guidance provides recommendations to stakeholders developing GT products for retinal disorders affecting adult and pediatric patients. These disorders vary in etiology, prevalence, diagnosis, and

management, and include genetic as well as age-related diseases. These disorders manifest with central or peripheral visual impairment and often with progressive visual loss. The draft guidance focuses on issues specific to GT products for retinal disorders and provides recommendations related to product development, preclinical testing, and clinical trial design for such GT products.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two other human gene therapy draft guidance documents entitled “Human Gene Therapy for Hemophilia; Draft Guidance for Industry” and “Human Gene Therapy for Rare Diseases; Draft Guidance for Industry.”

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Human Gene Therapy for Retinal Disorders.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0755; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910-0119; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910-0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; the collections of information in the guidance entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” have been approved under OMB control number 0910-0765; and the collections of information in the guidance entitled “Formal Meetings Between the FDA and Sponsors or Applicants” have been approved under OMB control number 0910-0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14870 Filed 7-11-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2258]

Human Gene Therapy for Rare Diseases; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Human Gene Therapy for Rare Diseases; Draft Guidance for Industry.” The draft guidance document provides recommendations to stakeholders developing a human gene therapy (GT) product intended to treat a rare disease in adult and/or pediatric patients regarding the manufacturing, preclinical, and clinical trial design issues for all phases of the clinical development program. Such information is intended to assist sponsors in designing clinical development programs for such products, where there may be limited study population size and potential feasibility and safety issues as well as issues relating to the interpretability of bioactivity/efficacy outcomes that may be unique to rare diseases or to the nature of the GT product itself.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

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- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

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- *Mail/Hand Delivery/Courier (for Written/Paper Submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-2258 for "Human Gene Therapy for Rare Diseases; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies, total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments, and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

The Orphan Drug Act of 1983 (Pub. L. 97-414) defines a rare disease as a disease or condition that affects fewer than 200,000 persons in the United States. Since most rare diseases have no approved therapies, there is a significant unmet need for effective treatments.

However, developing safe and effective products to treat rare diseases can be challenging. For example, it may be more difficult to find and recruit such patients into clinical trials, and many rare diseases exhibit a number of variations or subtypes. Consequently, patients may have highly diverse clinical manifestations and rates of disease progression with unpredictable clinical courses. Despite these challenges, GT-related research and development continue to grow at a rapid rate, with several products advancing in clinical development.

FDA is announcing the availability of a document entitled "Human Gene Therapy for Rare Diseases; Draft Guidance for Industry." The draft guidance provides recommendations to stakeholders developing a GT product intended to treat a rare disease in adult and/or pediatric patients regarding the manufacturing, preclinical, and clinical trial design issues for all phases of the clinical development program. Such information is intended to assist sponsors in designing clinical development programs for such products, where there may be limited study population size and potential feasibility and safety issues as well as issues relating to the interpretability of bioactivity/efficacy outcomes that may be unique to rare diseases or to the nature of the GT product itself.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two other human gene therapy draft guidance documents entitled "Human Gene Therapy for Hemophilia; Draft Guidance for Industry" and "Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry."

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Human Gene Therapy for Rare Diseases." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0755; the

collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in the guidance entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” have been approved under OMB control number 0910–0765; and the collections of information in the guidance entitled “Formal Meetings Between the FDA and Sponsors or Applicants” have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 5, 2018.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2018–14871 Filed 7–11–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2180]

**Concordia Pharmaceuticals, Inc., et al.;
 Withdrawal of Approval of 29 New
 Drug Applications**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 29 new drug applications (NDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no

longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 13, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 011287	Kayexalate (sodium polystyrene sulfonate) Powder for Suspension, 453.6 gram (g)/bottle.	Concordia Pharmaceuticals, Inc., c/o Mapi USA, Inc., 2343 Alexandria Dr., Lexington, KY 40504.
NDA 012249	Librium (chlordiazepoxide hydrochloride (HCl)) Capsules, 5 milligram (mg), 10 mg, and 25 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 016211	Miochol (acetylcholine chloride) for Ophthalmic Solution, 20 mg/vial	Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936.
NDA 018674	Metro I.V. (metronidazole) Injection, 500 mg/100 milliliter (mL)	B. Braun Medical, Inc., 901 Marcon Blvd., Allentown, PA 18109.
NDA 018852	Sulfamethoxazole and Trimethoprim Tablets USP, 400 mg; 80 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 018854	Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg; 160 mg	Do.
NDA 018988	Vasocidin (prednisolone sodium phosphate and sulfacetamide sodium) Ophthalmic Solution, equivalent to (EQ) 0.23% phosphate/10%.	Novartis Pharmaceuticals Corp.
NDA 019844	Isolyte H in Dextrose 5% in Plastic Container Injection	B. Braun Medical, Inc.
NDA 019870	Isolyte M in Dextrose 5% in Plastic Container Injection	Do.
NDA 019964	Terazol 3 (terconazole) Vaginal Cream, 0.8%	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 020000	Dextrose 5% in Ringer's in Plastic Container Injection	B. Braun Medical, Inc.
NDA 020393	Atrovent (ipratropium bromide) Nasal Spray, 0.021 mg/spray	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368.
NDA 020394	Atrovent (ipratropium bromide) Nasal Spray, 0.042 mg/spray	Do.
NDA 021180	Ortho Evra (ethinyl estradiol; norelgestromin) Transdermal Patch, 0.035 mg/24 h; 0.15 mg/24 h.	Janssen Pharmaceuticals, Inc., 1000 U.S. Route 202, P.O. Box 300, Raritan, NJ 08869–0602.
NDA 021633	Femtrace (estradiol acetate) Tablets, 0.45 mg, 0.9 mg, and 1.8 mg	Allergan Pharmaceuticals International, Ltd., c/o Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612.
NDA 022033	Luvox CR (fluvoxamine maleate) Extended-Release Capsules, 100 mg and 150 mg.	Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304.
NDA 022106	Doribax (doripenem) for Injection, 250 mg/vial and 500 mg/vial	Shionogi, Inc., 300 Campus Dr., Florham Park, NJ 07932.
NDA 022386	PrandiMet (metformin HCl; repaglinide) Tablets, 500mg; 1 mg and 500 mg; 2 mg.	Novo Nordisk, Inc., P.O. Box 846, Plainsboro, NJ 08536.
NDA 050201	Ophthocort (chloramphenicol, hydrocortisone acetate, polymyxin B sulfate) Ophthalmic Ointment USP, 10 mg/g; 5 mg/g; 10,000 units/g.	Parkedale Pharmaceuticals, Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 050344	Statrol (neomycin sulfate; polymyxin B sulfate) Ophthalmic Ointment, EQ 3.5 mg base/g; 10,000 units/g.	Alcon Laboratories, Inc., 6201 South Freeway, TC–45, Fort Worth, TX 76134.
NDA 050442	Vibramycin (doxycycline hyclate) Injection, EQ to 200 mg base/vial and EQ 100 mg base/vial.	Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
NDA 050497	Ticar (ticarcillin disodium) Injection, EQ 1 g base/vial, EQ 3 g base/vial, EQ 6 g base/vial, EQ 20 g base/vial, and EQ 30 g base/vial.	GlaxoSmithKline, 1250 Collegeville Rd., Collegeville, PA 19426.
NDA 050512	Duricef (cefadroxil monohydrate) USP Capsules, EQ 500 mg base and EQ 250 mg base.	Warner Chilcott Co., LLC, 100 Enterprise Dr., Rockaway, NJ 07866.
NDA 050527	Duricef (cefadroxil monohydrate) USP For Oral Suspension, EQ 125 mg base/5 mL, EQ 250 mg base/5 mL, and EQ 500 mg base/5 mL.	Do.
NDA 050593	Eryc Sprinkles (erythromycin) Capsules, 125 mg	Hospira Inc., 275 North Field Dr., Lake Forest, IL 60045.
NDA 050646	Ceptaz (ceftazidime) Injection, 500 mg/vial, 1 g/vial, 2 g/vial, and 10 g/vial.	GlaxoSmithKline.
NDA 050668	Lorabid (loracarbef) Capsules USP, 200 mg and 400 mg	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
NDA 050792	Cefotaxime and Dextrose 2.4% in Plastic Container, EQ 2 g base, and Cefotaxime and Dextrose 3.9% in Plastic Container, EQ 1 g base.	B. Braun Medical, Inc.

Application No.	Drug	Applicant
NDA 050807	Epirubicin HCl for Injection, 50 mg/vial, 200 mg/vial	Hospira, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 13, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on August 13, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14935 Filed 7-11-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2018-D-2238]

Human Gene Therapy for Hemophilia; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Human Gene Therapy for Hemophilia; Draft Guidance for Industry.” The draft guidance document provides recommendations to stakeholders developing human gene therapy (GT) products for the treatment of hemophilia. The draft guidance provides recommendations on the clinical trial design and related development of coagulation factor VIII (hemophilia A) and IX (hemophilia B) activity assays, including how to address discrepancies in factor VIII and factor IX activity assays. The draft guidance also includes recommendations regarding preclinical considerations to support development of GT products for the treatment of hemophilia.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2018 to ensure that the

Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA 2018-D-2238 for “Human Gene Therapy for Hemophilia; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9

a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies, total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments, and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-

800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Jessica Walker Udechukwu, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Human Gene Therapy for Hemophilia; Draft Guidance for Industry.” The draft guidance document provides recommendations to stakeholders developing GT products for the treatment of hemophilia. The draft guidance provides recommendations on the clinical trial design and related development of coagulation factor VIII (hemophilia A) and IX (hemophilia B) activity assays, including how to address discrepancies in factor VIII and factor IX activity assays. The draft guidance also includes recommendations regarding preclinical considerations to support development of GT products for the treatment of hemophilia. Hemophilia therapy in the United States has progressed from replacement therapies for on-demand treatment of bleeding to prophylaxis to reduce the frequency of bleeding. GT products for hemophilia are being developed as single-dose treatments that may provide long-term expression of the missing or abnormal coagulation factor in the patient at steady levels to reduce or eliminate the need for exogenous factor replacement.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two other human gene therapy draft guidance documents entitled “Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry” and “Human Gene Therapy for Rare Diseases; Draft Guidance for Industry.”

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Human Gene Therapy for Hemophilia.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in the guidance entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” have been approved under OMB control number 0910–0765; and the collections of information in the guidance entitled “Formal Meetings Between the FDA and Sponsors or Applicants” have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 5, 2018.

Leslie Kux.

Associate Commissioner for Policy.

[FR Doc. 2018–14875 Filed 7–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0205]

Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug

Applications (INDs); Draft Guidance for Industry.” The draft guidance document provides sponsors of a human gene therapy IND with recommendations regarding CMC information required to assure product safety, identity, quality, purity, and strength (including potency) of the investigational product. The draft guidance applies to human gene therapy products and to combination products that contain a human gene therapy in combination with a drug or device.

The draft guidance, when finalized, is intended to supersede the document entitled “Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs),” dated April 2008 (April 2008 guidance).

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Since your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for Written/Paper Submissions):* Dockets Management Staff (HFA–305), Food and

Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment as well as any attachments, except for information submitted, marked, and identified as confidential if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2008–D–0205 for “Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies, total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments, and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://>

www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gretchen Opper, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Draft Guidance for Industry.” The draft guidance provides sponsors of a human gene therapy IND with recommendations regarding CMC information required to assure product safety, identity, quality, purity, and strength (including potency) of the investigational product (21 CFR 312.23(a)(7)(i)). The draft guidance applies to human gene therapy products and to combination products that contain a human gene therapy in combination with a drug or device. The field of gene therapy has progressed rapidly since FDA issued the April 2008 guidance. Therefore, FDA is updating the guidance to provide current FDA recommendations regarding the CMC content of a gene therapy IND. In addition, the draft guidance is organized to follow the structure of the FDA guidance on the Common Technical Document.

The draft guidance, when finalized, is intended to supersede the April 2008 guidance. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two other draft guidances. In a separate document, FDA is announcing the availability of a draft document entitled “Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry” and the availability of a draft document entitled “Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry.”

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on CMC information for human gene therapy INDs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 and Form FDA 1571 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14866 Filed 7–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-1999-D-0081]

Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry; Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry.” The draft guidance document provides sponsors of retroviral vector-based human gene therapy products recommendations regarding the testing for replication competent retrovirus (RCR) during the manufacture of retroviral vector-based products, and during follow-up monitoring of patients who have received retroviral vector-based products. Recommendations include the identification and amount of material to be tested, and general testing methods. In addition, recommendations are provided on monitoring patients for evidence of retroviral infection after administration of retroviral vector-based gene therapy products. The draft guidance, when finalized, is intended to supersede the document entitled “Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors,” dated November 2006. The draft guidance, when finalized, is also intended to supplement the documents entitled “Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry” and “Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Draft Guidance for Industry,” when these draft guidance documents are finalized.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for Written/Paper Submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-1999-D-0081 for “Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your

comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301,

Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry." The draft guidance document provides sponsors of retroviral vector-based human gene therapy products recommendations regarding the testing for RCR during the manufacture of retroviral vector-based products, and during follow-up monitoring of patients who have received retroviral vector-based products. Recommendations are also provided for RCR testing during manufacture, including identification and amount of material to be tested, and general testing methods. In addition, recommendations are provided on monitoring patients for evidence of retroviral infection after administration of retroviral vector-based gene therapy products. The draft guidance, when finalized, is intended to supersede the document entitled "Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors," dated November 2006. The draft guidance, when finalized, is also intended to supplement the "Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry" and "Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Draft Guidance for Industry," when these draft guidance documents are finalized. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of these other two draft guidance documents.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on testing of retroviral vector-based human gene therapy products for replication competent retrovirus during product manufacture and patient follow-up. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and

regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14868 Filed 7-11-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2475]

Advisory Committee; Allergenic Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Allergenic Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Allergenic Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until July 9, 2020.

DATES: Authority for the Allergenic Products Advisory Committee expired on July 9, 2018; however, the Commissioner formally determined that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Division of

Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993-0002; 240-402-5771, serina.hunter-thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Allergenic Products Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease, and makes appropriate recommendations to the Commissioner of its findings regarding the affirmation or revocation of biological product licenses; on the safety, effectiveness, and labeling of the products; on clinical and laboratory studies of such products; on amendments or revisions to regulations governing the manufacture, testing, and licensing of allergenic biological products; and on the quality and relevance of FDA's research programs that provide the scientific support for regulating these agents.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of allergy, immunology, pediatrics, internal medicine, biochemistry, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include

one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/AllergenicProductsAdvisoryCommittee/ucm129360.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: July 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14942 Filed 7-11-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2173]

Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry.” The draft guidance provides sponsors, who are developing a human gene therapy (GT) product, recommendations regarding the design of long term follow-up (LTFU) observational studies for the collection of data on delayed adverse events following administration of a GT product. The draft guidance, when finalized, is intended to supersede the document entitled “Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events” dated November 2006. This draft guidance, when finalized, is also intended to supplement the guidance entitled “Testing of Retroviral Vector-Based

Human Gene Therapy Products for Replication Competent Retrovirus during Product Manufacture and Patient Follow-up; Draft Guidance for Industry.”

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for Written/Paper Submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-D-2173 for “Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for

those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See

the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry.” The draft guidance provides a brief introduction of the product characteristics, patient-related factors, and the preclinical and clinical data that should be considered when assessing the need for LTFU observations for your GT product. The draft guidance also describes the Agency’s current recommendations for the conduct of LTFU studies, specifically the information/data to support a sponsor’s rationale for the duration and design of a LTFU protocol when clinical trials are initiated. Also included in the draft guidance are GT product-specific clinical considerations for monitoring subjects under a LTFU protocol and recommendations on patient monitoring for licensed GT products. The draft guidance, when finalized, is intended to supersede the guidance entitled “Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events” dated November 2006. The draft guidance, when finalized, is also intended to supplement the guidance entitled “Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus during Product Manufacture and Patient Follow-up; Draft Guidance for Industry,” published elsewhere in this issue of the **Federal Register**. Also, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another draft guidance entitled “Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Draft Guidance for Industry.”

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on long term follow-up after administration of human gene therapy products. It does not establish any rights

for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0755; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; and the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-14867 Filed 7-11-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) will hold a public meeting.

DATES: Thursday, August 2, 2018, from 9:30 a.m. to 5:00 p.m. Eastern Time (ET).

ADDRESSES: This meeting is a webinar only and requires advanced registration. Please register online at <http://www.achdncmeetings.org/> by 12:00 p.m. ET on July 30, 2018.

FOR FURTHER INFORMATION CONTACT: Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, in one of three ways: (1) Send a request to the following address: Ann Ferrero, MCHB, HRSA 5600 Fishers Lane, Room 18N100C, Rockville, MD 20857; (2) call 301-443-3999; or (3) send an email to AFerrero@hrsa.gov.

SUPPLEMENTARY INFORMATION:

Background: The ACHDNC provides advice and recommendations to the Secretary of HHS on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, ACHDNC’s recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary’s adoption of the condition for screening.

Agenda: During the August 2, 2018, meeting, the ACHDNC will discuss issues related to long-term follow-up, timeliness, education and training, the evidence-based review process, and risk assessment in newborn screening. Information about the ACHDNC, a roster of members, and the meeting agenda, as well as past meeting summaries, is located on the ACHDNC website: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

Public Participation: Members of the public will have the opportunity to provide comments, which are part of the official Committee record. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on July 27, 2018, at <http://www.achdncmeetings.org>. Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and

present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.*, parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-14908 Filed 7-11-18; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Center for Advancing Translational Sciences.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cures Acceleration Network Review Board.

Date: September 27, 2018.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: Report from the Institute Director.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301-435-0809, annn.ramseyewing@nih.gov.

Name of Committee: National Center for Advancing Translational Sciences Advisory Council.

Date: September 27, 2018.

Open: 8:30 a.m. to 3:00 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:15 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301-435-0809, anna.ramseyewing@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: July 5, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-14873 Filed 7-11-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the ZAT1 PJ (02) meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Mechanisms of Mind and Body Interventions (MMB).

Date: August 1, 2018.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy

Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pamela Eugenia Jeter, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, 301-435-2591, pamela.jeter@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: July 6, 2018.

Michelle D. Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-14874 Filed 7-11-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP (Nederland, TX) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP (Nederland, TX) as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Saybolt LP (Nederland, TX) has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 8, 2017.

DATES: Saybolt LP (Nederland, TX) was approved and accredited as a commercial gauger and laboratory as of August 8, 2017. The next triennial inspection date will be scheduled for August 2020.

FOR FURTHER INFORMATION CONTACT: Christopher J. Mocella, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202-344-1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Saybolt LP, 4144 N Twin City Hwy., Nederland, TX 77627, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Saybolt

LP (Nederland, TX) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Saybolt LP (Nederland, TX) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27-03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27-05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27-06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27-13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27-48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
Pending	D4007	Standard Test Method for Water and Sediment in Crude Oil by the Centrifuge Method (Laboratory Procedure).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to CBPGaugersLabs@cbp.dhs.gov. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories>.

Dated: July 2, 2018.

Dave Fluty,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2018-14918 Filed 7-11-18; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025701; PPWOCRADN0-PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Berkshire Museum, Pittsfield, MA

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: The Berkshire Museum, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural item listed in this notice meets the definition of sacred object and object of cultural patrimony. Lineal

descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request to the Berkshire Museum. If no additional claimants come forward, transfer of control of the cultural item to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to the Berkshire Museum at the address in this notice by August 13, 2018.

ADDRESSES: Jason Vivori, Collections Experience Manager, Berkshire Museum, 39 South Street, Pittsfield, MA 01201, telephone (413) 443-7171 ext. 341, email jvivori@berkshitemuseum.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate a cultural item under the control of the Berkshire Museum, Pittsfield, MA, that meets the definitions of sacred objects and objects of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item

In 1903, one cultural item was removed from Pine Point in Becker County, MN, by John K. West, an entrepreneur from western Massachusetts, who arrived in Detroit Lakes in 1881 with his wife, Ms. Jessie Campbell West. Both individuals spent considerable time in Detroit Lakes and other areas within Becker County and acquired numerous objects from White Earth Reservation. Shortly after Ms. West’s death in January 1903, several objects were sent to Massachusetts and were acquired by the Berkshire Museum. The one sacred object/object of cultural patrimony is described as an “Ojibwa large drum” (#C1992.53) otherwise referred to as a “Big Drum” or “Manidoo Dewe’igan” (meaning “Spirit Drum”).

The Pine Point community, where this particular drum originated, is within the boundaries of Becker County on the White Earth Reservation. From the creation of the White Earth Reservation in 1867 through the mid-1900s, the people of White Earth existed often under great hardship due to significant economic, cultural, and religious oppression combined with well-documented dispossession of land and other resources. Historically, the Big Drum served an important role in maintaining peace between communities and such drums continue to hold a spiritual and healing role with ceremonies that are still held on the White Earth Reservation. In addition, the ongoing historical and spiritual importance of these drums is that they are central to the White Earth people as a whole and could never have been alienated, appropriated, or conveyed by any individual regardless of whether or not the individual was a member of the tribe. Thomas Vennum wrote in *The Ojibwa Dance Drum*, “Because song and

dance are traditionally considered to be sacred in origin they are for Native Americans a form of prayer . . . and because most song is accompanied by percussion of some sort—drums more often than not—the instruments themselves become sacred through their associations.” This feeling was reaffirmed by the White Earth Band of the Minnesota Chippewa Tribe during consultation with the Berkshire Museum. In a letter dated April 5, 2017, the White Earth Band of the Minnesota Chippewa Tribe requested the return of the Big Drum due to its substantial cultural and religious significance.

Determinations Made by the Berkshire Museum

Officials of the Berkshire Museum have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), the one cultural item described above is a specific ceremonial object needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(3)(D), the one cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the sacred object and object of cultural patrimony and the White Earth Band of the Minnesota Chippewa Tribe.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Jason Vivori, Collections Experience Manager, Berkshire Museum, 39 South Street, Pittsfield, MA 01201, telephone (413) 443-7171 ext. 341, email jvivori@berkshireremuseum.org, by August 13, 2018. After that date, if no additional claimants have come forward, transfer of control of the sacred object and object of cultural patrimony to the White Earth Band of the Minnesota Chippewa Tribe may proceed.

The Berkshire Museum is responsible for notifying the White Earth Band of the Minnesota Chippewa Tribe that this notice has been published.

Dated: June 1, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14896 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025846; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: State Historic Preservation Office, Lansing, MI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The State Historic Preservation Office (SHPO), Michigan State Housing Development Authority, has completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Michigan State Historic Preservation Office. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the State Historic Preservation Office at the address in this notice by August 13, 2018.

ADDRESSES: Dean L. Anderson, State Historic Preservation Office, Michigan State Housing Development Authority, 735 East Michigan Avenue, Lansing, MI 48909, telephone: (517) 373-1618, email andersond15@michigan.gov.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated

funerary objects under the control of the State Historic Preservation Office, Lansing, MI. The human remains and associated funerary objects were removed from a highway construction project on US-12, Lenawee County, MI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made during 1993-1995 by the former Office of the State Archaeologist (OSA) professional staff and by a physical anthropologist. According to documents held by the SHPO, in 1995 the OSA initiated consultation on the human remains and funerary objects with the Citizen Potawatomi Nation, Oklahoma; Forest County Potawatomi Community, Wisconsin; Hannahville Indian Community, Michigan; Pokagon Band of Potawatomi Indians, Michigan and Indiana; and Prairie Band Potawatomi Nation (previously listed as the Prairie Band of Potawatomi Nation, Kansas).

History and Description of the Remains

In the 1920s, human remains representing nine individuals were removed from a highway construction project in Lenawee County, MI. In 1925, the remains were re-interred on the grounds of the Walker Tavern historic site, located a few miles from the highway construction project. The Walker Tavern structure was built around 1832, as a farmhouse, and then became a tavern and inn along the Detroit to Chicago stagecoach route. In 1921, Frederic Hewitt converted the tavern into a museum, and in 1965, the structure was sold to the Michigan Department of Natural Resources. The Parks and Recreation Division of the Michigan Department of Conservation operated the historic site until 1975, when the Michigan Historical Museum, which was part of the Michigan Historical Center (MHC), took responsibility for the Walker Tavern museum and its collections.

In the mid-1990s, Barbara Mead, Assistant State Archaeologist, did the NAGPRA reporting for the Office of the State Archaeologist (OSA) and for the state museum. At that time, the state museum turned over to Ms. Mead a single cranium and associated funerary objects that she determined had been

part of the group of human remains that was re-interred on the grounds of the Walker Tavern site in 1925.

In 2009, the Department of History, Arts, and Libraries, which included both the OSA and the state museum, was eliminated. The state museum was moved into the Department of Natural Resources, and the OSA was moved into the Michigan State Housing Development Authority. Soon after that, the OSA was eliminated, and the archaeology staff were moved into the SHPO. Consequently, the archaeological collections, including the Walker Tavern materials, are now held by the SHPO.

The human remains in the Walker Tavern collection include a single cranium with no teeth present and lacking the mandible. The cranium was examined by a physical anthropologist who stated that the individual was approximately 10–15 years of age, and that no determination of sex or ethnic identity of the individual could be made. No known individuals were identified.

When the state museum assumed responsibility for the Walker Tavern collection in 1975, the cranium was recorded under Michigan Department of Conservation accession number A1253. The state museum assigned catalog number FA-155-75 to the cranium.

The state museum also cataloged a group of 18 funerary objects associated with the human remains disinterred during road construction in the 1920s. The 18 associated funerary objects are: One pewter spoon, one bottle, one oval stone, one deer mandible, three loose teeth, one lot of fur pieces with tassels wrapped in porcupine quill, one silver armband, one wooden bowl or toy canoe, one lot of wool scraps, one lot of linen scraps, one silver armband, one copper or brass kettle fragment, one iron knife blade, one lot of very small bone chips, one lot of shell and glass beads and one pewter bowl.

Based on the funerary objects, it is estimated that the original interment of the objects and the human remains took place between approximately 1760 and 1810. A typescript in the MHC Walker Tavern files identified as an article in the Lenawee County Exponent dated November 22, 1923, describes the discovery of Indian graves and artifacts during road construction work in the Irish Hills area. The article mentions some of the same funerary objects described above and associated with the cranium. This assemblage of funerary objects, including trade silver and beads, together with the cranium, represent a Native American interment.

The inventory that Assistant State Archaeologist Barbara Mead compiled in 1995 included the following information on cultural affiliation: Probably Potawatomi. Early in the eighteenth century, the Potawatomi, Miami, Ottawa, Huron/Wyandotte and Kickapoo were present in southern Michigan. Most of the reports for tribes other than the Potawatomi are from the pre-1720 era. By the 1760s, the Potawatomi territory included Lenawee County; no other tribes seemed to be present, except perhaps as travelers or temporary residents. (Cleland, Charles E., 1992, *Rites of Conquest*, the University of Michigan Press; Tanner, Helen Hornbeck (ed.), 1987, *Atlas of Great Lakes Indian History*, University of Oklahoma Press; Trigger, Bruce G. (ed.), 1978, *Handbook of North American Indians*, Vol. 15: Northeast, Smithsonian Institution).

Determinations Made by the State Historic Preservation Office

Officials of the State Historic Preservation Office have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 18 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Citizen Potawatomi Nation, Oklahoma; Forest County Potawatomi Community, Wisconsin; Hannahville Indian Community, Michigan; Pokagon Band of Potawatomi Indians, Michigan and Indiana; and Prairie Band Potawatomi Nation (previously listed as the Prairie Band of Potawatomi Nation, Kansas).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dean L. Anderson, State Historic Preservation Office, Michigan State Housing Development Authority, 735 East Michigan Avenue, P.O. Box 30044, Lansing, MI 48909, telephone (517) 373-1618, email andersond15@michigan.gov, by August 13, 2018. After

that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Citizen Potawatomi Nation, Oklahoma; Forest County Potawatomi Community, Wisconsin; Hannahville Indian Community, Michigan; Pokagon Band of Potawatomi Indians, Michigan and Indiana; and Prairie Band Potawatomi Nation (previously listed as the Prairie Band of Potawatomi Nation, Kansas) may proceed.

The State Historic Preservation Office is responsible for notifying the Citizen Potawatomi Nation, Oklahoma; Forest County Potawatomi Community, Wisconsin; Hannahville Indian Community, Michigan; Pokagon Band of Potawatomi Indians, Michigan and Indiana; and Prairie Band Potawatomi Nation (previously listed as the Prairie Band of Potawatomi Nation, Kansas) that this notice has been published.

Dated: June 21, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14905 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025769; PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: St. Joseph Museums, Inc., St. Joseph, MO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The St. Joseph Museum has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the St. Joseph Museum. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to

request transfer of control of these human remains should submit a written request with information in support of the request to the St. Joseph Museum at the address in this notice by August 13, 2018.

ADDRESSES: Trevor Tutt, Collections Manager, St. Joseph Museums, Inc., St. Joseph, MO 64506, telephone (816) 232-8471, email trevor@stjosephmuseum.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the St. Joseph Museums, Inc., St. Joseph, MO. The human remains were removed from Kake, AK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the St. Joseph Museum professional staff in consultation with representatives of the Organized Village of Kake.

History and Description of the Remains

Prior to 1910, human remains representing, at minimum, one individual were removed from Kake, AK. Subsequently, William H. Case transferred these human remains to Harry L. George, who, in turn donated them to the St. Joseph Museum. The human remains—a jaw bone—belonged to a Medicine Man who had died and was buried in a grave house, in accordance with Native custom. When a sickness, attributed to evil spirits, fell upon the village the Medicine Man's bones were thrown in salt water. A white missionary from Kake was said to have retrieved the jaw bone from the Pacific Ocean several years later, accounting for the barnacles found on the teeth. As Russian missionaries first arrived in Kake in the 1790s, the retrieval of the jaw by a white missionary would have occurred between the 1790s and early 1910, when Case photographed it and sent the images to George. George had purchased the jawbone along with a series of ivory buttons and a jade axe head for \$30.00 no later than July 14, 1911.

The Harry George collection was originally meant to be donated to the St. Joseph Museum prior to George's death in 1923, but due to lack of storage space, it was on loan to the Missouri State Museum in Jefferson City until it transferred to the St. Joseph Museum in October 1944. The bulk of the collection was stored in the basement of the St. Joseph City Hall while select items were displayed at the AJ August House, the second location of the St. Joseph Museum. After the St. Joseph Museum received the Wyeth-Tootle Mansion as their main display site in 1946, the vast majority of the items went on display there. That same year, funds were provided for the St. Joseph Museum to purchase the George Collection outright. The human remains in the collection have remained in storage since at least the 1970s. When the St. Joseph Museum, now the St. Joseph Museums, Inc., moved to the Glore Psychiatric Museum in 2004, much of the George Collection was moved as well, including the jaw bone. In 2017, it, and other human remains were returned to storage at the Wyeth-Tootle Mansion for processing under NAGPRA.

Research into the Harry George Collection, specifically the William H. Case photographs, began around 2017. Zachary Jones, Archivist at the Alaska State Archives, assisted in identifying objects in the collection and initiated consultation with the Organized Village of Kake. Frank Hughes, the NAGPRA Coordinator for the Organized Village of Kake, contacted Trevor Tutt, the Collections Manager for the St. Joseph Museums, Inc., and began correspondence related to items of cultural patrimony and remains related to Kake, Alaska. Through correspondence, the oral tradition of human remains being thrown in salt water in retaliation against a sickness in the village was confirmed. As research indicates that missionary activity in Kake peaked during the 1890s–1910 period, the jaw might have been removed during that two decade span.

Determinations Made by the St. Joseph Museum

Officials of the St. Joseph Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Organized Village of Kake.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Trevor Tutt, Collections Manager, St. Joseph Museums, Inc., St. Joseph, MO 64506, telephone (816) 232-8471, email trevor@stjosephmuseum.org, by August 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Organized Village of Kake may proceed.

The St. Joseph Museum is responsible for notifying the Organized Village of Kake that this notice has been published.

Dated: June 12, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14901 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025692; PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of Agriculture, Tongass National Forest, Juneau Ranger District, Juneau, AK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture, Tongass National Forest, Juneau Ranger District, (Tongass National Forest) has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of the human remains and associated funerary objects should submit a written request to the Tongass National Forest. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian

organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Tongass National Forest at the address in this notice by August 13, 2018.

ADDRESSES: M. Earl Stewart, Forest Supervisor, Tongass National Forest, 648 Mission Street, Ketchikan, AK 99901-6591, telephone (907) 228-6281, email estewart@fs.fed.us.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of the human remains and associated funerary objects under the control of the USDA Tongass National Forest, Juneau Ranger District, Juneau, AK. The human remains and associated funerary objects were removed from Entrance Island, near Hobart Bay, AK, on two separate occasions by two separate collectors.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Tongass National Forest archeologists in partnership with the professional staff of the Alaska State Museum and in consultation with representatives of Douglas Indian Association and the Organized Village of Kake.

History and Description of the Remains

In the summer of 1961, funerary objects, in several pieces, were removed from a small cave on Entrance Island near Hobart Bay, AK. An individual exploring the island reported that he found a small cave that contained human remains and portions of a bentwood box, as well as some other burial items believed to have been placed there at the time of burial. He collected a basket of a type that reportedly was used to cradle a baby and sometimes was used to bury the deceased. Additional items collected

include a piece of leather cordage, a portion of a woven cedar mat, and a piece of wood with evidence of a kerf corner, all of which were connected with either the basket or the bentwood box. The human remains and the bentwood box were not removed from the cave at that time. The individual returned the four burial items to the Tongass National Forest in 2017. Subsequently, it was determined that these funerary objects are associated with the below described human remains and funerary object that were separately collected by a different individual.

In 1961, the desiccated remains of an infant inside a bentwood box that had been wrapped in a cedar mat were removed from a small burial cave on Entrance Island, near Hobart Bay. In November 1961, these human remains and funerary objects were sent to the Alaska State Museum for curation. Based on oral testimony, this burial site and the above described burial cave are determined to be one and the same. The human remains consist of a single individual, a mummified infant, estimated to be between the ages of 6 and 9 months. Determination of sex or affinity based on skeletal features was not possible. The bentwood box containing the infant's remains was painted and uncarved. It was recovered from beneath the cedar bark mat. When found, the infant had ermine skins tied in its hair.

The human remains and associated funerary objects are believed to be of pre-contact or first contact date, as after contact, the Christian burial practice of underground internment became widespread. The human remains are reasonably believed to be associated with the Kéex Kwáan, who have traditionally used and occupied the island. The cultural affiliation of the human remains was determined by consulting *Haa Aani Our Land Tlingit and Haida Land Rights and Use*, by Walter R. Goldschmidt and Theodore H. Haas, edited by Thomas F. Thornton (1998). Additional cultural affiliation information was provided by the Organized Village of Kake and the Douglas Indian Association. The Kéex Kwáan continue to live in their traditional territory and use the Hobart Bay area. Their present-day descendants are the Organized Village of Kake.

Determinations Made by the Tongass National Forest

Officials of the Tongass National Forest have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice

represent the physical remains of one individual of Native American ancestry.

- Pursuant to 25 U.S.C. 3001(3)(A), the seven objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects and the Organized Village of Kake.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to M. Earl Stewart, Forest Supervisor, Tongass National Forest, 648 Mission Street, Ketchikan, AK 99901-6591, telephone (907) 228-6281, email estewart@fs.fed.us, by August 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Organized Village of Kake may proceed.

The Tongass National Forest is responsible for notifying the Douglas Indian Association and the Organized Village of Kake that this notice has been published.

Dated: May 31, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14903 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025756; PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: University of San Diego, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of San Diego has completed an inventory of human remains in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not

identified in this notice that wish to request transfer of control of these human remains should submit a written request to the University of San Diego. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the University of San Diego, at the address in this notice by August 13, 2018.

ADDRESSES: Derrick R. Cartwright, Ph.D., University of San Diego, 5998 Alcalá Park, San Diego, CA 92110, telephone (619) 260-7632, email dcartwright@sandiego.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the University of San Diego, San Diego, CA. The human remains were removed from Squaw Point, near Dove Creek, Delores County, CO.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains were made by the University of San Diego professional staff in consultation with representatives of the Hopi Tribe of Arizona; Kewa Pueblo, New Mexico (previously listed as the Pueblo of Santo Domingo); Navajo Nation, Arizona, New Mexico & Utah; Ohkay Owingeh, New Mexico (previously listed as the Pueblo of San Juan); Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa

Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; Ute Mountain Ute Tribe (previously listed as the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah); Ysleta del Sur Pueblo (previously listed as the Ysleta Del Sur Pueblo of Texas); and Zuni Tribe of the Zuni Reservation, New Mexico (hereafter referred to as "The Consulted Tribes").

History and Description of the Remains

At an unknown time, human remains representing, at minimum, one individual were removed from Squaw Point, near Dove Creek, CO. No information regarding the circumstances surrounding the removal is known. Rose Tyson, a physical anthropologist, received the human remains from Dr. Spencer L. Rogers, also a physical anthropologist, and gave them to the Anthropology Department at the University of San Diego in 2002. The human remains—one cranium and mandible—belong to a male and have been cradleboard flattened. Printed in ink on the left side of the cranium is "PII 7/55 Squaw Point near Dove Creek Colorado prop. S. L. Rogers. Dimensions: maximum length 143 mm, maximum width 168 mm." No known individual was identified. No associated funerary objects are present.

Determinations Made by the University of San Diego

Officials of the University of San Diego have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remain was removed is the aboriginal land of the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; and the Ute Mountain Ute Tribe (previously listed as the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah).
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado;

Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; and the Ute Mountain Ute Tribe (previously listed as the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Derrick R. Cartwright, University of San Diego, 5998 Alcalá Park, San Diego, CA 92110, telephone (619) 260-7632, email dcartwright@sandiego.edu by August 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remain to the Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; and the Ute Mountain Ute Tribe (previously listed as the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah) may proceed.

The University of San Diego is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: June 11, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14899 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025845; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: Heard Museum, Phoenix, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Heard Museum has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Heard Museum.

If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Heard Museum at the address in this notice by August 13, 2018.

ADDRESSES: David Roche, Director/CEO, Heard Museum, 2301 North Central Avenue, Phoenix, AZ 85004, telephone (602) 252-8840, email director@heard.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Heard Museum, Phoenix, AZ. The human remains were removed from Camp Verde, Yavapai County, AZ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Heard Museum professional staff in consultation with representatives of Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Hopi Tribe of Arizona; Hualapai Indian Tribe of the Hualapai Indian Reservation, Arizona; Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota; Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona; Yavapai-Prescott Indian Tribe (previously listed as the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona); and Zuni Tribe of the Zuni Reservation, New Mexico.

History and Description of the Remains

Sometime prior to 1991, human remains representing, at minimum, one individual were removed from Camp Verde in Yavapai County, AZ. The circumstances surrounding the removal are unknown. In 1991, the human remains were in the collection of the

Heard Museum and were assigned the catalog number NA-SW-PR-T-1. The human remains are those of an adult. No known individuals were identified. No associated funerary objects are present.

Based on consultation, the Camp Verde provenience, the type of burial (inhumation), and the presence of copper oxide stains which are often found on burials in the Tuzigoot area (Caywood and Spicer 1935:99-100; Wilcox 1987:128), the Heard Museum has determined that these human remains belong to the Sinagua culture. The Sinagua period was from A.D. 600 to A.D. 1450. The following present-day Indian Tribes descend from the Sinagua culture: Ak-Chin Indian Community (previously listed as the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona); Fort McDowell Yavapai Nation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Havasupai Tribe of the Havasupai Reservation, Arizona; Hopi Tribe of Arizona; Hualapai Indian Tribe of the Hualapai Indian Reservation, Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona; Yavapai-Prescott Indian Tribe (previously listed as the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona); and Zuni Tribe of the Zuni Reservation, New Mexico (hereafter referred to as "The Tribes").

Determinations Made by the Heard Museum

Officials of the Heard Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to David Roche, Director/CEO, Heard Museum, 2301 North Central Avenue, Phoenix, AZ 85004, telephone (602) 252-8840, email director@heard.org, by August 13, 2018. After that date, if no additional requestors have come forward, transfer

of control of the human remains to The Tribes may proceed.

The Heard Museum is responsible for notifying The Tribes that this notice has been published.

Dated: June 21, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14904 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025827; PPWOCRADN0-PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: U.S. Department of the Interior, National Park Service, Grand Canyon National Park, Grand Canyon, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, National Park Service, Grand Canyon National Park, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to Grand Canyon National Park. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Grand Canyon National Park at the address in this notice by August 13, 2018.

ADDRESSES: Christine Lehnertz, Superintendent, Grand Canyon National Park, P.O. Box 129, Grand Canyon, AZ 86023, telephone (928) 638-7945, email chris_lehnertz@nps.gov.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of Grand Canyon National Park, Grand Canyon, AZ, that meet the definition of

unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the Superintendent, Grand Canyon National Park.

History and Description of the Cultural Items

In 1935, three cultural items were removed from GC 62 in Coconino County, AZ, during a vegetation project by the Works Progress Administration and the National Park Service. The three objects were kept by Claude A. Wagner Jr. until 1974 when he donated them to Grand Canyon National Park. The three unassociated funerary objects are one copper bracelet and two metal bells.

GC 62 is described as a cremation site, about six feet in diameter with evidence of a large fire. No human remains were collected from GC 62. The site is located in an area traditionally used by the Havasupai Tribe and cremation was a Havasupai burial practice. The Havasupai Tribal Council has identified the items as likely coming from a tribal cremation.

Determinations Made by Grand Canyon National Park

Officials of Grand Canyon National Park have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the three cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Havasupai Tribe of the Havasupai Reservation, Arizona.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Christine Lehnertz, Superintendent, Grand Canyon National Park, P.O. Box 129, Grand Canyon, AZ 86023, telephone (928) 638-7945, email chris_lehnertz@nps.gov, by August 13, 2018. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary

objects to the Havasupai Tribe of the Havasupai Reservation, Arizona may proceed.

Grand Canyon National Park is responsible for notifying the Havasupai Tribe of the Havasupai Reservation, Arizona that this notice has been published.

Dated: June 18, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14902 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025702; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: University of Michigan, Ann Arbor, MI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Michigan has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the University of Michigan. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the University of Michigan at the address in this notice by August 13, 2018.

ADDRESSES: Dr. Ben Secunda, NAGPRA Project Manager, University of Michigan, Office of Research, 4080 Fleming Building, 503 South Thompson Street, Ann Arbor, MI 48109-1340, telephone (734) 647-9085, email bsecunda@umich.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and

Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the University of Michigan, Ann Arbor, MI. The human remains were removed from the Garry site (20AC19), Arenac County, MI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the University of Michigan Museum of Anthropological Archaeology (UMMAA) professional staff in consultation with representatives of the Bay Mills Indian Community, Michigan; Chippewa Cree Indians of the Rocky Boy's Reservation, Montana (previously listed as the Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana); Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band); Saginaw Chippewa Indian Tribe of Michigan; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; and Sokaogon Chippewa Community, Wisconsin (hereafter referred to as "The Consulted Tribes").

Requests for consultation were also sent to the Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin; Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; St. Croix Chippewa Indians of Wisconsin; and Turtle Mountain Band of Chippewa Indians of North Dakota (hereafter referred to as "The Tribes Invited to Consult").

History and Description of the Remains

In August of 1971, human remains representing, at minimum, one individual were removed from the Garry site (20AC19) in Arenac County, MI.

Workers contacted the Michigan State Police after encountering human remains while digging a trench for a water main on private land. The human remains were taken to the State Crime Lab for analysis and subsequently transferred to the UMMAA. After analyzing the human remains, archaeologists from the UMMAA and Indiana State Museum returned to the burial site to excavate the remaining portion of the trench. The individual had been buried in a semi-prone position within a bell-shaped pit. Several Post-Contact Period objects were found in association with the burial but were transferred to the Arenac County Historical Society instead of the UMMAA. The human remains are of one adolescent, indeterminate sex, 17–18 years old. Copper staining is present on the right ulna and radius. Perimortem sharp force trauma, possibly from a knife or blade, on some of the human remains may be the cause of death as there is no evidence of healing from this trauma. No known individuals were identified. There are no associated funerary objects under the control of UMMAA.

The human remains have been determined to be Native American based on burial treatment and diagnostic artifacts. A relationship of shared group identity can be reasonably traced between the Native American human remains from this site and the Chippewa based on multiple lines of evidence. The associated funerary objects noted from the site are typical of the types of goods traded in the region from approximately A.D. 1760 to 1820. Additionally, according to historical records, when the burial occurred, the Chippewa were the predominant tribe in the area. This is further evinced by a treaty creating two Chippewa reservations in the vicinity of the Garry site in 1837.

Determinations Made by the University of Michigan

Officials of the University of Michigan have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Consulted Tribes and The Tribes Invited to Consult.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice

that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Ben Secunda, NAGPRA Project Manager, University of Michigan, Office of Research, 4080 Fleming Building, 503 South Thompson Street, Ann Arbor, MI 48109–1340, telephone (734) 647–9085, email bsecunda@umich.edu, by August 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Consulted Tribes and The Tribes Invited to Consult may proceed.

The University of Michigan is responsible for notifying The Consulted Tribes and The Tribes Invited to Consult that this notice has been published.

Dated: June 1, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–14897 Filed 7–11–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0025758; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace, MI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace, has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these

human remains should submit a written request with information in support of the request to the Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace at the address in this notice by August 13, 2018.

ADDRESSES: Shirley Sorrels, Director, Museum of Ojibwa Culture and Marquette Mission Park, c/o Bernstein & Associates, 1041 N Lafayette Street, Denver, CO 80218, telephone (303) 894–0648, email jan@nagpra.info.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace. The human remains were removed from Marquette Mission Site (20MK82), Mackinac County, MI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace professional staff in consultation with representatives of the Forest County Potawatomi Community, Wisconsin; Little Traverse Bay Bands of Odawa Indians, Michigan; Saginaw Chippewa Indian Tribe of Michigan; and Sault Ste. Marie Tribe of Chippewa Indians, Michigan.

History and Description of the Remains

In 1983, 1997, and 2001, (during excavations by Michigan State University archeologists), human remains representing, at minimum, three individuals were removed with faunal remains from the Marquette Mission site (20MK82) in St. Ignace, Mackinac County, MI. After each excavation season, the excavated material were transported to the Michigan State University Museum, where they were curated. In early 2017, during an examination of the faunal remains, three human teeth were identified: A child's worn shovel-shaped maxillary incisor (5810.005.02 box 8), an adult shovel-shaped incisor (5810.169.91.01), and an adult molar (5810.123.03.03). No known individuals

were identified. No associated funerary objects are present.

The archeological site is within Marquette Mission Park. The Museum of Ojibwa Culture and Marquette Mission Park manages the Park. Both the Park and the Museum are under the auspices of the City of St. Ignace. Based on the archaeological context, the human remains date to A.D. 17th century, when Native Americans representing many different cultures, including but not limited to, the Wendat (Huron), Anishinaabek [Ojibwa/Ojibwe (Chippewa), Odawa (Ottawa)], Bodéwadmi (Potawatomi), and Haudenosaunee (Iroquois), lived in proximity to the Marquette Mission site.

Determinations Made by the Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace

Officials of the Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on the biological and archeological evidence.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian tribe.

- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, or Treaties, Acts of Congress, or Executive Orders, the land from which the Native American human remains were removed is the aboriginal land of the Absentee-Shawnee Tribe of Indians of Oklahoma; Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin; Bay Mills Indian Community, Michigan; Chippewa Cree Indians of the Rocky Boy's Reservation, Montana (previously listed as the Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana); Citizen Potawatomi Nation, Oklahoma; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Eastern Shawnee Tribe of Oklahoma; Forest County Potawatomi Community, Wisconsin; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Keweenaw Bay Indian Community, Michigan; Kickapoo Traditional Tribe of Texas; Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas; Kickapoo Tribe of Oklahoma; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of

Wisconsin; Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Miami Tribe of Oklahoma; Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band); Nottawaseppi Huron Band of the Potawatomi, Michigan (previously listed as the Huron Potawatomi, Inc.); Ottawa Tribe of Oklahoma; Peoria Tribe of Indians of Oklahoma; Pokagon Band of Potawatomi Indians, Michigan and Indiana; Prairie Band Potawatomi Nation (previously listed as the Prairie Band of Potawatomi Nation, Kansas); Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; Saginaw Chippewa Indian Tribe of Michigan; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; Shawnee Tribe, Oklahoma; Sokaogon Chippewa Community, Wisconsin; St. Croix Chippewa Indians of Wisconsin; Stockbridge Munsee Community, Wisconsin; Turtle Mountain Band of Chippewa Indians of North Dakota; and Wyandotte Nation (hereinafter referred to as "The Tribes")

- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Shirley Sorrels, Director, Museum of Ojibwa Culture and Marquette Mission Park, c/o Bernstein & Associates, 1041 N Lafayette Street, Denver, CO 80218, telephone (303) 894-0648, email jan@nagpra.info, by August 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Museum of Ojibwa Culture and Marquette Mission Park, City of St. Ignace is responsible for notifying The Tribes that this notice has been published.

Dated: June 11, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14900 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0025755; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: San Diego Museum of Man, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The San Diego Museum of Man has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the San Diego Museum of Man. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the San Diego Museum of Man at the address in this notice by August 13, 2018.

ADDRESSES: Ben Garcia, Deputy Director, San Diego Museum of Man, 1350 El Prado, San Diego, CA 92101, telephone (619) 239-2001 ext. 17, email bgarcia@museumofman.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the San Diego Museum of Man, San Diego, CA. The human remains were removed from Kanaga Island, AK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in

this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the San Diego Museum of Man professional staff in consultation with representatives of the Aleut Corporation and the Native Village of Atka.

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from Kanaga Island, part of the Andreanof Islands group of the Aleutian Islands in Alaska. These human remains lack conclusive collection documentation regarding the date of collection, collector, or specific geographic location other than a general association to Kanaga Island. The human remains were donated to the San Diego Museum of Man by Lieutenant M. Nolan some time before 1950. No known individuals were identified. No associated funerary objects are present.

An examination of the human remains by San Diego Museum of Man physical anthropology professional staff determined the individual to be Native Alaskan. The Aleutian Islands are known to be aboriginal lands of the modern Aleut peoples. Based on museum records, geographical location, physical examination, and consultation, the museum reasonably believes the individual is culturally affiliated with the Native Village of Atka.

Determinations Made by the San Diego Museum of Man

Officials of the San Diego Museum of Man have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Native Village of Atka.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Ben Garcia, Deputy Director, San Diego Museum of Man, 1350 El Prado, San Diego, CA 92101, telephone (619) 239-2001 ext.

17, email bgarcia@museumofman.org, by August 13, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Native Village of Atka may proceed.

The San Diego Museum of Man is responsible for notifying the Native Village of Atka that this notice has been published.

Dated: June 11, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018-14898 Filed 7-11-18; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000
189S180110; S2D2S SS08011000
SX064A000 18XS501520; OMB Control
Number 1029-0098]

Agency Information Collection Activities: Petition Process for Designation of Federal Lands as Unsuitable for All or Certain Types of Surface Coal Mining Operations and for Termination of Previous Designations

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing our intention to request renewed approval for the collection of information that establishes the minimum procedures and standards for designating Federal lands unsuitable for certain types of surface mining operations and for terminating designations pursuant to a petition. The information requested will aid the regulatory authority in the decision making process to approve or disapprove a request. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029-0098.

DATES: Interested persons are invited to submit comments on or before September 10, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to: The Office of Surface Mining Reclamation and Enforcement, Information Collection Clearance Officer, Attn: John Trelease, 1849 C

Street NW; Mail Stop 4559, Washington, DC 20240. Comments may also be submitted electronically to jtrelease@osmre.gov.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact John Trelease by email at jtrelease@osmre.gov, or by telephone at (202) 208-2783.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the OSMRE; (2) is the estimate of burden accurate; (3) how might the OSMRE enhance the quality, utility, and clarity of the information to be collected; and (4) how might the OSMRE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title of Collection: 30 CFR part 769—Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations.

OMB Control Number: 1029-0098.

Abstract: This part establishes the minimum procedures and standards for designating Federal lands unsuitable for

certain types of surface mining operations and for terminating designations pursuant to a petition. The information requested will aid the regulatory authority in the decision making process to approve or disapprove a request.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: People who may be adversely affected by surface mining on Federal lands.

Total Estimated Number of Annual Respondents: One every three years.

Total Estimated Number of Annual Responses: One every three years.

Estimated Completion Time per Response: 3,000 hours.

Total Estimated Number of Annual Burden Hours: 1,000 hours annually.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: \$0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Authority: The authorities for this action are the Surface Mining Control and Reclamation Act of 1977, as amended (30 U.S.C. 1201 *et seq.*), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2018-14891 Filed 7-11-18; 8:45 am]

BILLING CODE 4310-05-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000
189S180110; S2D2S SS08011000
SX064A000 18XS501520; OMB Control
Number 1029-0051]

Agency Information Collection Activities: State Regulatory Authority: Inspection and Enforcement

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing our intention to request renewed approval for the collection of

information which requires that each regulatory authority conduct periodic inspections of coal mining activities, and prepare and maintain inspection reports and other related documents for OSMRE and public review. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029-0051.

DATES: Interested persons are invited to submit comments on or before September 10, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to: The Office of Surface Mining Reclamation and Enforcement, Information Collection Clearance Officer, Attn: John Trelease, 1849 C Street NW, Mail Stop 4559, Washington, DC 20240. Comments may also be submitted electronically to jtrelease@osmre.gov.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact John Trelease by email at jtrelease@osmre.gov, or by telephone at (202) 208-2783.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the OSMRE; (2) is the estimate of burden accurate; (3) how might the OSMRE enhance the quality, utility, and clarity of the information to be collected; and (4) how might the OSMRE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may

be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title of Collection: 30 CFR part 840—State Regulatory Authority: Inspection and Enforcement.

OMB Control Number: 1029-0051.

Abstract: This provision requires the regulatory authority to conduct periodic inspections of coal mining activities, and prepare and maintain inspection reports and other related documents for OSMRE and public review. This information is necessary to meet the requirements of the Surface Mining Control and Reclamation Act of 1977 and its public participation provisions. Public review assures the public that the State is meeting the requirements of the Act and approved State regulatory program.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State Regulatory Authorities.

Total Estimated Number of Annual Respondents: 24 States.

Total Estimated Number of Annual Responses: 106,382.

Estimated Completion Time per Response: From 4.7 hours to 1,081 hours per response depending on activity.

Total Estimated Number of Annual Burden Hours: 296,938 hours for States.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Once, annually, quarterly, and monthly.

Total Estimated Annual Nonhour Burden Cost: \$1,440.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Authority: The authorities for this action are the Surface Mining Control and Reclamation Act of 1977, as amended (30 U.S.C. 1201 *et seq.*), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2018-14892 Filed 7-11-18; 8:45 am]

BILLING CODE 4310-05-P

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement**

[S1D1S SS08011000 SX064A000
189S180110; S2D2S SS08011000
SX064A000 18XS501520; OMB Control
Number 1029-0094]

Agency Information Collection Activities: General

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.
ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing our intention to request renewed approval for the collection of information establishes procedures and requirements for terminating jurisdiction of surface coal mining and reclamation operations, petitions for rulemaking, and citizen suits filed under the Surface Mining Control and Reclamation Act of 1977. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029-0094.

DATES: Interested persons are invited to submit comments on or before September 10, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to: The Office of Surface Mining Reclamation and Enforcement, Information Collection Clearance Officer, Attn: John Trelease, 1849 C Street NW, Mail Stop 4559, Washington, DC 20240. Comments may also be submitted electronically to jtrelease@osmre.gov.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact John Trelease by email at jtrelease@osmre.gov, or by telephone at (202) 208-2783.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below.

We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the OSMRE; (2) is the estimate of burden accurate; (3) how might the OSMRE enhance the quality, utility, and clarity of the information to be collected; and (4) how might the OSMRE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title of Collection: 30 CFR part 700—General.

OMB Control Number: 1029-0094.

Abstract: The information requested by this part establishes procedures and requirements for terminating jurisdiction of surface coal mining and reclamation operations, petitions for rulemaking, and citizen suits filed under the Surface Mining Control and Reclamation Act of 1977.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal regulatory authorities, private citizens and citizen groups, and surface coal mining companies.

Total Estimated Number of Annual Respondents: 23 respondents.

Total Estimated Number of Annual Responses: 23 responses.

Estimated Completion Time per Response: Varies from 1 to 50 hours.

Total Estimated Number of Annual Burden Hours: 80 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: \$0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Authority: The authorities for this action are the Surface Mining Control and Reclamation Act of 1977, as amended (30 U.S.C. 1201 *et seq.*), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2018-14890 Filed 7-11-18; 8:45 am]

BILLING CODE 4310-05-P

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement**

[S1D1S SS08011000 SX064A000
189S180110; S2D2S SS08011000
SX064A000 18XS501520; OMB Control
Number 1029-0057]

Agency Information Collection Activities: Reclamation on Private Lands

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.
ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing our intention to request renewed approval for the collection of information which authorizes Federal, State, and Tribal governments to reclaim private lands and allows for the establishment of procedures for the recovery of the cost of reclamation activities on privately owned lands. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029-0057.

DATES: Interested persons are invited to submit comments on or before September 10, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to: The Office of Surface Mining Reclamation and Enforcement, Information Collection Clearance Officer, Attn: John Trelease, 1849 C Street NW, Mail Stop 4559, Washington, DC 20240. Comments may also be submitted electronically to jtrelease@osmre.gov.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact John Trelease by email at jtrelease@osmre.gov, or by telephone at (202) 208-2783.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal

agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the OSMRE; (2) is the estimate of burden accurate; (3) how might the OSMRE enhance the quality, utility, and clarity of the information to be collected; and (4) how might the OSMRE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title of Collection: 30 CFR part 882—Reclamation on Private Lands.

OMB Control Number: 1029-0057.

Abstract: Public Law 95-87 authorizes Federal, State, and Tribal governments to reclaim private lands and allows for the establishment of procedures for the recovery of the cost of reclamation activities on privately owned lands. These procedures are intended to ensure that governments have sufficient capability to file liens so that certain landowners will not receive a windfall from reclamation.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State governments and Indian Tribes.

Total Estimated Number of Annual Respondents: 1 State or Tribe.

Total Estimated Number of Annual Responses: 1.

Estimated Completion Time per Response: 120 hours.

Total Estimated Number of Annual Burden Hours: 120 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: \$0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Authority: The authorities for this action are the Surface Mining Control and Reclamation Act of 1977, as amended (30 U.S.C. 1201 *et seq.*), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2018-14893 Filed 7-11-18; 8:45 am]

BILLING CODE 4310-05-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 189S180110; S2D2S SS08011000 SX064A000 18XS501520; OMB Control Number 1029-0087]

Agency Information Collection Activities: OSM-76—Abandoned Mine Land Problem Area Description Form

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing our intention to request renewed approval for the collection of information which is used to update the Office of Surface Mining Reclamation and Enforcement's electronic inventory of abandoned mine lands (e-AMLIS). From this inventory, the most serious problem areas are selected for reclamation through the apportionment of funds to States and Indian tribes. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029-0087.

DATES: Interested persons are invited to submit comments on or before September 10, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to: The Office of Surface Mining

Reclamation and Enforcement, Information Collection Clearance Officer, Attn: John Trelease, 1849 C Street NW, Mail Stop 4559, Washington, DC 20240. Comments may also be submitted electronically to jtrelease@osmre.gov.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact John Trelease by email at jtrelease@osmre.gov, or by telephone at (202) 208-2783.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the OSMRE; (2) is the estimate of burden accurate; (3) how might the OSMRE enhance the quality, utility, and clarity of the information to be collected; and (4) how might the OSMRE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title of Collection: Abandoned Mine Land Problem Area Description Form.

OMB Control Number: 1029-0087.

Abstract: The problem area description (PAD) form is used to update the Office of Surface Mining Reclamation and Enforcement's

electronic inventory of abandoned mine lands (e-AMLIS). From this inventory, the most serious problem areas are selected for reclamation through the apportionment of funds to States and Indian tribes.

Form Number: OSM-76.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal governments.

Total Estimated Number of Annual Respondents: 27 State and Tribal governments.

Total Estimated Number of Annual Responses: 1,888 responses.

Estimated Completion Time per Response: An average of 8 hours per new PAD and 1.5 hours for an updated PAD.

Total Estimated Number of Annual Burden Hours: 5,016 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: \$0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Authority: The authorities for this action are the Surface Mining Control and Reclamation Act of 1977, as amended (30 U.S.C. 1201 *et seq.*), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2018-14894 Filed 7-11-18; 8:45 am]

BILLING CODE 4310-05-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000
189S180110; S2D2S SS08011000
SX064A000 18XS501520; OMB Control
Number 1029-0120]

Agency Information Collection Activities: Nomination and Request for Payment Form for OSMRE's National Technical Training Courses

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining

Reclamation and Enforcement (OSMRE), are announcing our intention to request renewed approval for the collection of information which is used to identify and evaluate the training courses requested by students to enhance their job performance, to calculate the number of classes and instructors needed to complete OSMRE's technical training mission, and to estimate costs to the training program. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029-0120.

DATES: Interested persons are invited to submit comments on or before September 10, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to: The Office of Surface Mining Reclamation and Enforcement, Information Collection Clearance Officer, Attn: John Trelease, 1849 C Street NW, Mail Stop 4559, Washington, DC 20240. Comments may also be submitted electronically to jtrelease@osmre.gov.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact John Trelease by email at jtrelease@osmre.gov, or by telephone at (202) 208-2783.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the OSMRE; (2) is the estimate of burden accurate; (3) how might the OSMRE enhance the quality, utility, and clarity of the information to be collected; and (4) how might the OSMRE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before

including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title of Collection: Nomination and Request for Payment Form for OSMRE's National Technical Training Courses.

OMB Control Number: 1029-0120.

Abstract: The form is used to identify and evaluate the training courses requested by students to enhance their job performance, to calculate the number of classes and instructors needed to complete OSMRE's technical training mission, and to estimate costs to the training program.

Form Number: OSM-105.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal regulatory and reclamation employees.

Total Estimated Number of Annual Respondents: 944 respondents.

Total Estimated Number of Annual Responses: 944 responses.

Estimated Completion Time per Response: 120 hours.

Total Estimated Number of Annual Burden Hours: 79 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: \$0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Authority: The authorities for this action are the Surface Mining Control and Reclamation Act of 1977, as amended (30 U.S.C. 1201 *et seq.*), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2018-14895 Filed 7-11-18; 8:45 am]

BILLING CODE 4310-05-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-607 and 731-TA-1417 and 1419 (Preliminary)]

Steel Propane Cylinders From China and Thailand

Determinations

On the basis of the record¹ developed in the subject investigations, the United States International Trade Commission (“Commission”) determines, pursuant to the Tariff Act of 1930 (“the Act”), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of steel propane cylinders from China and Thailand that are alleged to be sold in the United States at less than fair value (“LTFV”) and imports of steel propane cylinders from China that are allegedly subsidized by the government of China.^{2,3} The products subject to these investigations are provided for in heading 7311.00.00 of the Harmonized Tariff Schedule of the United States.

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission’s rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission’s rules, upon notice from the U.S. Department of Commerce (“Commerce”) of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The

Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On May 22, 2018, Worthington Industries Inc., Columbus, Ohio, and Manchester Tank and Equipment, Franklin, Tennessee, filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of steel propane cylinders from China and LTFV imports of steel propane cylinders from China, Taiwan, and Thailand. Accordingly, effective May 22, 2018, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation No. 701-TA-607 and antidumping duty investigation Nos. 731-TA-1417-1419 (Preliminary). On June 14, 2018, petitioners withdrew the antidumping duty petition covering imports from Taiwan and the investigation was subsequently terminated.⁴

Notice of the institution of the Commission’s investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of May 29, 2018 (83 FR 24491). The conference was held in Washington, DC, on June 12, 2018, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on July 6, 2018. The views of the Commission are contained in USITC Publication 4804 (July 2018), entitled *Steel Propane Cylinders from China and Thailand: Investigation Nos. 701-TA-607 and 731-TA-1417 and 1419 (Preliminary)*.

By order of the Commission.

Issued: July 6, 2018.

Jessica Mullan,

Attorney-Advisor.

[FR Doc. 2018-14886 Filed 7-11-18; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731-TA-894 (Third Review)]

Ammonium Nitrate From Ukraine; Termination of Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission instituted the subject five-year review in May 2018 to determine whether revocation of the antidumping duty order on Ammonium Nitrate from Ukraine would be likely to lead to continuation or recurrence of material injury. On June 18, 2018, the Department of Commerce published notice that it was revoking the order effective June 12, 2018, because no domestic interested party filed a notice of intent to participate. Accordingly, the subject review is terminated.

DATES: June 29, 2018.

FOR FURTHER INFORMATION CONTACT:

Lawrence Jones (202-205-3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>).

Authority: This review is being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). This notice is published pursuant to section 207.69 of the Commission’s rules (19 CFR 207.69).

By order of the Commission.

Issued: July 6, 2018.

Jessica Mullan,

Attorney-Advisor.

[FR Doc. 2018-14883 Filed 7-11-18; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Oil Pollution Act

On July 5, 2018, the Department of Justice lodged a proposed Consent Decree with the United States District

¹ The record is defined in sec. 207.2(f) of the Commission’s Rules of Practice and Procedure (19 CFR 207.2(f)).

² *Steel Propane Cylinders from the People’s Republic of China, Taiwan, and Thailand: Initiation of Less-Than-Fair-Value Investigations*, 83 FR 28189, June 18, 2018; *Steel Propane Cylinders from China: Initiation of Countervailing Duty Investigation*, 83 FR 28196, June 18, 2018.

³ Commissioner Jason Kearns not participating.

⁴ *Steel Propane Cylinders from Taiwan: Termination of Less-Than-Fair-Value Investigation*, 83 FR 29748, June 26, 2018; *Steel Propane Cylinders from Taiwan: Termination of Investigation*, 83 FR 31174, July 3, 2018.

Court for the Eastern District of Louisiana in the lawsuit entitled *United States of America and Louisiana v. Shell Offshore Inc.*, Civil Action No. 2:18-cv-6495. The United States is acting at the request of the designated federal trustees: National Oceanic and Atmospheric Administration (“NOAA”) and the United States Department of the Interior (“DOI”) through the United States Fish and Wildlife Service. The State of Louisiana is acting through its designated State trustees: The Louisiana Oil Spill Coordinator’s Office, Department of Public Safety (“LOSCO”), Louisiana Department of Natural Resources (“LDNR”), Louisiana Department of Environmental Quality (“LDEQ”), Louisiana Department of Wildlife and Fisheries (“LDWF”), and the Coastal Protection and Restoration Authority (“CPRA”).

This is a civil action brought against Defendant Shell Offshore Inc. (“Shell”) for recovery of damages for injury to, destruction of, loss of, or loss of use of natural resources, under Section 1002 of the Oil Pollution Act (“OPA”), 33 U.S.C. 2702, and Section 2480 of the Louisiana Oil Spill Prevention and Response Act (“OSPRA”), La. Rev. Stat. 30:2480. The United States and Louisiana seek damages in order to compensate for and restore natural resources injured by Shell’s crude oil spill that occurred at Shell’s Green Canyon Block 248 subsea oil production system in the Gulf of Mexico beginning on or about May 11, 2016. The United States and the State also seek to recover unreimbursed costs of assessing such injuries.

The Complaint in this natural resource damages case was filed against Shell concurrently with the lodging of the proposed Consent Decree. The Complaint alleges that Shell is liable for damages under OPA and OSPRA. The Complaint alleges that Shell discharged crude oil into the Gulf of Mexico in May 2016 and that natural resources were injured as a result of the discharge.

Under the proposed Consent Decree, Shell will pay a total of \$3,871,169.54. Of this total, Shell will pay \$3.625 million to the trustees to restore, replace, or acquire the equivalent of the natural resources allegedly injured, destroyed, or lost as a result of the oil spill and \$246,169.54 to reimburse the trustees for all remaining unpaid assessment costs.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Acting Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America and Louisiana v.*

Shell Offshore Inc., D.J. Ref. No. 90–5–1–1–11920. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted by either email or by mail:

To submit comments:	Send them to:
By email	pubcomment-ees.enrd@usdoj.gov .
By mail	Acting Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>. We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for \$7.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Thomas Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2018–14907 Filed 7–11–18; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings; National Science Board

The National Science Board (NSB), pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of meetings for the transaction of NSB business as follows:

TIME AND DATE: Tuesday, July 17, 2018 from 8:00 a.m. to 4:45 p.m. and Wednesday, July 18, 2018, from 8:00 a.m. to 2:15 p.m. EDT.

PLACE: These meetings will be held at the NSF headquarters, 2415 Eisenhower Avenue, Alexandria, VA 22314.

Meetings are held in the boardroom on the 2nd floor. The public may observe public meetings held in the boardroom. All visitors must contact the Board Office (call 703–292–7000 or send an email to nationalsciencebrd@nsf.gov) at least 24 hours prior to the meeting and

provide your name and organizational affiliation. Visitors must report to the NSF visitor’s desk in the building lobby to receive a visitor’s badge.

STATUS: Some of these meetings will be open to the public. Others will be closed to the public. See full description below.

MATTERS TO BE CONSIDERED:

Tuesday, July 17, 2018

Plenary Board Meeting

Open Session: 8:00–8:25 a.m.

- NSB Chair’s Opening Remarks
- NSF Director’s Remarks
- Summary of DC Meetings

Committee on Oversight (CO)

Open Session: 8:25–9:15 a.m.

- Committee Chair’s Opening Remarks
- Approval of Prior Minutes
- Summary of Merit Review Retreat
- Presentation on Enterprise Risk Management
- Inspector General’s Update
- Chief Financial Officer’s Update

Committee on National Science and Engineering Policy (SEP)

Open Session: 9:15–10:05 a.m.

- Committee Chair’s Opening Remarks
- Approval of Prior Minutes
- Update on Future Indicators Project

Plenary Board

Open Session 10:15 a.m.–12:00 p.m.

Presentation and Panel Discussion—“Being Smart About Artificial Intelligence (AI)”

- Chair’s Opening Remarks and Introductions
- Presentation, Dr. Andrew Moore, Carnegie Mellon University
- Panel Presentations and Discussion
- Dr. Michael Jordan, University of California, Berkeley
- Dr. Daniela Rus, Massachusetts Institute of Technology
- Dr. Charles Isbell, Georgia Institute of Technology
- Dr. James Kurose, Assistant Director, Computer & Information Science & Engineering

Committee on Strategy (CS)

Open Session: 1:00–1:30 p.m.

- Committee Chair’s Opening Remarks
- Approval of Prior Minutes
- FY 2018 Appropriations and FY 2019 Budget Request Update
- Committee on Awards and Facilities (A&F)

Open Session: 1:30–2:00 p.m.

- Committee Chair's Opening

Remarks

- Approval of Prior Minutes
- CY 2018–2019 Schedule of Planned Action and Information Items

Update on the Status of Regional Class Research Vessel Construction

- Discussion of the Information Item/

Action Item Sequence

Committee on Awards and Facilities (A&F)

Closed Session: 2:00–4:45 p.m.

- Committee Chair's Opening

Remarks

- Approval of Prior Minutes
- Action Item: Leadership-Class

Computing Phase I Acquisition

Action Item: Seismological facility for the Advancement of GEosciences (SAGE) Operations & Maintenance Award

Action Item: Geodetic facility for the Advancement of GEosciences (GAGE) Operations & Maintenance Award

Action Item: Candidate MREFC-funded Upgrades of the ATLAS and CMS Detectors at the Large Hadron Collider

Information Item: Astronomy Facility Transitions

MATTERS TO BE DISCUSSED:

Wednesday, July 18, 2018

Committee on External Engagement (EE)

Open Session: 8:00–8:50 a.m.

- Committee Chair's Opening

Remarks

- Approval of Prior Minutes
- Listening Session Report
- NSB Alumni Network
- Congressional Engagement Plan

Task Force on the Skilled Technical Workforce (STW)

Open Session: 8:50–9:30 a.m.

- Chair's Opening Remarks
- Approval of Prior Minutes
- Update and Discussion on

Stakeholder Meetings

Discussion of Focus Areas for the Task Force

Committee on Strategy (CS)

Closed Session: 9:30–10:30 a.m.

- Committee Chair's Opening

Remarks

- Approval of Prior Minutes
- FY 2020 Budget Discussion

Plenary Board

Closed Session: 10:45–11:35 a.m.

- Board Chair's Opening Remarks
- Director's Remarks

- Approval of Prior Minutes
- Closed Committee Reports
- Midscale Research Infrastructure

Report

- Vote: ATLAS and CMS Upgrades
- Vote: GAGE O&M
- Vote: SAGE O&M
- Vote: Leadership-Class Computing Phase I Acquisition

Vote: Contract Services for Arctic Research Support and Logistics

Plenary Board (Executive)

Closed Session: 11:35–11:50 a.m.

- Board Chair's Opening Remarks
- Approval of Prior Minutes
- Director's Remarks

Plenary Board

Open Session: 11:50 a.m.–2:15 p.m.

Board Chair's Opening Remarks
Introduction of Presentation on the National Academies and Board of International Scientific Organizations (Break for lunch from 12:20–1:15 p.m.)

- Board Chair's Opening Remarks
- NSF Director's Remarks
- Approval of Prior Minutes
- Vote: NSB Calendar for CY 2019
- Open Committee Reports
- NSF INCLUDES Presentation
- Board Chair's Closing Remarks

Meeting Adjourns: 2:15 p.m.

MEETINGS THAT ARE OPEN TO THE PUBLIC:

Tuesday, July 17, 2018

8:00–8:25 a.m. Plenary NSB

Introduction

8:20–9:15 a.m. Committee on Oversight (CO)

9:15–10:05 a.m. Committee on Science & Engineering Policy (SEP)

10:15 a.m.– 12:00 p.m. Plenary Panel on Artificial Intelligence

1:00–1:30 p.m. Committee on Strategy (CS)

1:30–2:00 p.m. Committee on Awards & Facilities (A&F)

Wednesday, July 18, 2018

8:00–8:50 a.m. Committee on External Engagement (EE)

8:50–9:30 a.m. Task Force on Skilled Technical Workforce (STW)

11:50 a.m.–2:15 p.m. Plenary (break for lunch from 12:20–1:15 p.m.)

MEETINGS THAT ARE CLOSED TO THE PUBLIC:

Tuesday, July 17, 2018

2:00–4:45 p.m. (A&F)

Wednesday, July 18, 2018

9:30–10:30 a.m. (CS)

10:45–11:35 a.m. Plenary

11:35–11:50 a.m. Plenary Executive

CONTACT PERSONS FOR MORE

INFORMATION: The NSB Office contact is Brad Gutierrez, bgutierrez@nsf.gov, 703–292–7000. The NSB Public Affairs contact is Nadine Lynn, nlynn@nsf.gov, 703–292–2490.

SUPPLEMENTAL INFORMATION: Public meetings and public portions of meetings held in the 2nd floor boardroom will be webcast. To view these meetings, go to: <http://www.tvworldwide.com/events/nsf/180717> and follow the instructions. The public may observe public meetings held in the boardroom. The address is 2415 Eisenhower Avenue, Alexandria, VA, 22314.

Please refer to the NSB website for additional information. You will find any updated meeting information and schedule updates (time, place, subject matter, or status of meeting) at <https://www.nsf.gov/nsb/meetings/notices.jsp#sunshine>.

The NSB will continue its program to provide some flexibility around meeting times. After the first meeting of each day, actual meeting start and end times will be allowed to vary by no more than 15 minutes in either direction. As an example, if a 10:00 meeting finishes at 10:45, the meeting scheduled to begin at 11:00 may begin at 10:45 instead. Similarly, the 10:00 meeting may be allowed to run over by as much as 15 minutes if the Chair decides the extra time is warranted. The next meeting would start no later than 11:15. Arrive at the NSB boardroom or check the webcast 15 minutes before the scheduled start time of the meeting you wish to observe.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2018–14984 Filed 7–10–18; 11:15 am]

BILLING CODE 7555–01–P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Notice of a Modified System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Occupational Safety and Health Review Commission (OSHR) is revising the notice for Privacy Act system-of-records OSHRC–3.

DATES: Comments must be received by OSHRC on or before August 13, 2018.

The revised system of records will become effective on that date, without any further notice in the **Federal Register**, unless comments or government approval procedures necessitate otherwise.

ADDRESSES: You may submit comments by any of the following methods:

- *Email:* rbailey@oshrc.gov. Include "PRIVACY ACT SYSTEM OF RECORDS" in the subject line of the message.

- *Fax:* (202) 606-5417.

- *Mail:* One Lafayette Centre, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457.

- *Hand Delivery/Courier:* Same as mailing address.

Instructions: All submissions must include your name, return address, and email address, if applicable. Please clearly label submissions as "PRIVACY ACT SYSTEM OF RECORDS."

FOR FURTHER INFORMATION CONTACT: Ron Bailey, Attorney-Advisor, Office of the General Counsel, via telephone at (202) 606-5410, or via email at rbailey@oshrc.gov.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, 5 U.S.C. 552a(e)(4), requires federal agencies such as OSHRC to publish in the **Federal Register** notice of any new or modified system of records. As detailed below, OSHRC is revising Public Transportation Benefit Program Records, OSHRC-3, to revise the system's name; account for changes in the names of the pertinent office and positions within the agency; revise the categories of records maintained; and update the reference to the applicable General Records Schedule for disposal of records. In addition, OSHRC in the past has relied on blanket routine uses to describe the circumstances under which records may be disclosed. Going forward, as revised notices are published for new and modified systems of records, a full description of the routine uses—rather than a reference to blanket routine uses—will be included in each notice. This is simply a change in format, however, and has not resulted in any substantive changes to the routine uses for this system of records.

The notice for OSHRC-3, provided below in its entirety, is as follows.

SYSTEM NAME AND NUMBER

Transportation Subsidy Program Records, OSHRC-3.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of the Executive Director, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457; Atlanta Office, 100 Alabama Street, Room 2R90, Atlanta, GA 30303-3104.

SYSTEM MANAGER(S):

Support Services Specialist, Office of the Executive Director, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457; (202) 606-5100. Lead Legal Assistant, Atlanta Office, 100 Alabama Street, Room 2R90, Atlanta, GA 30303-3104; (404) 562-1640.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

29 U.S.C. 661; Executive Order 13150.

PURPOSE(S) OF THE SYSTEM:

This system of records is maintained for the purpose of documenting an employee's participation in the Transportation Subsidy Program.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records covers all current and former employees who are, or were, enrolled in the Transportation Subsidy Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records includes information submitted by current and former participants via the OSHRC Transportation Subsidy Program Application. This form contains the employee's name and home address. The system also contains a Pre-tax Transportation Program Application which includes the employee's name and the last four digits of his or her social security number. Lastly, the system includes a SmartTrip form with the employee's name.

RECORD SOURCE CATEGORIES:

Information in this system of records comes from applicants to, and current and former participants in, the Transportation Subsidy Program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

(1) To the Department of Justice (DOJ), or to a court or adjudicative body before

which OSHRC is authorized to appear, when any of the following entities or individuals—(a) OSHRC, or any of its components; (b) any employee of OSHRC in his or her official capacity; (c) any employee of OSHRC in his or her individual capacity where DOJ (or OSHRC where it is authorized to do so) has agreed to represent the employee; or (d) the United States, where OSHRC determines that litigation is likely to affect OSHRC or any of its components—is a party to litigation or has an interest in such litigation, and OSHRC determines that the use of such records by DOJ, or by a court or other tribunal, or another party before such tribunal, is relevant and necessary to the litigation.

(2) To an appropriate agency, whether federal, state, local, or foreign, charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes civil, criminal or regulatory violations, and such disclosure is proper and consistent with the official duties of the person making the disclosure.

(3) To a federal, state, or local agency maintaining civil, criminal or other relevant enforcement information, such as current licenses, if necessary to obtain information relevant to an OSHRC decision concerning the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit.

(4) To a federal, state, or local agency, in response to that agency's request for a record, and only to the extent that the information is relevant and necessary to the requesting agency's decision in the matter, if the record is sought in connection with the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit by the requesting agency.

(5) To an authorized appeal grievance examiner, formal complaints manager, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee, only to the extent that the

information is relevant and necessary to the case or matter.

(6) To OPM in accordance with the agency's responsibilities for evaluation and oversight of federal personnel management.

(7) To officers and employees of a federal agency for the purpose of conducting an audit, but only to the extent that the record is relevant and necessary to this purpose.

(8) To OMB in connection with the review of private relief legislation at any stage of the legislative coordination and clearance process, as set forth in Circular No. A-19.

(9) To a Member of Congress or to a person on his or her staff acting on the Member's behalf when a written request is made on behalf and at the behest of the individual who is the subject of the record.

(10) To the National Archives and Records Administration (NARA) for records management inspections and such other purposes conducted under the authority of 44 U.S.C. 2904 and 2906.

(11) To appropriate agencies, entities, and persons when: (a) OSHRC suspects or has confirmed that there has been a breach of the system of records; (b) OSHRC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, OSHRC, the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OSHRC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(12) To NARA, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with FOIA, and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

(13) To another federal agency or federal entity, when OSHRC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(14) To other federal agencies to effect salary or administrative offsets, or for

other purposes connected with the collection of debts owed to the United States, pursuant to sections 5 and 10 of the Debt Collection Act of 1982, as amended by the Debt Collection Improvement Act of 1996.

(15) To other federal, state, local or foreign agencies conducting computer matching programs to help eliminate fraud and abuse and to detect unauthorized overpayments made to individuals. When disclosures are made as part of computer matching programs, OSHRC will comply with the Computer Matching and Privacy Protection Act of 1988, and the Computer Matching and Privacy Protections Amendments of 1990.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored on paper in locked file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Paper records can be retrieved manually by name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained and disposed of in accordance with NARA's General Records Schedule 2.4, Items 130 and 131.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper records are maintained in locked file cabinets. Access to the cabinets is limited to personnel having a need for access to perform their official functions.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.6 (procedures for requesting records).

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036-3457. For an explanation on the specific procedures for contesting the contents of a record, refer to 29 CFR 2400.8 (Procedures for requesting amendment), and 29 CFR 2400.9 (Procedures for appealing).

NOTIFICATION PROCEDURES:

Individuals interested in inquiring about their records should notify: Privacy Officer, OSHRC, 1120 20th

Street NW, Ninth Floor, Washington, DC 20036-3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.5 (notification), and 29 CFR 2400.6 (procedures for requesting records).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

April 14, 2006, 71 FR 19556; August 4, 2008, 73 FR 45256; October 5, 2015, 80 FR 60182; and September 28, 2017, 82 FR 45324.

Dated: July 5, 2018.

Nadine N. Mancini,

General Counsel, Senior Agency Official for Privacy.

[FR Doc. 2018-14878 Filed 7-11-18; 8:45 am]

BILLING CODE 7600-01-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2018-190 and CP2018-264]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 13, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

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- I. Introduction
- II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the

modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s)*: MC2018-190 and CP2018-264; *Filing Title*: USPS Request to Add Priority Mail Express & Priority Mail Contract 70 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: July 5, 2018; *Filing Authority*: 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative*: Christopher C. Mohr, *Comments Due*: July 13, 2018.

This Notice will be published in the **Federal Register**.

Ruth Ann Abrams,
Acting Secretary.

[FR Doc. 2018-14877 Filed 7-11-18; 8:45 am]

BILLING CODE 7710-FW-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15580 and #15581; NEBRASKA Disaster Number NE-00070]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Nebraska

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Nebraska (FEMA-4375-DR), dated 06/29/2018.

Incident: Severe Winter Storm and Straight-line Winds.

Incident Period: 04/13/2018 through 04/18/2018.

DATES: Issued on 06/29/2018.

Physical Loan Application Deadline Date: 08/28/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 03/29/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 06/29/2018, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Antelope, Blaine, Boone, Boyd, Cheyenne, Clay, Custer, Deuel, Fillmore, Garfield, Gosper, Greeley, Hall, Hamilton, Holt, Howard, Keith, Knox, Logan, Loup, Madison, Merrick, Nance, Nuckolls, Pierce, Platte, Rock, Sherman, Valley, Webster, Wheeler.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations With Credit Available Elsewhere ...	2.500
Non-Profit Organizations Without Credit Available Elsewhere	2.500
<i>For Economic Injury:</i>	
Non-Profit Organizations Without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 15580B and for economic injury is 155810. (Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,
Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2018-14932 Filed 7-11-18; 8:45 am]

BILLING CODE 8025-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2018-38]

Petition for Exemption; Summary of Petition Received; 3GLP, Inc. dba Precision Flight Devices

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 1, 2018.

ADDRESSES: Send comments identified by docket number FAA-2018-0325 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments,

without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683-7788, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Lirio Liu,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2018-0325.

Petitioner: 3GLP, Inc. dba Precision Flight Devices.

Section(s) of 14 CFR Affected: Part 21, subpart H; part 27; 45.23(b); 45.27(a); 61.113; 91.7(a); 91.9(b)(2); 91.9(c); 91.103; 91.109(a); 91.119; 91.121; 91.151(a); 91.203(a) & (b); 91.405(a); 91.407(a)(1); 91.409(a)(1) & (2); 91.417(a) & (b).

Description of Relief Sought: The petitioner is requesting relief to commercially operate a CW-30, hybrid fixed wing and vertical takeoff and land multi-copter, unmanned aircraft (UA) that weighs more than 55 pounds (lbs.). The proposed operation would allow the petitioner to conduct aerial data collection to include remote sensing and measuring by an instrument or combination of instruments aboard the UA. Specifically, Precision Flight Devices intends to operate the UA at less than 30 miles per hour with a maximum takeoff weight of 75 lbs. The operations would be conducted within visual line of sight over a 15.56 square mile area situated at and around Kiana and Nulato airfields (8 square miles per airport) in Western Alaska. The collection of UA high resolution data and images may require operations as close as 200 feet from non-participating persons.

[FR Doc. 2018-14913 Filed 7-11-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2018-57]

Petition for Exemption; Summary of Petition Received; NextEra Energy, Inc.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before August 1, 2018.

ADDRESSES: Send comments identified by docket number FAA-2018-0225 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200

New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683-7788, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Lirio Liu,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2018-0225.

Petitioner: NextEra Energy, Inc.

Section(s) of 14 CFR Affected:

§§ 61.23(a) & (c); 61.101(e)(4) & (5); 61.113(a); 61.315(a); 91.7(a), 91.105(a)(2), 91.119(c); 91.121; 91.151(a)(1); 91.403(b); 91.405(a); 91.407(a)(1); 91.409(a)(1) & (2); 91.417(a) & (b).

Description of Relief Sought: The petitioner proposes to operate unmanned aircraft systems, weighing more than 55 pounds, for aerial data collection operations, including support of storm response. The operations will be within visual line of site of the pilot or visual observer, under 400 feet, and at speeds at or less than 100 miles an hour.

[FR Doc. 2018-14912 Filed 7-11-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Subordinated Debt Licensing Requirements

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of its

information collection titled, “Subordinated Debt Licensing Requirements.” The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before August 13, 2018.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.
- *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557-0320, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Fax:* (571) 465-4326.

Instructions: You must include “OCC” as the agency name and “1557-0320” in your comment. In general, the OCC will publish your comment on www.reginfo.gov without change, including any business or personal information that you provide, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557-0320, U.S. Office of Management and Budget, 725 17th Street NW, #10235, Washington, DC 20503 or by email to oir_submission@omb.eop.gov.

You may review comments and other related materials that pertain to this information collection¹ following the close of the 30-day comment period for this notice by any of the following methods:

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Click on the “Information Collection Review” tab. Underneath the “Currently under Review” section heading, from the drop-down menu, select “Department of Treasury” and then click “submit.” This information collection can be located by searching by OMB control number “1557-0320” or “Subordinated Debt Licensing Requirements.” Upon finding the appropriate information collection, click on the related “ICR Reference Number.” On the next screen, select

“View Supporting Statement and Other Documents” and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482-7340.

- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649-6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649-5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: OCC Clearance Officer, (202) 649-5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649-5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks OMB to extend its approval of the following collection.

Title: Subordinated Debt Licensing Requirements.

OMB Control No.: 1557-0320.

Frequency of Response: On occasion.

Affected Public: Business or other for-profit.

Burden Estimates:

Prepayment of Subordinated Debt in Form of Call Option: 184 Respondents; 1.30 burden hours per respondent; 239 total burden hours.

Authority to Limit Distributions: 42 Respondents; 0.5 hours per respondent; 21 total burden hours.

Total Burden: 260 hours.

Description: The scope of this Information Collection Renewal is limited to the following: (1) The 12 CFR 5.47(g) and 12 CFR 5.56(b) requirements that national banks and federal savings associations (collectively, “institutions”) apply for OCC approval prior to prepaying subordinated debt if the prepayment is in the form of a call option and (2) the 12 CFR 5.47(d) requirement that national banks issuing

subordinated debt disclose the OCC’s authority under 12 CFR 3.11 to limit distributions.

National banks must receive prior OCC approval in order to prepay subordinated debt that is included in tier 2 capital, and certain banks must receive prior approval to prepay subordinated debt that is not included in tier 2 capital. If the prepayment is in the form of a call option, a national bank must submit the information required for general prepayment requests under 12 CFR 5.47(g)(1)(ii)(A) and also comply with 12 CFR 5.47(g)(1)(ii)(B)(2), which requires a national bank to submit either: (1) A statement explaining why the bank believes that following the proposed prepayment the bank would continue to hold an amount of capital commensurate with its risk or (2) a description of the replacement capital instrument that meets the criteria for tier 1 or tier 2 capital under 12 CFR 3.20, including the amount of such instrument and the time frame for issuance.

Federal savings associations must receive OCC approval prior to prepaying subordinated debt securities or mandatorily redeemable preferred stock included in tier 2 capital. If the prepayment is in the form of a call option, a federal savings association must submit the information required for general prepayment requests under 12 CFR 5.56(b)(2)(i) and also comply with 12 CFR 5.56(b)(2)(ii)(A), which requires a federal savings association to submit either: (1) A statement explaining why the federal savings association believes that following the proposed prepayment the savings association would continue to hold an amount of capital commensurate with its risk or (2) a description of the replacement capital instrument that meets the criteria for tier 1 or tier 2 capital under 12 CFR 3.20, including the amount of such instrument and the time frame for issuance.

Pursuant to 12 CFR 5.47(d)(3)(ii)(C), a national bank issuing subordinated debt must disclose on the face of the note the OCC’s authority under 12 CFR 3.11 to limit distributions, including interest payments on any tier 2 capital instrument if the national bank has full discretion to permanently or temporarily suspend such payments without triggering an event of default.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

- (a) Whether the collections of information are necessary for the proper

¹ On April 3, 2018, the OCC published a 60-day notice for this information collection; no public comments were received.

performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology.

Dated: July 6, 2018.

Karen Solomon,

Acting First Deputy Comptroller and Chief Counsel.

[FR Doc. 2018-14941 Filed 7-11-18; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Open Meeting of the Financial Research Advisory Committee

AGENCY: Office of Financial Research, Department of the Treasury.

ACTION: Notice of open meeting; time change.

SUMMARY: The Financial Research Advisory Committee for the Treasury's Office of Financial Research (OFR) previously announced its 12th meeting to be held on Thursday, July 26, 2018, in the Benjamin Strong Room, Federal Reserve Bank of New York, 33 Liberty Street, New York, New York, 10045, beginning at 11:00 a.m. Eastern Time. By this notice, the OFR is changing the start time for the meeting to 1:00 p.m. Eastern Time. The meeting will be open to the public and limited seating will be available.

DATES: The meeting will be held on Thursday, July 26, 2018, beginning at 1:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held in the Benjamin Strong Room, Federal Reserve Bank of New York, 33 Liberty Street, New York, New York, 10045. The meeting will be open to the public. A limited number of seats will be available for those interested in attending the meeting, and those seats would be on a first-come, first-served basis. Because the meeting will be held in a secured facility, members of the public who plan to attend the meeting **MUST** contact the OFR by email at OFR_FRAC@ofr.treasury.gov by 5 p.m. ET on Thursday, July 19, 2018, to inform the OFR of their desire to attend the meeting and receive further instructions about building clearance.

FOR FURTHER INFORMATION CONTACT:

Melissa Avstreich, Designated Federal Officer, Office of Financial Research, Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, (202) 927-8032 (this is not a toll-free number), or OFR_FRAC@ofr.treasury.gov. Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION: On July 2, 2018 (83 FR 31035), the OFR announced the 12th meeting of the Financial Research Advisory Committee. The OFR has had to change the start time for the meeting until 1:00 p.m. Eastern Time. All other information in the notice is unchanged, including the location and tentative agenda/topics for discussion.

Dated: July 3, 2018.

Barbara Shycoff,

Chief of External Affairs.

[FR Doc. 2018-14949 Filed 7-11-18; 8:45 am]

BILLING CODE 4810-25-P

DEPARTMENT OF VETERANS AFFAIRS

Creating Options for Veterans Expedited Recovery (COVER) Commission; Notice of Meeting

In accordance with the Federal Advisory Committee Act, the Creating Options for Veterans Expedited Recovery (COVER) Commission gives notice that the first meeting will be held on July 24 and July 25, 2018 at the Capital Hilton, 1001 16th Street NW, Washington, DC. The meeting will convene at 8:00 a.m. and adjourn at 5:00 p.m. EST on July 24 and July 25. The meeting will be partially closed to the public on July 24, 2018 and July 25, 2018. In accordance with 5 U.S.C. 552b(c)(2) and (6), which exempt a meeting from the requirement to be open to the public, the meeting will be closed on July 24 from 8:00 a.m. to 12:00 p.m. because it is likely to "relate solely to the internal personnel rules and practices of an agency" or "disclose . . . information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy." On July 25, the meeting will be closed from 12:00 p.m. to 5:00 p.m. under section 552b(c)(9)(B) because it would reveal information the disclosure of which would, "in the case of an agency, be likely to significantly frustrate implementation of a proposed agency action." This closed session will include discussion of ground rules, decision making protocol, and strategy

to establish ground rules. Any precipitous release of those discussions through an open session will frustrate program implementation, to the detriment of our Veterans who we consider our greatest customer/benefactor of the commission.

Open sessions will be held on both days in Capital Hilton's South American AB room. The open session on Day 1 will focus current VHA Whole Health Practices, VA's Mental Health Services and Resources. The open session Day 2 will include review and discussion of the objectives of the Commission as described in the Comprehensive Addiction and Recovery Act (CARA) of 2016. A listening line will be available to the public who prefer to call in rather than attend the open sessions at the Capital Hilton. This listening line number will be activated 10 minutes before each of the two open sessions. The listening line number is 800-767-1750; access code 48664#.

The purpose of the COVER Commission is to examine the evidence-based therapy treatment model used by the Department of Veterans Affairs (VA) for treating mental health conditions of Veterans and the potential benefits of incorporating complementary and integrative health approaches as standard practice throughout the Department. The Commission will: (1) Examine the efficacy of the evidence-based therapy model used by VA to treat mental health illnesses and identify areas of improvement; (2) conduct a patient-centered survey within each VISN to examine: The experiences of veterans with VA facilities regarding mental health care, the experiences of veterans with non-VA facilities regarding mental health care, the preferences of veterans regarding available treatment for mental health issues and which methods the veterans believe to be most effective, the experience, if any, of veterans with respect to complementary and integrative health approaches, the prevalence of prescribing medication to veterans seeking treatment for mental health disorders through VA, and the outreach efforts of VA regarding the availability of benefits and treatments for veterans for addressing mental health issues; (3) examine available research on complementary and integrative health approaches for mental health disorders in areas of therapy including: Music therapy, equine therapy, training and caring for service dogs, yoga therapy, acupuncture therapy, meditation therapy, outdoor sports therapy, hyperbaric oxygen therapy, accelerated resolution therapy, art therapy, magnetic resonance therapy,

and others; (4) study the sufficiency of VA resources to deliver quality mental health care; and (5) study the current treatments and resources available within VA and assess: The effectiveness of such treatments and resources in decreasing the number of suicides per day by veterans, the number of veterans who have been diagnosed with mental health issues, the percentage of veterans who have completed VA counseling sessions, and the efforts of VA to expand complementary and integrative

health treatments viable to the recovery of veterans with mental health issues as determined by the Secretary to improve the effectiveness of treatments offered by VA.

Any member of the public seeking additional information should email [COVER Commission@va.gov](mailto:COVER_Commission@va.gov). The Designated Federal Officer for the Commission is Ms. Sheila B. Hickman. Ms. Hickman and the staff will be monitoring and responding to questions or comments sent to this email box. The

Committee will also accept written comments which may be sent to the same email box. In the public's communications with the Committee, the writers must identify themselves and state the organizations, associations, or persons they represent.

Dated: July 9, 2018.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2018-14936 Filed 7-11-18; 8:45 am]

BILLING CODE P



FEDERAL REGISTER

Vol. 83

Thursday,

No. 134

July 12, 2018

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 484, et al.

Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 484, 486, and 488

[CMS-1689-P]

RIN 0938-AT29

Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the home health prospective payment system (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor, effective for home health episodes of care ending on or after January 1, 2019. It also proposes updates to the HH PPS case-mix weights for calendar year (CY) 2019 using the most current, complete data available at the time of rulemaking; discusses our efforts to monitor the potential impacts of the rebasing adjustments that were implemented in CYs 2014 through 2017; proposes a rebasing of the HH market basket (which includes a decrease in the labor-related share); proposes the methodology used to determine rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the Bipartisan Budget Act of 2018 hereinafter referred to as the “BBA of 2018”; proposes regulations text changes regarding certifying and recertifying patient eligibility for Medicare home health services; and proposes to define “remote patient monitoring” and recognize the cost associated as an allowable administrative cost. Additionally, it proposes case-mix methodology refinements to be implemented for home health services beginning on or after January 1, 2020, including a change in the unit of payment from 60-day episodes of care to 30-day periods of care, as required by section 51001 of the BBA of 2018; includes information

on the implementation of temporary transitional payments for home infusion therapy services for CYs 2019 and 2020, as required by section 50401 of the BBA of 2018; solicits comments regarding payment for home infusion therapy services for CY 2021 and subsequent years; proposes health and safety standards for home infusion therapy; and proposes an accreditation and oversight process for home infusion therapy suppliers. This rule proposes changes to the Home Health Value-Based Purchasing (HHVBP) Model to remove two OASIS-based measures, replace three OASIS-based measures with two new proposed composite measures, rescore the maximum number of improvement points, and reweight the measures in the applicable measures set. Also, the Home Health Quality Reporting Program provisions include a discussion of the Meaningful Measures Initiative and propose the removal of seven measures to further the priorities of this initiative. In addition, the HH QRP offers a discussion on social risk factors and an update on implementation efforts for certain provisions of the IMPACT Act. This proposed rule clarifies the regulatory text to note that not all OASIS data is required for the HH QRP. Finally, it would require that accrediting organization surveyors take CMS-provided training.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS-1689-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1689-P, P.O. Box 8013, Baltimore, MD 21244-8013. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human

Services, Attention: CMS-1689-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to: HomehealthPolicy@cms.hhs.gov.

For general information about home infusion payment, send your inquiry via email to: HomeInfusionPolicy@cms.hhs.gov.

For information about the Home Health Value-Based Purchasing (HHVBP) Model, send your inquiry via email to: HHVBPquestions@cms.hhs.gov.

For information about the Home Health Quality Reporting Program (HH QRP) contact: Joan Proctor, (410) 786-0949.

For information about home infusion therapy health and safety standards, contact: Sonia Swancy, (410) 786-8445 or CAPT Jacqueline Leach, (410) 786-4282.

For information about health infusion therapy accreditation and oversight, contact: Caroline Gallaher (410) 786-8705.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

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I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This proposed rule would update the payment rates for home health agencies (HHAs) for calendar year (CY) 2019, as required under section 1895(b) of the Social Security Act (the Act). This proposed rule would also update the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for CY 2019. For home health services beginning on or after January 1, 2020, this rule proposes case-mix methodology refinements, which eliminate the use of therapy thresholds for case-mix adjustment purposes; and proposes to change the unit of payment from a 60-day episode of care to a 30-day period of care, as mandated by section 51001 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) (hereinafter referred to as the “BBA of 2018”). This proposed rule also: Proposes the methodology used to determine rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the BBA of 2018; proposes regulations text changes regarding certifying and recertifying patient eligibility for Medicare home health services under sections 1814(a) and 1835(a) of the Act; and proposes to define “remote patient monitoring” under the Medicare home health benefit and to include the costs of such monitoring as an allowable administrative cost. Lastly, this rule proposes changes to the Home Health Value Based Purchasing (HHVBP) Model under the authority of section 1115A of the Act, and the Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act.

2. Home Infusion Therapy Services

This proposed rule would establish a transitional payment for home infusion therapy services for CYs 2019 and 2020, as required by section 50401 of the BBA of 2018. In addition, this rule proposes health and safety standards for home

infusion therapy, proposes an accreditation and oversight process for qualified home infusion therapy suppliers, and solicits comments regarding payment for the home infusion therapy services benefit for CY 2021 and subsequent years, as required by section 5012 of the 21st Century Cures Act (Pub. L. 114–255).

3. Safety Standards for Home Infusion Therapy Services

This proposed rule would establish health and safety standards for qualified home infusion therapy suppliers as required by Section 5012 of the 21st Century Cures Act. These proposed standards would establish a foundation for ensuring patient safety and quality care by establishing requirements for the plan of care to be initiated and updated by a physician; 7-day-a-week, 24-hour-a-day access to services and remote monitoring; and patient education and training regarding their home infusion therapy care.

B. Summary of the Major Provisions

1. Home Health Prospective Payment System (HH PPS)

Section III.A. of this rule discusses our efforts to monitor for potential impacts due to the rebasing adjustments implemented in CY 2014 through CY 2017, as mandated by section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted March 23, 2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010), collectively referred to as the “Affordable Care Act”. In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with the most current and complete data available at the time of rulemaking. In section III.B of this rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner. In section III.C., we propose to rebase the home health market basket and update the payment rates under the HH PPS by the home health payment update percentage of 2.1 percent (using the proposed 2016-based Home Health Agency (HHA) market basket update of 2.8 percent, minus 0.7 percentage point for multifactor productivity) as required by section 1895(b)(3)(B)(vi)(I) of the Act. Also in section III.C. of this proposed rule, we propose to decrease the labor-related share from 78.5 to 76.1 percent of total costs on account of the rebasing of the home health market basket. Lastly, in

section III.C. of this rule, we propose to update the CY 2019 home health wage index using FY 2015 hospital cost report data. In section III.D. of this proposed rule, we are proposing a new methodology for applying rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the BBA of 2018. In section III.E. of this rule, we are proposing to reduce the fixed-dollar loss ratio from 0.55 to 0.51 for CY 2019 in order to increase outlier payments as a percentage of total payments so that this percentage is closer to, but no more than, 2.5 percent.

In the CY 2018 HH PPS proposed rule, CMS proposed an alternative case-mix model, called the Home Health Groupings Model (HHGM). Ultimately the HHGM, including a proposed change in the unit of payment from 60 days to 30 days, was not finalized in the CY 2018 HH PPS final rule in order to allow CMS additional time to consider public comments for potential refinements to the model and other alternative case-mix models (82 FR 51676). In section III.F. of this proposed rule, we are again proposing to implement case-mix methodology refinements and a change in the unit of payment from a 60-day episode of care to a 30-day period of care; however, these changes would be effective January 1, 2020 and would be implemented in a budget neutral manner, as required by section 51001 of the BBA of 2018. Since the proposed case-mix methodology refinements represent a more patient-driven approach to payment we are renaming the proposed case-mix adjustment methodology refinements, formerly known as the Home Health Groupings Model or “HHGM”, as the “Patient-Driven Groupings Model” or PDGM. The proposed PDGM relies more heavily on clinical characteristics and other patient information to place patients into meaningful payment categories and eliminates the use of therapy service thresholds, as required by section 51001(a)(3) of the BBA of 2018, that are currently used to case-mix adjust payments under the HH PPS. There is also a proposal regarding how CMS would determine whether 30-day periods of care are subject to a Low-Utilization Payment Adjustment (LUPA). The LUPA add-on policy, the partial episode payment adjustment policy, and the methodology used to calculate payments for high-cost outliers would remain unchanged except for occurring on a 30-day basis rather than a 60-day basis.

In section III.G. of this proposed rule, we are proposing regulation text changes at 42 CFR 424.22(b)(2) to

eliminate the requirement that the certifying physician must estimate how much longer skilled services will be needed as part of the recertification statement. In addition, in section III.G of this rule, consistent with section 51002 of the BBA of 2018, we are proposing to align the regulations text at 42 CFR 424.22(c) with current subregulatory guidance to allow medical record documentation from the HHA to be used to support the basis for certification and/or recertification of home health eligibility, if certain requirements are met.

In section III.H. of this proposed rule, we propose to define “remote patient monitoring” under the Medicare home health benefit as the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA. Additionally in this section of the rule, we propose changes to the regulations at 42 CFR 409.46 to include costs of remote patient monitoring as allowable administrative costs.

2. Home Health Value Based Purchasing

In section IV of this proposed rule, we are proposing changes to the Home Health Value Based Purchasing (HHVBP) Model implemented January 1, 2016. We are proposing, beginning with performance year (PY) 4, to: Remove two Outcome and Assessment Information Set (OASIS) based measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures; replace three OASIS-based measures (Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing) with two proposed composite measures on total normalized composite change in self-care and mobility; change how we calculate the Total Performance Scores by changing the weighting methodology for the OASIS-based, claims-based, and HHCAHPS measures; and change the scoring methodology by reducing the maximum amount of improvement points an HHA could earn, from 10 points to 9 points. While we are not making a specific proposal at this time, we are also providing an update on the progress towards developing public reporting of performance under the HHVBP Model and seeking comment on what information should be made publicly available.

3. Home Health Quality Reporting Program

In section V. of this proposed rule, we are proposing to update our policy for removing previously adopted Home Health (HH) Quality Reporting Program (QRP) measures and to adopt eight measure removal factors to align with other QRPs, to remove seven measures beginning with the CY 2021 HH QRP, and to update our regulations to clarify that not all OASIS data is required for the HH QRP. We are also providing an update on the implementation of certain provisions of the IMPACT Act, and a discussion of accounting for social risk factors in the HH QRP. Finally, we are proposing to increase the number of years of data used to calculate the Medicare Spending per Beneficiary measure for purposes of display from 1 year to 2 years.

4. Home Infusion Therapy

In section VI.A. of this proposed rule, we discuss general background of home infusion therapy services and how that will relate to the implementation of the new home infusion benefit. In section VI.B. of this proposed rule, we are proposing to add a new subpart I under the regulations at 42 CFR part 486 to incorporate health and safety requirements for home infusion therapy suppliers. The proposed regulations would provide a framework for CMS to approve home infusion therapy accreditation organizations. Proposed subpart I would include General Provisions (Scope and Purpose, and Definitions) and Standards for Home Infusion Therapy (Plan of Care and Required Services). In section VI.C. of this proposed rule, we include information on temporary transitional payments for home infusion therapy services for CYs 2019 and 2020 as mandated by section 50401 of the BBA of 2018, and solicits comments on the proposed regulatory definition of “Infusion Drug Administration Calendar Day”. Also in section VI.C. of this proposed rule, we solicit comments regarding payment for home infusion therapy services for CY 2021 and subsequent years as required by section 5012(d) of the 21st Century Cures Act.

In section VI.D. of this proposed rule, we discuss the requirements set forth in section 1861(iii)(3)(D)(III) of the Act, which mandates that suppliers of home infusion therapy receive accreditation from a CMS-approved Accrediting Organization (AO) in order to receive Medicare payment. The Secretary must designate AOs to accredit suppliers furnishing Home Infusion therapy (HIT) not later than January 1, 2021. Qualified

HIT suppliers are required to receive accreditation before receiving Medicare payment for services provided to Medicare beneficiaries.

At this time, no regulations exist to address the following elements of CMS' approval and oversight of the AOs that accredit suppliers of Home Infusion Therapy: (1) The required components to be included in a Home Infusion Therapy AO's initial or renewal accreditation program application; (2) regulations related to CMS' review and approval of the Home Infusion Therapy AOs application for approval of its accreditation program; and (3) the ongoing monitoring and oversight of CMS-approved Home Infusion Therapy

AOs. Therefore in this rule, we propose to establish a set of regulations that will govern the CMS approval and oversight process for all HIT AOs.

We also propose to modify the regulations for oversight for AOs that accredit any Medicare-certified providers and suppliers at 42 CFR 488.5 by adding a requirement that the AOs must include a statement with their application acknowledging that all AO surveyors are required to complete the relevant program specific CMS online trainings initially, and thereafter, consistent with requirements established by CMS for state and federal surveyors. We would also add another requirement at § 488.5 that would

require the AOs for Medicare certified providers and suppliers to provide a written statement with their application stating that if a fully accredited and facility deemed to be in good-standing provides written notification that they wish to voluntarily withdraw from the AO's CMS-approved accreditation program, the AO must continue the facility's current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

C. Summary of Costs, Transfers, and Benefits

TABLE 1—SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision description	Costs and cost savings	Transfers	Benefits
CY 2019 HH PPS Payment Rate Update.		The overall economic impact of the HH PPS payment rate update is an estimated \$400 million (2.1 percent) in increased payments to HHAs in CY 2019.	To ensure home health payments are consistent with statutory payment authority for CY 2019.
CY 2019 Temporary Transitional Payments for Home Infusion Therapy Services.		The overall economic impact of the temporary transitional payment for home infusion therapy services is an estimated \$60 million in increased payments to home infusion therapy suppliers in CY 2019.	To ensure temporary transitional payments for home infusion therapy are consistent with statutory authority for CY 2019.
CY 2019 HHVBP Model		The overall economic impact of the HHVBP Model provision for CY 2018 through 2022 is an estimated \$378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry (none of which is attributable to the changes proposed in this proposed rule). As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.	
CY 2020 OASIS Changes	The overall economic impact of the HH QRP and the case-mix adjustment methodology changes is annual savings to HHAs of an estimated \$60 million.		A reduction in burden to HHAs of approximately 73 hours annually for a savings of approximately \$5,150 annually per HHA.
CY 2020 Case-Mix Adjustment Methodology Changes, Including a Change in the Unit of Service from 60 to 30 days.		The overall economic impact of the proposed case-mix adjustment methodology changes, including a change in the unit of service from 60 to 30 days, for CY 2020 results in no estimated dollar impact to HHAs, as section 51001(a) of the BBA of 2018 requires such change to be implemented in a budget-neutral manner.	To ensure home health payments are consistent with statutory payment authority for CY 2020.

TABLE 1—SUMMARY OF COSTS, TRANSFERS, AND BENEFITS—Continued

Provision description	Costs and cost savings	Transfers	Benefits
Accreditation for Home Infusion Therapy suppliers.		<p>The cost related to an AO obtaining CMS approval of a home infusion therapy accreditation program is estimated to be \$8,014.50 per each AO, for AOs that have previously submitted an accreditation application to CMS. The cost across the potential 6 home infusion therapy AOs would be \$48,087.</p> <p>The cost related to each home infusion therapy AO for obtaining CMS approval of a home infusion therapy accreditation program is estimated to be \$12,453 per each AO, for AOs that <i>have not</i> previously submitted an accreditation application to CMS. The cost across the potential 6 home infusion therapy AOs would be \$74,718.</p> <p>We further estimate that each home infusion therapy AO would incur an estimated cost burden in the amount of \$23,258 for compliance with the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050 (including the filing of an application). The cost across the 6 potential home infusion therapy AOs would be \$139,548.</p>	

D. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for us. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.¹ This initiative is one component of our agency-wide Patients Over Paperwork Initiative² which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for

quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and will reduce costs including, the collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;

- Fulfill each program’s statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Provide significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 2:

TABLE 2—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections. Preventable Healthcare Harm.

¹ Meaningful Measures web page: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

² See Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017 <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html>.

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html>.

TABLE 2—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS—Continued

Quality priority	Meaningful measure area
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals. End of Life Care according to Preferences. Patient's Experience of Care.
Promote Effective Communication and Coordination of Care	Patient Reported Functional Outcomes. Medication Management. Admissions and Readmissions to Hospitals.
Promote Effective Prevention and Treatment of Chronic Disease	Transfer of Health Information and Interoperability. Preventive Care. Management of Chronic Conditions. Prevention, Treatment, and Management of Mental Health. Prevention and Treatment of Opioid and Substance Use Disorders.
Work with Communities to Promote Best Practices of Healthy Living	Risk Adjusted Mortality. Equity of Care. Community Engagement.
Make Care Affordable	Appropriate Use of Healthcare. Patient-focused Episode of Care. Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers and promoting operational efficiencies.

II. Background

A. Statutory Background

1. Home Health Prospective Payment System

a. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare home health services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled “Prospective Payment For Home Health Services.” Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. Section 1895(b)(2)

of the Act requires that, in defining a prospective payment amount, the Secretary will consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount that includes all costs for HH services covered and paid for on a reasonable cost basis, and that such amounts be initially based on the most recent audited cost report data available to the Secretary (as of the effective date of the 2000 final rule), and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act requires the standard prospective payment amounts be annually updated by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national

average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Affordable Care Act revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full

description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable payment percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) amended section 421(a) of the MMA to extend the 3 percent rural add-on payment for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) through January 1, 2018. In addition, section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that CY 2018 home health payments be updated by a 1 percent market basket increase. This year, section 50208(a)(1) of the BBA of 2018 again extended the rural add-on through the end of 2018. In addition, this section of the BBA of 2018 made some important changes to the rural add-on for CYs 2019 through 2022, to be discussed below.

b. Current System for Payment of Home Health Services

Generally, Medicare currently makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 60-day episode rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is not part of the national, standardized 60-day episode rate, but is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor. Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode. Therapy service use is measured by the number of therapy visits provided during the episode and can be categorized into nine visit level categories (or thresholds): 0 to 5; 6 to 9; 10; 11 to 13; 14 to 15; 16 to 17; 18 to 19; and 20 or more visits.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

c. Updates to the Home Health Prospective Payment System

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the HH PPS for CY 2008.

The CY 2008 HH PPS final rule included an analysis performed on CY 2005 home health claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. Case-mix represents the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 2005 case-mix data to evaluate if any portion of the 12.78 percent increase was associated with a change in the actual clinical condition of home health patients. We identified 8.03 percent of the total case-mix change as real, and therefore, decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent ($0.1278 * (1 - 0.0803) = 0.1175$).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented the 1.32 percent reduction to the payment rates for CY 2013 finalized the previous year, to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from

2000 to 2010 ($0.2390 * (1 - 0.1597) = 0.2008$). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532). Section 3131(a) of the Affordable Care Act added new section 1895(b)(3)(A)(iii) to the Act, which required that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we were required to phase in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the payment amount (or amounts) as of the date of enactment of the Affordable Care Act in 2010, and fully implement the rebasing adjustments by CY 2017. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of \$80.95 per year, increases to the national per-visit payment rates per year, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper. In the CY 2015 HH PPS final rule (79 FR 66032), we implemented the second year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates and made changes to the HH PPS case-mix weights. In addition, we simplified the face-to-face encounter regulatory requirements and the therapy reassessment timeframes.

In the CY 2016 HH PPS final rule (80 FR 68624), we implemented the third year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as discussed previously). In the CY 2016 HH PPS

final rule, we also recalibrated the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner and finalized reductions to the national, standardized 60-day episode payment rate in CY 2016, CY 2017, and CY 2018 of 0.97 percent in each year to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. Finally, section 421(a) of the MMA, as amended by section 210 of the MACRA, extended the payment increase of 3 percent for HH services provided in rural areas (as defined in section 1886(d)(2)(D) of the Act) to episodes or visits ending before January 1, 2018.

In the CY 2017 HH PPS final rule (81 FR 76702), we implemented the last year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined previously). We also finalized changes to the methodology used to calculate outlier payments under the authority of section 1895(b)(5) of the Act. Lastly, in accordance with section 1834(s) of the Act, as added by section 504(a) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted December 18, 2015), we implemented changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act.

2. Home Infusion Therapy

Section 5012 of the 21st Century Cures Act (“the Cures Act”) (Pub. L. 114–255), which amended sections 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy benefit. The Medicare home infusion therapy benefit covers the professional services including nursing services furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries. Section 50401 of the BBA of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that establishes a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for

certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of the same items and services, as defined in section 1861(iii)(2)(A) and (B) of the Act, related to the administration of home infusion drugs. The temporary transitional payment would begin on January 1, 2019 and end the day before the full implementation of the home infusion therapy benefit on January 1, 2021, as required by section 5012 of the 21st Century Cures Act.

Home infusion therapy is a treatment option for patients with a wide range of acute and chronic conditions, ranging from bacterial infections to more complex conditions such as late-stage heart failure and immune deficiencies. Home infusion therapy affords a patient independence and better quality of life, because it is provided in the comfort of the patient’s home at a time that best fits his or her needs. This is significant, because generally patients can return to their daily activities after they receive their infusion treatments and, in many cases, they can continue their activities while receiving their treatments. In addition, home infusion therapy can provide improved safety and better outcomes. The home has been shown to be a safe setting for patients to receive infusion therapy.³ Additionally, patients receiving treatment outside of the hospital setting may be at lower risk of hospital-acquired infections, which can be more difficult to treat because of multi-drug resistance than those that are community-acquired. This is particularly important for vulnerable patients such as those who are immunocompromised, as hospital-acquired infections are increasingly caused by antibiotic-resistant pathogens.

Infusion therapy typically means that a drug is administered intravenously, but the term may also refer to situations where drugs are provided through other non-oral routes, such as intramuscular injections and epidural routes (into the membranes surrounding the spinal cord). Diseases that may require infusion therapy include infections that are unresponsive to oral antibiotics, cancer and cancer-related pain,

³ Bhole, M.V., Burton, J., & Chapel, H.M., (2008). Self-infusion programs for immunoglobulin replacement at home: Feasibility, safety and efficacy. *Immunology and Allergy Clinics of North America*, 28(4), 821–832. doi:10.1016/j.iac.2008.06.005.

Souayah, N., Hasan, A., Khan, H., et al. (2011). The safety profile of home infusion of intravenous immunoglobulin in patients with neuroimmunologic disorders. *Journal of Clinical Neuroimmunology*, 12(suppl 4), S1–10. doi: 10.1097/CND.0b013e3182212589.

dehydration, and gastrointestinal diseases or disorders which prevent normal functioning of the gastrointestinal system. Other conditions treated with specialty infusion therapies may include some forms of cancers, congestive heart failure, Crohn's Disease, hemophilia, hepatitis, immune deficiencies, multiple sclerosis and rheumatoid arthritis. Infusion therapy originates with a prescription order from a physician or another qualified prescriber who is overseeing the care of the patient. The prescription order is sent to a home infusion therapy supplier, which is a state-licensed pharmacy, physician, or other provider of services or suppliers licensed by the state.

A 2010 Government Accountability Office (GAO) report (10–426) found that most health insurers rely on credentialing, accreditation, or both to help ensure that plan members receive quality home infusion services from their network suppliers.⁴ Home infusion AOs conduct on-site surveys to evaluate all components of the service, including medical equipment, nursing, and pharmacy. Accreditation standards can include such requirements as the CMS Conditions of Participation for home health services, other Federal government regulations, and industry best practices. All of the accreditation standards evaluate a range of provider competencies, such as having a complete plan of care, response to adverse events, and implementation of a quality improvement plan.

Sections 1861(iii)(3)(D)(III) and 1834(u)(5) of the Act, as amended by section 5012 of the Cures Act requires that, in order to participate in Medicare, home infusion therapy suppliers must select a CMS-approved AO and undergo an accreditation review process to demonstrate that the home infusion therapy program meets the accreditation organization's standards. Section 1861(iii) of the Act, as amended by section 5012 of the Cures Act, sets forth standards in three areas: (1) Ensuring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient-specific needs, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a

patient's home are provided, and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act) requires assessment data to be standardized and interoperable to allow for exchange of the data among post-acute providers and other providers. To further interoperability in post-acute care, CMS is developing a Data Element Library to serve as a publically available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. These interoperable data elements can reduce provider burden by allowing the use and reuse of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Once available, standards in the Data Element Library can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA).

The 2018 Interoperability Standards Advisory (ISA) is available at: <https://www.healthit.gov/standards-advisory>.

Most recently, the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. Specifically, Congress directed ONC to “develop or support a trusted exchange framework, including a common agreement among health information networks nationally.” This framework (<https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>) outlines a common set of principles for

trusted exchange and minimum terms and conditions for trusted exchange in order to enable interoperability across disparate health information networks. In another important provision, Congress defined “information blocking” as practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, and established new authority for HHS to discourage these practices. We invite providers to learn more about these important developments and how they are likely to affect HHAs.

III. Proposed Provisions for Payment Under the Home Health Prospective Payment System (HH PPS)

A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments

1. Analysis of FY 2016 HHA Cost Report Data

As part of our efforts in monitoring the potential impacts of the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72293), we continue to update our analysis of home health cost report and claims data. Previous years' cost report and claims data analyses and results can be found in the CY 2018 HH PPS proposed rule (82 FR 35277–35278). For this proposed rule, we analyzed the 2016 HHA cost report data (the most recent, complete data available at the time of this proposed rule) and 2016 HHA claims data to obtain the average number of visits per episode that match to the year of cost report data analyzed. To determine the 2016 average cost per visit per discipline, we applied the same trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) and weighted the costs per visit from the 2016 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative according to 2016 claims data. The 2016 average number of visits was taken from 2016 claims data. We estimated the cost of a 60-day episode in CY 2016 to be \$2,538.54 using 2016 cost report data (Table 2). However, the national, standardized 60-day episode payment amount in CY 2016 was \$2,965.12. The difference between the 60-day episode payment rate and average cost per episode of care for CY 2016 was 16.8 percent.

⁴ <https://www.gao.gov/assets/310/305261.pdf>.

TABLE 2—2016 ESTIMATED COST PER EPISODE

Discipline	2016 Average costs per visit	2016 Average NRS costs per visit	2016 Average cost + NRS per visit	2016 Average number of visits	2016 60-Day episode costs
Skilled Nursing	\$132.83	\$3.41	\$136.24	8.81	\$1,200.27
Physical Therapy	156.04	3.41	159.45	5.58	889.73
Occupational Therapy	153.53	3.41	156.94	1.56	244.83
Speech Pathology	170.06	3.41	173.47	0.32	55.51
Medical Social Services	219.73	3.41	223.14	0.14	31.24
Home Health Aides	60.50	3.41	63.91	1.83	116.96
Total				18.24	2,538.54

Source: Medicare cost reports pulled in March 2018 and Medicare claims data from 2015 and 2016 for episodes (excluding low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes), linked to OASIS assessments for episodes ending in CY 2016.

2. Analysis of CY 2017 HHA Claims Data

In the CY 2014 HH PPS final rule (78 FR 72256), some commenters expressed concern that the rebasing of the HH PPS payment rates would result in HHA closures and would therefore diminish access to home health services. In addition to examining more recent cost report data, for this proposed rule we examined home health claims data from all four years during which rebasing adjustments were made (CY 2014, CY 2015, CY 2016, and CY 2017), the first calendar year of the HH PPS (CY 2001),

and claims data for the year prior to the implementation of the rebasing adjustments (CY 2013). Preliminary analysis of CY 2017 home health claims data indicates that the number of episodes decreased by 5.3 percent and the number of home health users that received at least one episode of care decreased by 3.2 percent from 2016 to 2017, while the number of FFS beneficiaries decreased 0.1 percent from 2016 to 2017. Between 2013 and 2014 there appears to be a net decrease in the number of HHAs billing Medicare for home health services of 1.6 percent, a continued decrease of 1.7 percent from

2014 to 2015, a decrease of 3.4 percent from 2015 to 2016, and a decrease of 4.4 percent from 2016 to 2017. We note that in CY 2016 there were 2.9 HHAs per 10,000 FFS beneficiaries and 2.8 HHAs per 10,000 FFS beneficiaries in CY 2017, which remains markedly higher than the 1.9 HHAs per 10,000 FFS beneficiaries close to the inception of the HH PPS in 2001 (the HH PPS was implemented on October 1, 2000). The number of home health users, as a percentage of FFS beneficiaries, has decreased from 9.0 percent in 2013 to 8.4 percent in 2017.

TABLE 3—HOME HEALTH STATISTICS, CY 2001 AND CY 2013 THROUGH CY 2017

	2001	2013	2014	2015	2016	2017
Number of episodes	3,896,502	6,708,923	6,451,283	6,340,932	6,294,234	5,963,780
Beneficiaries receiving at least 1 episode (Home Health Users)	2,412,318	3,484,579	3,381,635	3,365,512	3,350,174	3,242,346
Part A and/or B FFS beneficiaries	34,899,167	38,505,609	38,506,534	38,506,534	38,555,150	38,509,031
Episodes per Part A and/or B FFS beneficiaries	0.11	0.17	0.17	0.17	0.16	0.15
Home health users as a percentage of Part A and/or B FFS beneficiaries	6.9%	9.0%	8.8%	8.8%	8.7%	8.4%
HHAs providing at least 1 episode	6,511	11,889	11,693	11,381	11,102	10,612
HHAs per 10,000 Part A and/or B FFS beneficiaries	1.9	3.1	3.0	3.0	2.9	2.8

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on May 14, 2014 and August 19, 2014 for CY 2013 data; accessed on May 7, 2015 for CY 2001 and CY 2014 data; accessed on April 7, 2016 for CY 2015 data; accessed on March 20, 2017 for CY 2016 data; accessed on March 8, 2018 for CY 2017 data; and Medicare enrollment information obtained from the CCW Master Beneficiary Summary File. Beneficiaries are the total number of beneficiaries in a given year with at least 1 month of Part A and/or Part B Fee-for-Service coverage without having any months of Medicare Advantage coverage.

Note(s): These results include all episode types (Normal, PEP, Outlier, LUPA) and also include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to “0” (“Non-payment/zero claims”) and “2” (“Interim—first claim”) are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state’s unique number of beneficiaries served.

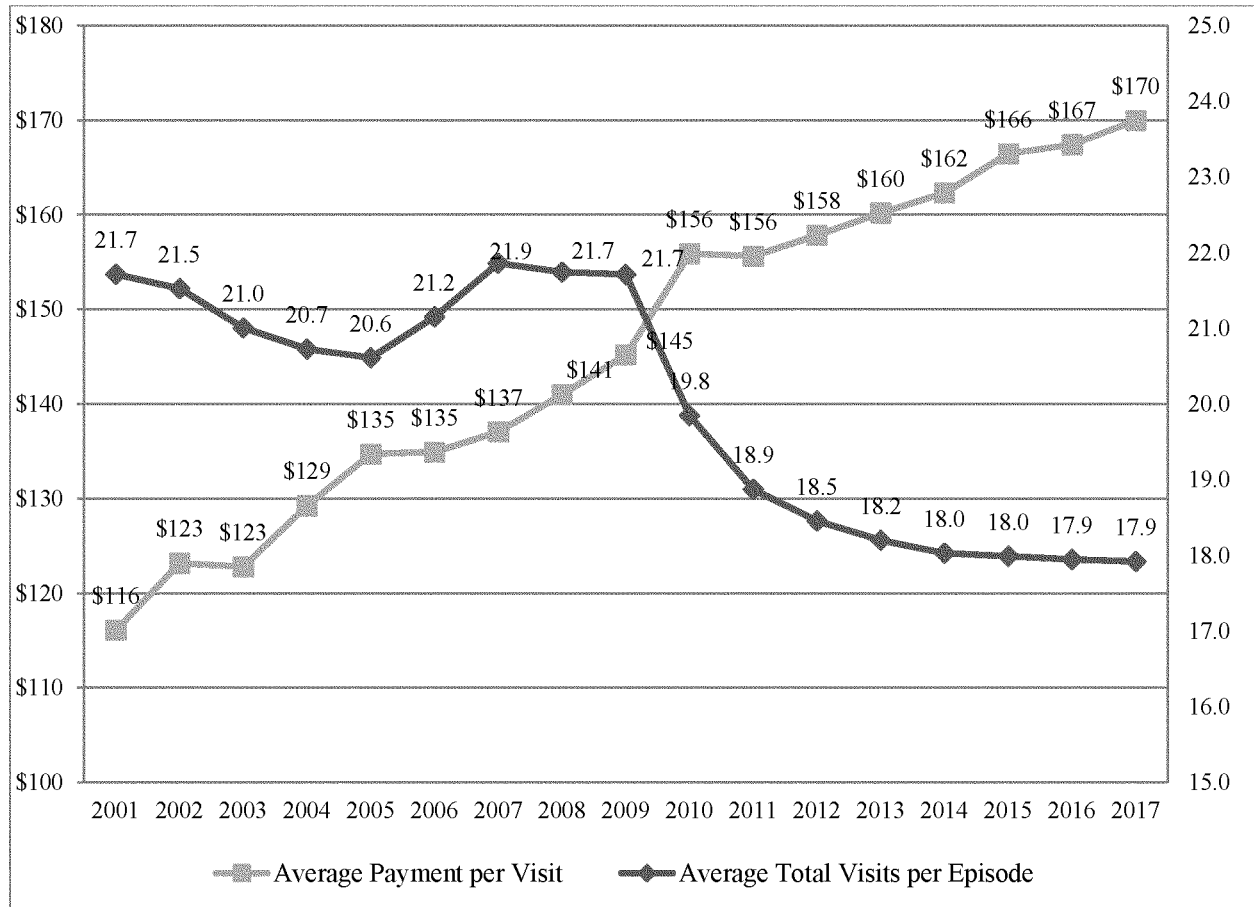
In addition to examining home health claims data from all four years of the implementation of rebasing adjustments required by the Affordable Care Act, we examined trends in home health utilization for all years starting in CY 2001 and up through CY 2017. Figure 1, displays the average number of visits per 60-day episode of care and the

average payment per visit. While the average payment per visit has steadily increased from approximately \$116 in CY 2001 to \$170 for CY 2017, the average total number of visits per 60-day episode of care has declined, most notably between CY 2009 (21.7 visits per episode) and CY 2010 (19.8 visits per episode), which was the first year

that the 10 percent agency-level cap on HHA outlier payments was implemented. The average of total visits per episode has steadily decreased from 21.7 in 2009 to 17.9 in 2017.

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FIGURE 1: AVERAGE TOTAL NUMBER OF VISITS AND AVERAGE PAYMENT PER VISIT FOR A MEDICARE HOME HEALTH 60-DAY EPISODE OF CARE, CY 2001 THROUGH CY 2017



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) – 2001 to 2014 data accessed on May 21, 2014, CY 2015 data accessed on April 25, 2016, CY 2016 data accessed on March 16, 2017, and CY 2017 data accessed on March 6, 2018.

Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

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Figure 2 displays the average number of visits by discipline type for a 60-day episode of care and shows that while the number of therapy visits per 60-day episode of care has increased steadily, the number of skilled nursing and home health aide visits have decreased between CY 2009 and CY 2017. The results of the Report to Congress, "Medicare Home Health Study: An Investigation on Access to Care and

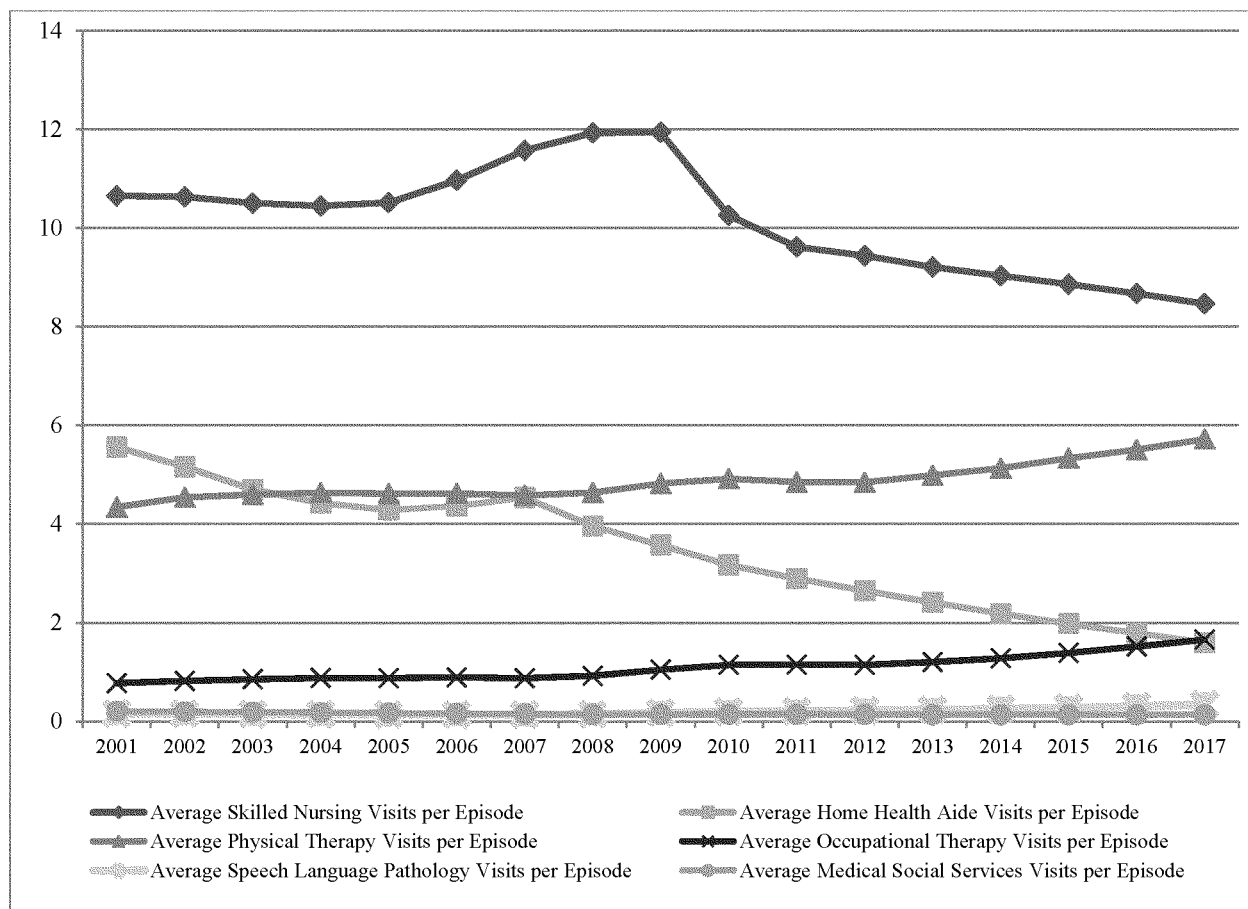
Payment for Vulnerable Patient Populations", required by section 3131(d) of the Affordable Care Act, suggests that the current home health payment system may discourage HHAs from serving patients with clinically complex and/or poorly controlled chronic conditions who do not qualify for therapy but require a large number of skilled nursing visits.⁵ The home

⁵ Report to Congress Medicare Home Health Study: An Investigation on Access to Care and

health study results seem to be consistent with the recent trend in the decreased number of visits per episode of care driven by decreases in skilled nursing and home health aide services evident in Figures 1 and 2.

Payment for Vulnerable Patient Populations (2014). Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf>.

FIGURE 2: AVERAGE NUMBER OF VISITS BY DISCIPLINE TYPE FOR A MEDICARE HOME HEALTH 60-DAY EPISODE OF CARE, CY 2001 THROUGH CY 2017



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - 2001 to 2014 data accessed on May 21, 2014, CY 2015 data accessed on April 25, 2016, CY 2016 data accessed on March 16, 2017, and CY 2017 data accessed on March 6, 2018.

Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

As part of our monitoring efforts, we also examined the trends in episode timing and service use over time. Specifically, we examined the percentage of early episodes with 0 to 19 therapy visits, late episodes with 0 to 19 therapy visits, and episodes with 20+ therapy visits from CY 2008 to CY 2017. In CY 2008, we implemented refinements to the HH PPS case-mix system. As part of those refinements, we added additional therapy thresholds and differentiated between early and late episodes for those episodes with less than 20+ therapy visits. Early episodes are defined as the 1st or 2nd episode in a sequence of adjacent

covered episodes. Late episodes are defined as the 3rd and subsequent episodes in a sequence of adjacent covered episodes. Table 4 shows that the percentage of early and late episodes from CY 2008 to CY 2017 has remained relatively stable over time. There has been a decrease in the percentage of early episodes with 0 to 19 therapy visits from 65.9 percent in CY 2008 to 61.3 percent in CY 2017 and a slight increase in the percentage of late episodes with 0 to 19 therapy visits from 29.5 percent in CY 2008 to 31.2 percent in CY 2017. In 2015, the case-mix weights for the third and later episodes of care with 0 to 19 therapy

visits decreased as a result of the CY 2015 recalibration of the case-mix weights. Despite the decreases in the case-mix weights for the later episodes, the percentage of late episodes with 0 to 19 therapy visits did not change substantially. However, episode timing is not a variable in the determination of the case-mix weights for those episodes with 20+ therapy visits and the percentage of episodes with 20+ therapy visits has increased from 4.6 percent in CY 2008 to 7.6 percent in CY 2017.

TABLE 4—HOME HEALTH EPISODES BY EPISODE TIMING, CY 2008 THROUGH CY 2017

Year	All episodes	Number of early episodes (excluding episodes with 20+ visits)	% of early episodes (excluding episodes with 20+ visits)	Number of late episodes (excluding episodes with 20+ visits)	% of late episodes (excluding episodes with 20+ visits)	Number of episodes with 20+ visits	% of episodes with 20+ visits
2008	5,423,037	3,571,619	65.9	1,600,587	29.5	250,831	4.6
2009	6,530,200	3,701,652	56.7	2,456,308	37.6	372,240	5.7
2010	6,877,598	3,872,504	56.3	2,586,493	37.6	418,601	6.1
2011	6,857,885	3,912,982	57.1	2,564,859	37.4	380,044	5.5
2012	6,767,576	3,955,207	58.4	2,458,734	36.3	353,635	5.2
2013	6,733,146	4,023,486	59.8	2,347,420	34.9	362,240	5.4
2014	6,616,875	3,980,151	60.2	2,263,638	34.2	373,086	5.6
2015	6,644,922	4,008,279	60.3	2,205,052	33.2	431,591	6.5
2016	6,294,232	3,802,254	60.4	2,053,972	32.6	438,006	7.0
2017	5,963,778	3,655,636	61.3	1,857,840	31.2	450,302	7.6

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on March 6, 2018.

Note(s): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to “0” (“Non-payment/zero claims”) and “2” (“Interim—first claim”) are excluded.

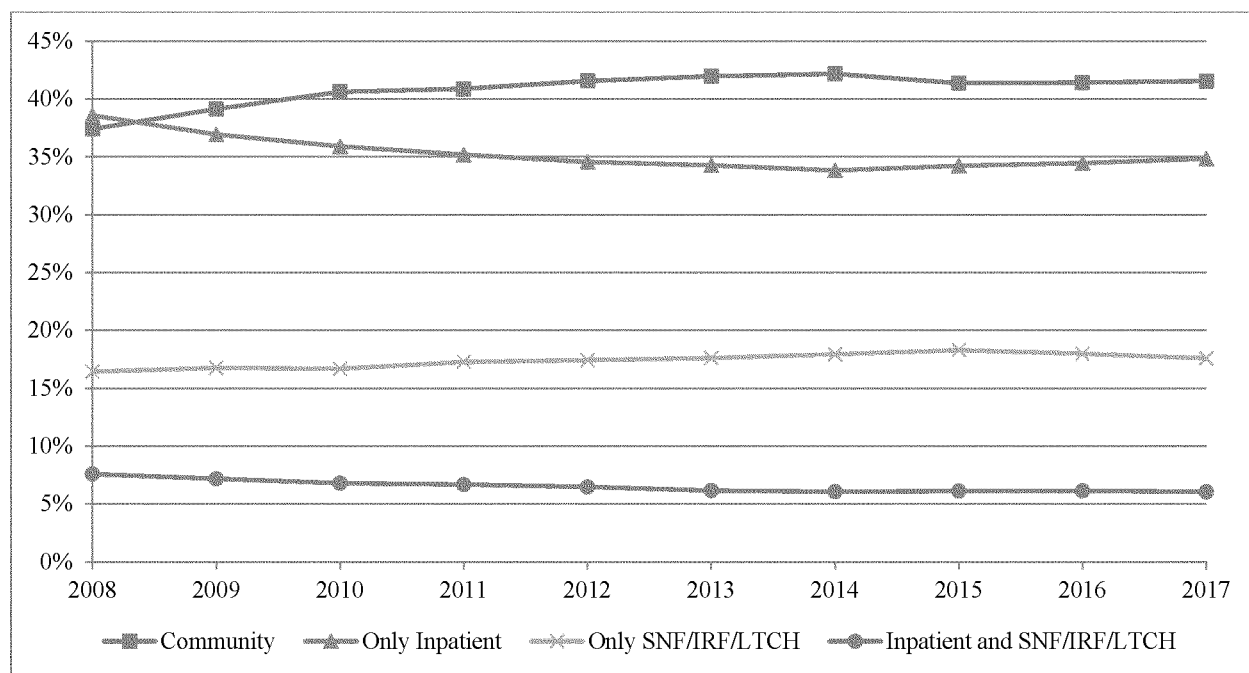
We also examined trends in admission source for home health episodes over time. Specifically, we examined the admission source for the “first or only” episodes of care (first episodes in a sequence of adjacent episodes of care or the only episode of care) from CY 2008 through CY 2017 (Figure 3). The percentage of first or only episodes with an acute admission source, defined as episodes with an inpatient hospital stay within the 14 days prior to a home health episode, has decreased from 38.6 percent in CY 2008 to 34.8 percent in CY 2017. The percentage of first or only episodes with a post-acute admission source, defined as episodes which had a stay at a skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long term care hospital (LTCH) within 14 days

prior to the home health episode, has slightly increased from 16.4 percent in CY 2008 to 17.6 percent in CY 2017. The percentage of first or only episodes with a community admission source, defined as episodes which did not have an acute or post-acute stay in the 14 days prior to the home health episode, increased from 37.4 percent in CY 2008 to 41.5 percent in CY 2017. Our findings on the trends in admission source show a similar pattern with MedPAC’s as outlined in their 2015 Report to the Congress.⁶ MedPAC concluded that

⁶ Medicare Payment Advisory Commission (MedPAC). “Home Health Care Services.” *Report to the Congress: Medicare Payment Policy*. Washington, DC, March 2015. P. 214. Accessed on 3/28/2017 at: <http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0>.

there has been tremendous growth in the use of home health for patients residing in the community (that is, episodes not preceded by a prior hospitalization) and that these episodes have more than doubled since 2001. However, MedPAC examined admission source trends from 2002 up through 2013 and included first and subsequent episodes of care, whereas CMS analysis, as described above, included “first or only” episodes of care. Nonetheless, both analyses show a trend of increasing episodes of care without a preceding inpatient stay. MedPAC suggests there is significant potential for overuse, particularly since Medicare does not currently require any cost sharing for home health care.

FIGURE 3: HOME HEALTH EPISODE TRENDS BY ADMISSION SOURCE (FIRST OR ONLY EPISODES), CY 2008 THROUGH CY 2017



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - Accessed on March 6, 2018.

Note(s): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded.

We will continue to monitor for potential impacts due to the rebasing adjustments required by section 3131(a) of the Affordable Care Act and other policy changes in the future. Independent effects of any one policy may be difficult to discern in years where multiple policy changes occur in any given year.

B. Proposed CY 2019 HH PPS Case-Mix Weights

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized a policy to annually recalibrate the HH PPS case-mix weights—adjusting the weights relative to one another—using the most current, complete data available. To recalibrate the HH PPS case-mix weights for CY 2018, we will use the same methodology finalized in the CY 2008 HH PPS final rule (72 FR 49762), the CY

2012 HH PPS final rule (76 FR 68526), and the CY 2015 HH PPS final rule (79 FR 66032). Annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns.

To generate the proposed CY 2019 HH PPS case-mix weights, we used CY 2017 home health claims data (as of March 2, 2018) with linked OASIS data. These data are the most current and complete data available at this time. We will use CY 2017 home health claims data (as of June 30, 2018 or later) with linked OASIS data to generate the CY 2019 HH PPS case-mix weights in the CY 2019 HH PPS final rule. The process we used to calculate the HH PPS case-mix weights are outlined below.

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the CY 2016 Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim. The points for each of the variables for each leg of the model, updated with CY 2017 home health claims data, are shown in Table 5. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

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TABLE 5: CASE-MIX ADJUSTMENT VARIABLES AND SCORES

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	<i>EQUATION:</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
<i>CLINICAL DIMENSION</i>					
1	Primary or Other Diagnosis = Blindness/Low Vision
2	Primary or Other Diagnosis = Blood disorders	.	2	.	.
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms	.	4	.	4
4	Primary Diagnosis = Diabetes	.	2	.	2
5	Other Diagnosis = Diabetes
6	Primary or Other Diagnosis = Dysphagia <i>AND</i> Primary or Other Diagnosis = Neuro 3 – Stroke	2	15	.	15
7	Primary or Other Diagnosis = Dysphagia <i>AND</i> M1030 (Therapy at home) = 3 (Enteral)	.	5	.	5
8	Primary or Other Diagnosis = Gastrointestinal disorders	.	1	.	2
9	Primary or Other Diagnosis = Gastrointestinal disorders <i>AND</i> M1630 (ostomy)= 1 or 2	.	5	.	.
10	Primary or Other Diagnosis = Gastrointestinal disorders <i>AND</i> Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis, OR Neuro 2 - Peripheral neurological disorders, OR Neuro 3 - Stroke, OR Neuro 4 - Multiple Sclerosis
11	Primary or Other Diagnosis = Heart Disease OR Hypertension	2	3	.	2
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	2	7	4	7
13	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis <i>AND</i> M1840 (Toilet transfer) = 2 or more	.	2	.	.
14	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis <i>OR</i> Neuro 2 - Peripheral neurological disorders <i>AND</i> M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	3	5	2	3
15	Primary or Other Diagnosis = Neuro 3 - Stroke	3	6	2	.
16	Primary or Other Diagnosis = Neuro 3 - Stroke <i>AND</i> M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	.	3	.	.
17	Primary or Other Diagnosis = Neuro 3 - Stroke <i>AND</i> M1860 (Ambulation) = 4 or more
18	Primary or Other Diagnosis = Neuro 4 - Multiple Sclerosis <i>AND AT LEAST ONE OF THE FOLLOWING:</i> M1830 (Bathing) = 2 or more <i>OR</i> M1840 (Toilet transfer) = 2 or more <i>OR</i> M1850 (Transferring) = 2 or more	2	7	3	7

	OR M1860 (Ambulation) = 4 or more				
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders AND M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	7	2	7	.
20	Primary or Other Diagnosis = Ortho 1 - Leg OR Ortho 2 - Other orthopedic disorders AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.	2	3	.
21	Primary or Other Diagnosis = Psych 1 – Affective and other psychoses, depression
22	Primary or Other Diagnosis = Psych 2 - Degenerative and other organic psychiatric disorders
23	Primary or Other Diagnosis = Pulmonary disorders
24	Primary or Other Diagnosis = Pulmonary disorders AND M1860 (Ambulation) = 1 or more	.	1	.	.
25	Primary Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications	2	14	6	14
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post-operative complications	5	11	7	11
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications OR Skin 2 – Ulcers and other skin conditions AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	1	14	7	14
29	Primary or Other Diagnosis = Tracheostomy	1	10	.	10
30	Primary or Other Diagnosis = Urostomy/Cystostomy	.	17	.	10
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	.	10	1	10
32	M1030 (Therapy at home) = 3 (Enteral)	.	13	.	7
33	M1200 (Vision) = 1 or more	1	.	.	.
34	M1242 (Pain)= 3 or 4	3	.	2	.
35	M1308 = Two or more pressure ulcers at stage 3 or 4	2	4	2	.
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	3	16	6	15
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	5	27	8	22
38	M1334 (Stasis ulcer status)= 2	3	12	5	12
39	M1334 (Stasis ulcer status)= 3	5	15	7	15
40	M1342 (Surgical wound status)= 2	2	6	4	11
41	M1342 (Surgical wound status)= 3	.	5	4	8
42	M1400 (Dyspnea) = 2, 3, or 4	1	1	.	.
43	M1620 (Bowel Incontinence) = 2 to 5	.	4	.	3
44	M1630 (Ostomy)= 1 or 2	2	9	2	7
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3
FUNCTIONAL DIMENSION					
46	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	1	2	.	.
47	M1830 (Bathing) = 2 or more	6	4	5	.
48	M1840 (Toilet transferring) = 2 or more	1	.	.	.
49	M1850 (Transferring) = 2 or more	2	1	2	.

50	M1860 (Ambulation) = 1, 2 or 3	6	.	4	.
51	M1860 (Ambulation) = 4 or more	7	7	6	7

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Note(s): Points are additive; however, points may not be given for the same line item in the table more than once. Please see Medicare Home Health Diagnosis Coding guidance at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.html for definitions of primary and secondary diagnoses.

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In updating the four-equation model for CY 2019, using 2017 home health claims data (the last update to the four-equation model for CY 2018 used CY 2016 home health claims data), there were few changes to the point values for the variables in the four-equation model. These relatively minor changes reflect the change in the relationship between the grouper variables and resource use between CY 2016 and CY 2017. The CY 2019 four-equation model resulted in 113 point-giving variables being used in the model (as compared to the 119 variables for the CY 2018 recalibration, which can be found in Table 2 of the CY 2018 HH PPS final rule (82 FR 51684)). There were 7 variables that were added to the model and 13 variables that were dropped from the model due to the absence of additional resources associated with the variable. Of the variables that were in both the four-equation model for CY 2019 and the four-equation model for

CY 2018, the points for 10 variables increased in the CY 2019 four-equation model and the points for 67 variables decreased in the CY 2019 4-equation model. There were 29 variables with the same point values.

Step 2: Re-defining the clinical and functional thresholds so they are reflective of the new points associated with the CY 2019 four-equation model. After estimating the points for each of the variables and summing the clinical and functional points for each episode, we look at the distribution of the clinical score and functional score, breaking the episodes into different steps. The categorizations for the steps are as follows:

- Step 1: First and second episodes, 0–13 therapy visits.
- Step 2.1: First and second episodes, 14–19 therapy visits.
- Step 2.2: Third episodes and beyond, 14–19 therapy visits.
- Step 3: Third episodes and beyond, 0–13 therapy visits.

- Step 4: Episodes with 20+ therapy visits.

We then divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.⁷ Also, we looked at the average resource use associated with each clinical and functional score and used that as a guide for setting our thresholds. We grouped scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off the CY 2019 four-equation model points are shown in Table 6.

TABLE 6—PROPOSED CY 2019 CLINICAL AND FUNCTIONAL THRESHOLDS

		1st and 2nd Episodes		3rd+ Episodes		All Episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step		1	2	3	4	5
Equations used to calculate points (see Table 2)		1	2	3	4	(2&4)
Dimension	Severity Level
Clinical	C1	0 to 1	0 to 1	0 to 1	0 to 1	0 to 3.
	C2	2 to 3	2 to 7	2	2 to 9	4 to 16.
	C3	4+	8+	3+	10+	17+.
Functional	F1	0 to 12	0 to 7	0 to 6	0 to 2	0 to 2.
	F2	13	8 to 12	7 to 10	3 to 7	3 to 6.
	F3	14+	13+	11+	8+	7+.

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode’s wage-weighted minutes of

care as the dependent variable. Independent variables in the model are indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment

regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 7 shows the regression coefficients for the variables in the payment regression model updated with CY 2017 home

⁷ For Step 1, 41% of episodes were in the medium functional level (All with score 13).

For Step 2.1, 86.7% of episodes were in the low functional level (Most with scores 6 to 7).

For Step 2.2, 81.5% of episodes were in the low functional level (Most with score 0).

For Step 3, 46.7% of episodes were in the medium functional level (Most with score 9).

For Step 4, 29.9% of episodes were in the medium functional level (Most with score 6).

health claims data. The R-squared value for the payment regression model is 0.5508 (an increase from 0.5095 for the CY 2018 recalibration).

TABLE 7—PAYMENT REGRESSION MODEL

	Payment regression from 4-equation model for CY 2019
Step 1, Clinical Score Medium	\$21.81
Step 1, Clinical Score High	54.06
Step 1, Functional Score Medium	70.54
Step 1, Functional Score High	99.78
Step 2.1, Clinical Score Medium	50.90
Step 2.1, Clinical Score High	118.77
Step 2.1, Functional Score Medium	25.36
Step 2.1, Functional Score High	31.96
Step 2.2, Clinical Score Medium	48.03
Step 2.2, Clinical Score High	187.73
Step 2.2, Functional Score Medium	50.06
Step 2.2, Functional Score High	0.00
Step 3, Clinical Score Medium	18.05
Step 3, Clinical Score High	83.67
Step 3, Functional Score Medium	56.10
Step 3, Functional Score High	81.90
Step 4, Clinical Score Medium	70.97
Step 4, Clinical Score High	245.97
Step 4, Functional Score Medium	4.60
Step 4, Functional Score High	17.77
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	515.04
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	510.26
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	– 60.34
Step 4, All Episodes, 20+ Therapy Visits	895.79
Intercept	375.32

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018) for which we had a linked OASIS assessment.

Step 4: We use the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divide these predicted values by the mean of the dependent variable (that is, the average wage-weighted minutes of care across all episodes used in the payment regression). This division constructs the weight for each episode, which is simply the ratio of the episode's predicted wage-weighted minutes of care divided by the average wage-weighted minutes of care in the sample. Each episode is then aggregated into one of the 153 home health resource groups (HHRGs) and the "raw" weight for each HHRG was calculated as the average of the episode weights within the HHRG.

Step 5: The raw weights associated with 0 to 5 therapy visits are then increased by 3.75 percent, the weights associated with 14–15 therapy visits are decreased by 2.5 percent, and the weights associated with 20+ therapy

visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.⁸

Step 6: After the adjustments in step 5 are applied to the raw weights, the weights are further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same clinical severity level, functional severity level, and early/late episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds are gradually increased. We do this by

⁸ Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*. March 2011, P. 176.

interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We use a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) are constant. This interpolation is identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.⁹ This last step creates the proposed CY 2019 case-mix weights shown in Table 8.

⁹ When computing the average, we compute a weighted average, assigning a value of one to each normal episode and a value equal to the episode length divided by 60 for PEPs.

TABLE 8—PROPOSED CY 2019 CASE-MIX PAYMENT WEIGHTS

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed weights for CY 2019
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5459
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.6801
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8143
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9485
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0828
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6485
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.7691
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8897
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0104
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1310
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6910
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8049
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9189
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0328
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1467
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5776
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7194
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8612
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0030
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1448
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.6802
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8084
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9366
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0648
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1930
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7227
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8442
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9657
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.0872
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2087
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6245
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.7755
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9264
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.0774
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2284
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7271
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.8645
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0019
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1392
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.2766
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7696
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9003
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0310
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.1617
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.2923
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2170
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3756
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5342
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2516
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4008
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5499
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2607
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4126
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.5646
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2866
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4535
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6204
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3212
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4786
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6361
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3302
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.4905
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.6508
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.3793
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.5930
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8067
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4140
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6182

TABLE 8—PROPOSED CY 2019 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed weights for CY 2019
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8224
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.4230
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6300
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.8371
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2104
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3713
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5321
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2789
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4189
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5589
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2789
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4248
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.5706
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2761
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4465
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6169
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3445
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4942
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6438
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3445
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5000
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.6555
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4670
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6515
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8360
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5355
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6992
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8629
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5355
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7050
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	1.8746
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4581
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6086
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7591
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9095
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0600
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5397
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6876
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8354
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9832
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1310
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.5772
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7176
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8579
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	0.9982
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1385
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4844
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6427
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8011
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9594
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1178
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5660
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7217
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8774
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0331
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1888
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6035
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7517
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.8999
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0481
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.1963
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.5798
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7573
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9347
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1122
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2896
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6614
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8362

TABLE 8—PROPOSED CY 2019 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed weights for CY 2019
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0110
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1858
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3607
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.6989
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.8662
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0336
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2009
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3682
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.6929
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.6990
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.7165
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.7874
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.7935
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.8110
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.0204
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.0266
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.0441

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the proposed CY 2019 national, standardized 60-day episode payment rate (see section III.C.3. of this proposed rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2019 HH PPS case-mix weights (developed using CY 2017 home health claims data) are applied to CY 2017 utilization (claims) data to total payments when CY 2018 HH PPS case-mix weights (developed using CY 2016 home health claims data) are applied to CY 2017 utilization data. This produces a case-mix budget neutrality factor for CY 2019 of 1.0163.

C. CY 2019 Home Health Payment Rate Update

1. Rebasings and Revising of the Home Health Market Basket

a. Background

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2019 be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. Effective for cost reporting periods beginning on or after July 1, 1980, we developed and adopted an HHA input price index (that is, the home health “market basket”). Although “market basket” technically describes the mix of goods and services used to produce home health care, this term is also commonly used to denote the input price index derived from that market

basket. Accordingly, the term “home health market basket” used in this document refers to the HHA input price index.

The percentage change in the home health market basket reflects the average change in the price of goods and services purchased by HHAs in providing an efficient level of home health care services. We first used the home health market basket to adjust HHA cost limits by an amount that reflected the average increase in the prices of the goods and services used to furnish reasonable cost home health care. This approach linked the increase in the cost limits to the efficient utilization of resources. For a greater discussion on the home health market basket, see the notice with comment period published in the February 15, 1980 **Federal Register** (45 FR 10450, 10451), the notice with comment period published in the February 14, 1995 **Federal Register** (60 FR 8389, 8392), and the notice with comment period published in the July 1, 1996 **Federal Register** (61 FR 34344, 34347). Beginning with the FY 2002 HHA PPS payments, we used the home health market basket to update payments under the HHA PPS. We last rebased the home health market basket effective with the CY 2013 update (77 FR 67081).

The home health market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use 2016 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called “cost weights” or “expenditure weights.” Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a “price proxy.” In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted previously, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide HHA services. The effects on total expenditures resulting from changes in the mix of goods and services purchased

subsequent to the base period are not measured. For example, a HHA hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the HHA, but would not be factored into the price change measured by a fixed-weight home health market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that HHAs purchase (HHA inputs) to furnish inpatient care between base periods.

b. Rebasing and Revising the Home Health Market Basket

We believe that it is desirable to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. We based the cost category weights in the current home health market basket on CY 2010 data. We are proposing to rebase and revise the home health market basket to reflect 2016 Medicare cost report (MCR) data, the latest available and most complete data on the actual structure of HHA costs.

The terms “rebasing” and “revising,” while often used interchangeably, denote different activities. The term “rebasing” means moving the base year for the structure of costs of an input price index (that is, in this exercise, we are proposing to move the base year cost structure from CY 2010 to CY 2016) without making any other major changes to the methodology. The term “revising” means changing data sources, cost categories, and/or price proxies used in the input price index.

For this proposed rebasing and revising, we are rebasing the detailed wages and salaries and benefits cost weights to reflect 2016 BLS Occupational Employment Statistics (OES) data on HHAs. The 2010-based home health market basket used 2010 BLS OES data on HHAs. We are also proposing to break out the All Other (residual) cost category weight into more detailed cost categories, based on the 2007 Benchmark U.S. Department of Commerce, Bureau of Economic Analysis (BEA) Input-Output (I-O) Table for HHAs. The 2010-based home health market basket used the 2002 I-O data. Finally, due to its small weight, we are proposing to eliminate the cost category ‘Postage’ and include these expenses in the ‘All Other Services’ cost weight.

c. Derivation of the Proposed 2016-Based Home Health Market Basket Cost Weights

The major cost weights for this proposed revised and rebased home health market basket are derived from the Medicare Cost Reports (MCR; CMS Form 1728–94) data for freestanding HHAs whose cost reporting period began on or after October 1, 2015 and before October 1, 2016. Of the 2016 Medicare cost reports for freestanding HHAs, approximately 84 percent of the reports had a begin date on January 1, 2016, approximately 6 percent had a begin date on July 1, 2016, and approximately 4 percent had a begin date on October 1, 2015. Using this methodology allowed our sample to include HHAs with varying cost report years including, but not limited to, the Federal fiscal or calendar year. We refer to the market basket as a calendar year market basket because the base period for all price proxies and weights are set to CY 2016.

We propose to maintain our policy of using data from freestanding HHAs, which account for over 90 percent of HHAs (82 FR 35383), because we have determined that they better reflect HHAs’ actual cost structure. Expense data for hospital-based HHAs can be affected by the allocation of overhead costs over the entire institution.

We are proposing to derive eight major expense categories (Wages and Salaries, Benefits, Contract Labor, Transportation, Professional Liability Insurance (PLI), Fixed Capital, Movable Capital, and a residual “All Other”) from the 2016 Medicare HHA cost reports. Due to its small weight, we are proposing to eliminate the cost category ‘Postage’ and include these expenses in the “All Other (residual)” cost weight. These major expense categories are based on those cost centers that are reimbursable under the HHA PPS, specifically Skilled Nursing Care, Physical Therapy, Occupational Therapy, Speech Pathology, Medical Social Services, Home Health Aide, and Supplies. These are the same cost centers that were used in the 2014 base payment rebasing (78 FR 72276), which are described in the Abt Associates Inc. June 2013, Technical Paper, “Analyses In Support of Rebasing and Updating Medicare Home Health Payment Rates” (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf>). Total costs for the HHA PPS reimbursable services reflect overhead allocation. We provide

detail on the calculations for each major expense category.

(1) Wages and Salaries: Wages and Salaries costs reflect direct patient care wages and salaries costs as well as wages and salaries costs associated with Plant Operations and Maintenance, Transportation, and Administrative and General. Specifically, we are proposing to calculate Wages and Salaries by summing costs from Worksheet A, column 1, lines 3 through 12 and subtracting line 5.03 (A&G Nonreimbursable costs).

(2) Benefits: Benefits costs reflect direct patient care benefit costs as well as benefit costs associated with Plant Operations and Maintenance, Transportation, and Administrative and General. Specifically, we are proposing to calculate Benefits by summing costs from Worksheet A, column 2, lines 3 through 12 and subtracting line 5.03 (A&G Nonreimbursable costs).

(3) Direct Patient Care Contract Labor: Contract Labor costs reflect direct patient care contract labor. Specifically, we are proposing to calculate Contract Labor by summing costs from Worksheet A, column 4, lines 6 through 11.

(4) Transportation: Transportation costs reflect direct patient care costs as well as transportation costs associated with Capital Expenses, Plant Operations and Maintenance, and Administrative and General. Specifically, we are proposing to calculate Transportation by summing costs from Worksheet A, column 3, lines 1 through 12 and subtracting line 5.03 (A&G Nonreimbursable costs).

(5) Professional Liability Insurance: Professional Liability Insurance reflects premiums, paid losses, and self-insurance costs. Specifically we are proposing to calculate Professional Liability Insurance by summing costs from Worksheet S2, lines 27.01, 27.02 and 27.03.

(6) Fixed Capital: Fixed Capital-related costs reflect the portion of Medicare-allowable costs reported in “Capital Related Buildings and Fixtures” (Worksheet A, column 5, line 1). We calculate this Medicare allowable portion by first calculating a ratio for each provider that reflects fixed capital costs as a percentage of HHA reimbursable services. Specifically this ratio is calculated as the sum of costs from Worksheet B, column 1, lines 6 through 12 divided by the sum of costs from Worksheet B, column 1, line 1 minus lines 3 through 5. This percentage is then applied to the sum of the costs from Worksheet A, column 5, line 1.

(7) Movable Capital: Movable Capital-related costs reflect the portion of Medicare-allowable costs reported in “Capital Related Moveable Equipment” (Worksheet A, column 5, line 2). We calculate this Medicare allowable portion by first calculating a ratio for each provider that reflects movable capital costs as a percentage of HHA reimbursable services. Specifically this ratio is calculated as the sum of costs from Worksheet B, column 2, lines 6 through 12 divided by the sum of costs from Worksheet B, column 2, line 2 minus lines 3 through 5. This percentage is then applied to the sum of the costs from Worksheet A, column 5, line 2.

(8) All Other (residual): The “All Other” cost weight is a residual, calculated by subtracting the major cost weight percentages (Wages and Salaries, Benefits, Direct Patient Care Contract Labor, Transportation, Professional Liability Insurance, Fixed Capital, and Movable Capital) from 1.

As prescription drugs and DME are not payable under the HH PPS, we continue to exclude those items from the home health market basket. Totals within each of the major cost categories were edited to remove reports where the data were deemed unreasonable (for example, when total costs were not greater than zero). We then determined the proportion of total Medicare allowable costs that each category

represents. For all of the major cost categories except the “residual” All Other cost weight, we then removed those providers whose derived cost weights fall in the top and bottom five percent of provider-specific cost weights to ensure the removal of outliers. After the outliers were removed, we summed the costs for each category across all remaining providers. We then divided this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2016-based home health market basket for the given category.

Table 9 shows the major cost categories and their respective cost weights as derived from the Medicare cost reports for this proposed rule.

TABLE 9—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major cost categories	2010 based	Proposed 2016 based
Wages and Salaries (including allocated direct patient care contract labor)	66.3	65.1
Benefits (including allocated direct patient care contract labor)	12.2	10.9
Transportation	2.5	2.6
Professional Liability Insurance (Malpractice)	0.4	0.3
Fixed Capital	1.5	1.4
Moveable Capital	0.6	0.6
“All Other” residual	16.5	19.0

* Figures may not sum to 100.0 due to rounding.

The decrease in the wages and salaries cost weight of 1.2 percentage points and the decrease in the benefits cost weight of 1.3 percentage points is attributable to both employed compensation and direct patient care contract labor costs as reported on the MCR data. Our analysis of the MCR data shows that the decrease in the compensation cost weight of 2.4 percentage points (calculated by combining wages and salaries and benefits) from 2010 to 2016 occurred among for-profit, nonprofit, and government providers and among providers serving only rural beneficiaries, only urban beneficiaries, or both rural and urban beneficiaries.

Over the 2010 to 2016 time period, the average number of FTEs per provider decreased considerably. This corresponds with the HHA claims analysis published on page 35279 of the CY 2018 proposed rule (<https://www.gpo.gov/fdsys/pkg/FR-2017-07-28/pdf/2017-15825.pdf>), which shows that the number of visits per 60-day episode has decreased from 19.8 visits in 2010 to 17.9 visits in 2016 for Medicare PPS. Medicare visits account for approximately 60 percent of total visits.

The direct patient care contract labor costs are contract labor costs for skilled nursing, physical therapy, occupational

therapy, speech therapy, and home health aide cost centers. We allocated these direct patient care contract labor costs to the Wages and Salaries and Benefits cost categories based on each provider’s relative proportions of both employee wages and salaries and employee benefits costs. For example, the direct patient care contract labor costs that are allocated to wages and salaries is equal to: (A) The employee wages and salaries costs as a percent of the sum of employee wages and salaries costs and employee benefits costs times; and (B) direct patient care contract labor costs. Nondirect patient care contract labor costs (such as contract labor costs reported in the Administrative and General cost center of the MCR) are captured in the “All Other” residual cost weight and later disaggregated into more detail as described below. This is a similar methodology that was implemented for the 2010-based home health market basket.

We further divide the “All Other” residual cost weight estimated from the 2016 Medicare cost report data into more detailed cost categories. To divide this cost weight we are proposing to use the 2007 Benchmark I–O “Use Tables/ Before Redefinitions/Purchaser Value” for NAICS 621600, Home Health Agencies, published by the BEA. These

data are publicly available at http://www.bea.gov/industry/io_annual.htm. The BEA Benchmark I–O data are generally scheduled for publication every five years. The most recent data available at the time of rebasing was for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA’s economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.¹⁰ Besides Benchmark I–O estimates, BEA also produces Annual I–O estimates. While based on a similar methodology, the Annual I–O estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we are proposing to inflate the detailed 2007 Benchmark I–O data forward to 2016 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I–O data. We repeated this practice for each year. We then calculated the cost shares that each cost

¹⁰ http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.

category represents of the 2007 data inflated to 2016. These resulting 2016 cost shares were applied to the “All Other” residual cost weight to obtain the detailed cost weights for the proposed 2016-based home health market basket. For example, the cost for Operations and Maintenance represents 8.0 percent of the sum of the “All Other” 2007 Benchmark I–O HHA Expenditures inflated to 2016. Therefore, the Operations and Maintenance cost weight represents 8.0 percent of the proposed 2016-based home health market basket’s “All Other” cost category (19.0 percent),

yielding an Operations and Maintenance proposed cost weight of 1.5 percent in the proposed 2016-based home health market basket (0.080 × 19.0 percent = 1.5 percent). For the 2010-based home health market basket, we used the same methodology utilizing the 2002 Benchmark I–O data (aged to 2010).

Using this methodology, we are proposing to derive nine detailed cost categories from the proposed 2016-based home health market basket “All Other” residual cost weight (19.0 percent). These categories are: (1) Operations and Maintenance; (2) Administrative Support; (3) Financial

Services; (4) Medical Supplies; (5) Rubber and Plastics; (6) Telephone; (7) Professional Fees; (8) Other Products; and (9) Other Services. The 2010-based home health market basket included a separate cost category for Postage; however, due to its small weight for the 2016-based home health market basket, we propose to eliminate the stand-alone cost category for Postage and include these expenses in the Other Services cost category.

Table 10 lists the proposed 2016-based home health market basket cost categories, cost weights, and price proxies.

TABLE 10—COST CATEGORIES, WEIGHTS, AND PRICE PROXIES IN PROPOSED 2016-BASED HOME HEALTH MARKET BASKET

Cost categories	Weight	Price proxy
Compensation, including allocated contract services' labor.	76.1	
Wages and Salaries, including allocated contract services' labor.	65.1	Proposed Home Health Blended Wages and Salaries Index (2016).
Benefits, including allocated contract services' labor.	10.9	Proposed Home Health Blended Benefits Index (2016).
Operations & Maintenance	1.5	CPI-U for Fuel and utilities.
Professional Liability Insurance	0.3	CMS Physician Professional Liability Insurance Index.
Administrative & General & Other Expenses including allocated contract services' labor.	17.4	
Administrative Support	1.0	ECI for Total compensation for Private industry workers in Office and administrative support.
Financial Services	1.9	ECI for Total compensation for Private industry workers in Financial activities.
Medical Supplies	0.9	PPI Commodity data for Medical, surgical & personal aid devices.
Rubber & Plastics	1.6	PPI Commodity data for Rubber and plastic products.
Telephone	0.7	CPI-U for Telephone services.
Professional Fees	5.3	ECI for Total compensation for Private industry workers in Professional and related.
Other Products	2.8	PPI Commodity data for Finished goods less foods and energy.
Other Services	3.2	ECI for Total compensation for Private industry workers in Service occupations.
Transportation	2.6	CPI-U for Transportation.
Capital-Related	2.1	
Fixed Capital	1.4	CPI-U for Owners' equivalent rent of residences.
Movable Capital	0.6	PPI Commodity data for Machinery and equipment.
Total	* 100.0	

* Figures may not sum due to rounding.

d. Proposed 2016-Based Home Health Market Basket Price Proxies

After we computed the CY 2016 cost category weights for the proposed rebased home health market basket, we selected the most appropriate wage and price indexes to proxy the rate of change for each expenditure category. With the exception of the price index for Professional Liability Insurance costs, the proposed price proxies are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- *Employment Cost Indexes*—Employment Cost Indexes (ECIs) measure the rate of change in employee

wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. They are not affected by shifts in skill mix. ECIs are superior to average hourly earnings as price proxies for input price indexes for two reasons: (a) They measure pure price change; and (b) they are available by occupational groups, not just by industry.

- *Consumer Price Indexes*—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Consumer price indexes are

used when the expenditure is more similar to that of a purchase at the retail level rather than at the wholesale level, or if no appropriate Producer Price Indexes (PPIs) were available.

- *Producer Price Indexes*—PPIs measures average changes in prices received by domestic producers for their goods and services. PPIs are used to measure price changes for goods sold in other than retail markets. For example, a PPI for movable equipment is used rather than a CPI for equipment. PPIs in some cases are preferable price proxies for goods that HHAs purchase at wholesale levels. These fixed-weight indexes are a measure of price change

at the producer or at the intermediate stage of production.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in way that can be replicated. Low sampling variability is desirable because it indicates that sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because a sample was surveyed rather than the entire population.) Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly and therefore it is important the underlying price proxies be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly helps ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently because we believe that this is an optimal way to stay abreast of the most current data available. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the

public to be able to obtain the price proxy data on a regular basis. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs selected by us to be proposed in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

As part of the revising and rebasing of the home health market basket, we are proposing to rebase the home health blended Wages and Salaries index and the home health blended Benefits index. We propose to use these blended indexes as price proxies for the Wages and Salaries and the Benefits portions of the proposed 2016-based home health market basket, as we did in the 2010-based home health market basket. A more detailed discussion is provided below.

- *Wages and Salaries:* For measuring price growth in the 2016-based home health market basket, we are proposing to apply six price proxies to six occupational subcategories within the Wages and Salaries component, which would reflect the HHA occupational mix. This is the same approach used for the 2010-based index. We use a blended wage proxy because there is not a published wage proxy specific to the home health industry.

We are proposing to continue to use the National Industry-Specific

Occupational Employment and Wage estimates for North American Industrial Classification System (NAICS) 621600, Home Health Care Services, published by the BLS Office of Occupational Employment Statistics (OES) as the data source for the cost shares of the home health blended wage and benefits proxy. This is the same data source that was used for the 2010-based HHA blended wage and benefit proxies; however, we are proposing to use the May 2016 estimates in place of the May 2010 estimates. Detailed information on the methodology for the national industry-specific occupational employment and wage estimates survey can be found at http://www.bls.gov/oes/current/oes_tec.htm.

The needed data on HHA expenditures for the six occupational subcategories (Health-Related Professional and Technical, Non Health-Related Professional and Technical, Management, Administrative, Health and Social Assistance Service, and Other Service Workers) for the wages and salaries component were tabulated from the May 2016 OES data for NAICS 621600, Home Health Care Services. Table 11 compares the proposed 2016 occupational assignments to the 2010 occupational assignments of the six CMS designated subcategories. If an OES occupational classification does not exist in the 2010 or 2016 data we use “n/a.”

TABLE 11—PROPOSED 2016 OCCUPATIONAL ASSIGNMENTS COMPARED TO 2010 OCCUPATIONAL ASSIGNMENTS FOR CMS HOME HEALTH WAGES AND SALARIES BLEND

2016 proposed occupational groupings		2010 occupational groupings	
Group 1	Health-related professional and technical	Group 1	Health-related professional and technical
n/a	n/a	29-1021	Dentists, General.
29-1031	Dietitians and Nutritionists	29-1031	Dietitians and Nutritionists.
29-1051	Pharmacists	29-1051	Pharmacists.
29-1062	Family and General Practitioners	29-1062	Family and General Practitioners.
29-1063	Internists, General	29-1063	Internists, General.
29-1065	Pediatricians, General	n/a	n/a.
29-1066	Psychiatrists	n/a	n/a.
29-1069	Physicians and Surgeons, All Other	29-1069	Physicians and Surgeons, All Other.
29-1071	Physician Assistants	29-1071	Physician Assistants.
n/a	n/a	29-1111	Registered Nurses.
29-1122	Occupational Therapists	29-1122	Occupational Therapists.
29-1123	Physical Therapists	29-1123	Physical Therapists.
29-1125	Recreational Therapists	29-1125	Recreational Therapists.
29-1126	Respiratory Therapists	29-1126	Respiratory Therapists.
29-1127	Speech-Language Pathologists	29-1127	Speech-Language Pathologists.
29-1129	Therapists, All Other	29-1129	Therapists, All Other.
29-1141	Registered Nurses	n/a	n/a.
29-1171	Nurse Practitioners	n/a	n/a.
29-1199	Health Diagnosing and Treating Practitioners, All Other.	29-1199	Health Diagnosing and Treating Practitioners, All Other.

2016 proposed occupational groups		2010 occupational groupings	
Group 2	Non health related professional & technical	Group 2	Non health related professional & technical
13-0000	Business and Financial Operations Occupations	13-0000	Business and Financial Operations Occupations.
15-0000	Computer and Mathematical Occupations	15-0000	Computer and Mathematical Science Occupations.
n/a	n/a	17-0000	Architecture and Engineering Occupations.
19-0000	Life, Physical, and Social Science Occupations	19-0000	Life, Physical, and Social Science Occupations.
n/a	n/a	23-0000	Legal Occupations.
25-0000	Education, Training, and Library Occupations	25-0000	Education, Training, and Library Occupations.
27-0000	Arts, Design, Entertainment, Sports, and Media Occupations.	27-0000	Arts, Design, Entertainment, Sports, and Media Occupations.
Group 3	Management	Group 3	Management
11-0000	Management Occupations	11-0000	Management Occupations.
Group 4	Administrative	Group 4	Administrative
43-0000	Office and Administrative Support Occupations	43-0000	Office and Administrative Support Occupations.
Group 5	Health and social assistance services	Group 5	Health and social assistance services
21-0000	Community and Social Service Occupations	21-0000	Community and Social Services Occupations.
29-2011	Medical and Clinical Laboratory Technologists	29-2011	Medical and Clinical Laboratory Technologists.
29-2012	Medical and Clinical Laboratory Technicians	29-2012	Medical and Clinical Laboratory Technicians.
29-2021	Dental Hygienists	29-2021	Dental Hygienists.
29-2032	Diagnostic Medical Sonographers	29-2032	Diagnostic Medical Sonographers.
29-2034	Radiologic Technologists	29-2034	Radiologic Technologists and Technicians.
29-2041	Emergency Medical Technicians and Paramedics	29-2041	Emergency Medical Technicians and Paramedics.
29-2051	Dietetic Technicians	29-2051	Dietetic Technicians.
29-2052	Pharmacy Technicians	29-2052	Pharmacy Technicians.
29-2053	Psychiatric Technicians	n/a	n/a.
29-2054	Respiratory Therapy Technicians	29-2054	Respiratory Therapy Technicians.
29-2055	Surgical Technologists	n/a	n/a.
29-2061	Licensed Practical and Licensed Vocational Nurses	29-2061	Licensed Practical and Licensed Vocational Nurses.
29-2071	Medical Records and Health Information Technicians	29-2071	Medical Records and Health Information Technicians.
29-2099	Health Technologists and Technicians, All Other	29-2099	Health Technologists and Technicians, All Other.
n/a	n/a	29-9012	Occupational Health and Safety Technicians.
29-9099	Healthcare Practitioners and Technical Workers, All Other.	29-9099	Healthcare Practitioner and Technical Workers, All Other.
31-0000	Healthcare Support Occupations	31-0000	Healthcare Support Occupations.
Group 6	Other service workers	Group 6	Other service workers
33-0000	Protective Service Occupations	33-0000	Protective Service Occupations.
35-0000	Food Preparation and Serving Related Occupations	35-0000	Food Preparation and Serving Related Occupations.
37-0000	Building and Grounds Cleaning and Maintenance Occupations.	37-0000	Building and Grounds Cleaning and Maintenance Occupations.
39-0000	Personal Care and Service Occupations	39-0000	Personal Care and Service Occupations.
41-0000	Sales and Related Occupations	41-0000	Sales and Related Occupations.
47-0000	Construction and Extraction Occupations	n/a	n/a.
49-0000	Installation, Maintenance, and Repair Occupations	49-0000	Installation, Maintenance, and Repair Occupations.
51-0000	Production Occupations	51-0000	Production Occupations.
53-0000	Transportation and Material Moving Occupations	53-0000	Transportation and Material Moving Occupations.

Total expenditures by occupation were calculated by taking the OES number of employees multiplied by the OES annual average salary for each subcategory, and then calculating the proportion of total wage costs that each subcategory represents. The proportions listed in Table 12 represent the Wages and Salaries blend weights.

TABLE 12—COMPARISON OF THE PROPOSED 2016-BASED HOME HEALTH WAGES AND SALARIES BLEND AND THE 2010-BASED HOME HEALTH WAGES AND SALARIES BLEND

Cost subcategory	Proposed 2016 weight	2010 weight	Price proxy	BLS series ID
Health-Related Professional and Technical.	33.7	33.4	ECI for Wages and salaries for All Civilian workers in Hospitals.	CIU1026220000000I.
Non Health-Related Professional and Technical.	2.3	2.3	ECI for Wages and salaries for Private industry workers in Professional, scientific, and technical services.	CIU2025400000000I.
Management	7.6	8.3	ECI for Wages and salaries for Private industry workers in Management, business, and financial.	CIU2020000110000I.

TABLE 12—COMPARISON OF THE PROPOSED 2016-BASED HOME HEALTH WAGES AND SALARIES BLEND AND THE 2010-BASED HOME HEALTH WAGES AND SALARIES BLEND—Continued

Cost subcategory	Proposed 2016 weight	2010 weight	Price proxy	BLS series ID
Administrative	6.7	7.7	ECI for Wages and salaries for Private industry workers in Office and administrative support. ECI for Wages and salaries for All Civilian workers in Health care and social assistance. ECI for Wages and salaries for Private industry workers in Service occupations.	CIU2020000220000I.
Health and Social Assistance Services.	35.3	35.8		CIU1026200000000I.
Other Service Occupations	14.4	12.6		CIU2020000300000I.
Total *	100.0	100.0		

* Totals may not sum due to rounding.

A comparison of the yearly changes from CY 2016 to CY 2019 for the 2010-based home health Wages and Salaries

blend and the proposed 2016-based home health Wages and Salaries blend is shown in Table 13. The annual

increases in the two price proxies are the same when rounded to one decimal place.

TABLE 13—ANNUAL GROWTH IN PROPOSED 2016 AND 2010 HOME HEALTH WAGES AND SALARIES BLEND

	2016	2017	2018	2019
Wage Blend 2016	2.3	2.5	2.6	3.0
Wage Blend 2010	2.3	2.5	2.6	3.0

Source: IHS Global Insight Inc. 1st Quarter 2018 forecast with historical data through 4th Quarter 2017.

• *Benefits:* For measuring Benefits price growth in the proposed 2016-based home health market basket, we are proposing to apply applicable price

proxies to the six occupational subcategories that are used for the Wages and Salaries blend. The proposed six categories in Table 14 are the same

as those in the 2010-based home health market basket and include the same occupational mix as listed in Table 14.

TABLE 14—COMPARISON OF THE PROPOSED 2016-BASED HOME HEALTH BENEFITS BLEND AND 2010-BASED HOME HEALTH BENEFITS BLEND

Cost category	Proposed 2016 weight	2010 weight	Price proxy
Health-Related Professional and Technical	33.9	33.5	ECI for Benefits for All Civilian workers in Hospitals. ECI for Benefits for Private industry workers in Professional, scientific, and technical services.
Non Health-Related Professional and Technical.	2.3	2.2	
Management	7.3	8.0	ECI for Benefits for Private industry workers in Management, business, and financial.
Administrative	6.7	7.8	ECI for Benefits for Private industry workers in Office and administrative support.
Health and Social Assistance Services	35.5	35.9	ECI for Benefits for All Civilian workers in Health care and social assistance.
Other Service Workers	14.2	12.5	ECI for Benefits for Private industry workers in Service occupations.
Total *	100.0	100.0	

* Totals may not sum due to rounding.

There is no available data source that exists for benefit expenditures by occupation for the home health industry. Thus, to construct weights for the home health benefits blend we calculated the ratio of benefits to wages and salaries for CY 2016 for the six ECI series we are proposing to use in the blended ‘wages and salaries’ and ‘benefits’ indexes. To derive the relevant benefits weight, we applied the benefit-to-wage ratios to each of the six occupational subcategories from the

2016 OES wage and salary weights, and normalized. For example, the ratio of benefits to wages from the 2016 home health wages and salaries blend and the benefits blend for the management category is 0.984. We apply this ratio to the 2016 OES weight for wages and salaries for management, 7.6 percent, and then normalize those weights relative to the other five benefit occupational categories to obtain a benefit weight for management of 7.3 percent.

A comparison of the yearly changes from CY 2016 to CY 2019 for the 2010-based home health Benefits blend and the proposed 2016-based home health Benefits blend is shown in Table 15. With the exception of a 0.1 percentage point difference in 2019, the annual increases in the two price proxies are the same when rounded to one decimal place.

TABLE 15—ANNUAL GROWTH IN THE PROPOSED 2016 HOME HEALTH BENEFITS BLEND AND THE 2010 HOME HEALTH BENEFITS BLEND

	2016	2017	2018	2019
Benefits Blend 2016	1.7	1.9	2.4	3.0
Benefits Blend 2010	1.7	1.9	2.4	2.9

Source: IHS Global Insight Inc. 1st Quarter 2018 forecast with historical data through 4th Quarter 2017.

- *Operations and Maintenance:* We are proposing to use CPI U.S. city average for Fuel and utilities (BLS series code #CUUR0000SAH2) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Professional Liability Insurance:* We are proposing to use the CMS Physician Professional Liability Insurance price index to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

To accurately reflect the price changes associated with physician PLI, each year we collect PLI premium data for physicians from a representative sample of commercial carriers and publically available rate filings as maintained by each State’s Association of Insurance Commissioners. As we require for our other price proxies, the PLI price proxy is intended to reflect the pure price change associated with this particular cost category. Thus, the level of liability coverage is held constant from year to year. To accomplish this, we obtain premium information from a sample of commercial carriers for a fixed level of coverage, currently \$1 million per occurrence and a \$3 million annual limit. This information is collected for every State by physician specialty and risk class. Finally, the State-level, physician-specialty data are aggregated to compute a national total, using counts of physicians by State and specialty as provided in the AMA publication, *Physician Characteristics and Distribution in the U.S.*

- *Administrative and Support:* We are proposing to use the ECI for Total compensation for Private industry

workers in Office and administrative support (BLS series code #CIU2010000220000I) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Financial Services:* We are proposing to use the ECI for Total compensation for Private industry workers in Financial activities (BLS series code #CIU201520A000000I) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Medical Supplies:* We are proposing to use the PPI Commodity data for Miscellaneous products-Medical, surgical & personal aid devices (BLS series code #WPU156) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Rubber and Plastics:* We are proposing to use the PPI Commodity data for Rubber and plastic products (BLS series code #WPU07) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Telephone:* We are proposing to use CPI U.S. city average for Telephone services (BLS series code #CUUR0000SEED) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Professional Fees:* We are proposing to use the ECI for Total compensation for Private industry workers in Professional and related (BLS series code #CIS2010000120000I) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

- *Other Products:* We are proposing to use the PPI Commodity data for Final demand-Finished goods less foods and energy (BLS series code #WPUFD4131) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

- *Other Services:* We are proposing to use the ECI for Total compensation for Private industry workers in Service occupations (BLS series code #CIU2010000300000I) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

- *Transportation:* We are proposing to use the CPI U.S. city average for Transportation (BLS series code #CUUR0000SAT) to measure price growth of this category. The same proxy was used for the 2010-based home health market basket.

- *Fixed capital:* We are proposing to use the CPI U.S. city average for Owners’ equivalent rent of residences (BLS series code #CUUS0000SEHC) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

- *Movable Capital:* We are proposing to use the PPI Commodity data for Machinery and equipment (BLS series code #WPU11) to measure price growth of this cost category. The same proxy was used for the 2010-based home health market basket.

e. Rebasing Results

A comparison of the yearly changes from CY 2014 to CY 2021 for the 2010-based home health market basket and the proposed 2016-based home health market basket is shown in Table 16.

TABLE 16—COMPARISON OF THE 2010-BASED HOME HEALTH MARKET BASKET AND THE PROPOSED 2016-BASED HOME HEALTH MARKET BASKET, PERCENT CHANGE, 2014–2021

	Home health market basket, 2010-based	Proposed home health market basket, 2016-based	Difference (proposed 2016-based less 2010-based)
Historical data:			
CY 2014	1.6	1.6	0.0
CY 2015	1.6	1.5	-0.1
CY 2016	2.0	2.0	0.0
CY 2017	2.3	2.3	0.0

TABLE 16—COMPARISON OF THE 2010-BASED HOME HEALTH MARKET BASKET AND THE PROPOSED 2016-BASED HOME HEALTH MARKET BASKET, PERCENT CHANGE, 2014–2021—Continued

	Home health market basket, 2010-based	Proposed home health market basket, 2016-based	Difference (proposed 2016-based less 2010-based)
Average CYs 2014–2017	1.9	1.9	0.0
Forecast:			
CY 2018	2.5	2.5	0.0
CY 2019	2.8	2.8	0.0
CY 2020	3.0	3.0	0.0
CY 2021	3.0	3.0	0.0
Average CYs 2018–2021	2.8	2.8	0.0

Source: IHS Global Inc. 1st Quarter 2018 forecast with historical data through 4th Quarter 2017.

Table 16 shows that the forecasted rate of growth for CY 2019 for the proposed 2016-based home health market basket is 2.8 percent, the same rate of growth as estimated using the 2010-based home health market basket; other forecasted years also show a similar increase. Similarly, the historical estimates of the growth in the 2016-based and 2010-based home health market basket are the same except for CY 2015 where the 2010-based home health market basket is 0.1 percentage point higher. We note that if more recent data are subsequently available (for example, a more recent estimate of

the market basket), we would use such data to determine the market basket increases in the final rule.

f. Labor-Related Share

Effective for CY 2019, we are proposing to revise the labor-related share to reflect the proposed 2016-based home health market basket Compensation (Wages and Salaries plus Benefits) cost weight. The current labor-related share is based on the Compensation cost weight of the 2010-based home health market basket. Based on the proposed 2016-based home health market basket, the labor-related share would be 76.1 percent and the

proposed non-labor-related share would be 23.9 percent. The labor-related share for the 2010-based home health market basket was 78.5 percent and the non-labor-related share was 21.5 percent. As explained earlier, the decrease in the compensation cost weight of 2.4 percentage points is attributable to both employed compensation (wages and salaries and benefits for employees) and direct patient care contract labor costs as reported in the MCR data. Table 17 details the components of the labor-related share for the 2010-based and proposed 2016-based home health market baskets.

TABLE 17—LABOR-RELATED SHARE OF CURRENT AND PROPOSED HOME HEALTH MARKET BASKETS

Cost category	2010-based market basket weight	Proposed 2016-based market basket weight
Wages and Salaries	66.3	65.1
Employee Benefits	12.2	11.0
Total Labor-Related	78.5	76.1
Total Non Labor-Related	21.5	23.9

We propose to implement the proposed revision to the labor-related share of 76.1 percent in a budget neutral manner. This proposal would be consistent with our policy of implementing the annual recalibration of the case-mix weights and update of the home health wage index in a budget neutral manner.

g. Multifactor Productivity

In the CY 2015 HHA PPS final rule (79 FR 38384 through 38384), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1895(b)(3)(B)(vi) of the Act, requires that, in CY 2015 (and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP

Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), the market basket percentage under the HHA prospective payment system as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the “MFP adjustment”). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business

MFP. Please see <http://www.bls.gov/mfp>, to obtain the BLS historical published MFP data.

Based on IHS Global Inc.’s (IGI’s) first quarter 2018 forecast with history through the fourth quarter of 2017, the projected MFP adjustment (the 10-year moving average of MFP for the period ending December 31, 2019) for CY 2019 is 0.7 percent. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. We note that if more recent data are subsequently available (for example, a more recent estimate of the MFP adjustment), we would use such data to determine the MFP adjustment in the final rule.

2. Proposed CY 2019 Market Basket Update for HHAs

Using IGI's first quarter 2018 forecast, the MFP adjustment for CY 2019 is projected to be 0.7 percent. In accordance with section 1895(b)(3)(B)(iii) of the Act, we propose to base the CY 2019 market basket update, which is used to determine the applicable percentage increase for HHA payments, on the most recent estimate of the proposed 2016-based home health market basket. Based on IGI's first quarter 2018 forecast with history through the fourth quarter of 2017, the projected increase of the proposed 2016-based home health market basket for CY 2019 is 2.8 percent. We propose to then reduce this percentage increase by the current estimate of the MFP adjustment for CY 2019 of 0.7 percentage point in accordance with 1895(b)(3)(B)(vi) of the Act. Therefore, the current estimate of the CY 2019 HHA payment update is 2.1 percent (2.8 percent market basket update, less 0.7 percentage point MFP adjustment). Furthermore, we note that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the CY 2019 market basket update and MFP adjustment in the final rule.

Section 1895(b)(3)(B)(v) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2019, the home health payment update will be 0.1 percent (2.1 percent minus 2 percentage points).

3. CY 2019 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We propose to continue this practice for CY 2019, as we continue to believe that, in the absence of HH-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we propose to continue to use the pre-floor, pre-reclassified hospital wage index as the

wage adjustment to the labor portion of the HH PPS rates. For CY 2019, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2014, and before October 1, 2015 (FY 2015 cost report data). We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2019 HH PPS wage index, we propose to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we propose to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we propose to continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2019, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

On February 28, 2013, OMB issued Bulletin No. 13-01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted the OMB's new area delineations using a 1-year transition.

On August 15, 2017, OMB issued Bulletin No. 17-01 in which it announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. The new CBSA (46300) comprises the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The CY 2019 HH PPS wage index value for CBSA 46300, Twin

Falls, Idaho, will be 0.8335. Bulletin No. 17-01 is available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.¹¹

The most recent OMB Bulletin (No. 18-03) was published on April 10, 2018 and is available at <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>.¹² The revisions contained in OMB Bulletin No. 18-03 have no impact on the geographic area delineations that are used to wage adjust HH PPS payments.

The CY 2019 wage index is available on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html>.

4. CY 2019 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in § 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. As discussed in section III.C.1 of this proposed rule, based on the proposed 2016-based home health market basket, the proposed labor-related share would be 76.1 percent and the proposed non-labor-related share would be 23.9 percent for CY 2019. The CY 2019 HH PPS rates use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and will be adjusted as described in section III.B of this proposed rule. The following are the steps we take to compute the case-mix

¹¹ "Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas". OMB BULLETIN NO. 17-01. August 15, 2017. <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.

¹² "Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas". OMB BULLETIN NO. 18-03. April 10, 2018. <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>.

and wage-adjusted 60-day episode rate for CY 2019:

- Multiply the national 60-day episode rate by the patient’s applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (76.1 percent) and a non-labor portion (23.9 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

In accordance with section 1895(b)(3)(B) of the Act, we propose the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43.

The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare will use to pay the claim.

We may also adjust the 60-day case-mix and wage-adjusted episode payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(c) and 484.230.
- A partial episode payment (PEP) adjustment as set forth in §§ 484.205(d) and 484.235.
- An outlier payment as set forth in §§ 484.205(e) and 484.240.

b. CY 2019 National, Standardized 60-Day Episode Payment Rate

Section 1895(b)(3)(A)(i) of the Act requires that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2019 national, standardized 60-day episode payment rate, we apply a wage index budget neutrality factor and a case-mix budget neutrality factor described in section III.B of this proposed rule; and the home health payment update percentage discussed in section III.C.2 of this proposed rule.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using

the CY 2019 wage index (including the application of the proposed labor-related share of 76.1 percent and the proposed non-labor-related share of 23.9 percent) and compared it to our simulation of total payments for non-LUPA episodes using the CY 2018 wage index and CY 2018 (including the application of the current labor-related share of 78.535 percent and the non-labor-related of 21.465). By dividing the total payments for non-LUPA episodes using the CY 2019 wage index by the total payments for non-LUPA episodes using the CY 2018 wage index, we obtain a wage index budget neutrality factor of 0.9991. We would apply the wage index budget neutrality factor of 0.9991 to the calculation of the CY 2019 national, standardized 60-day episode payment rate.

As discussed in section III.B of this proposed rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we propose to apply a case-mix weight budget neutrality factor to the CY 2019 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2019 case-mix weights are applied to CY 2017 utilization (claims) data to total payments when CY 2018 case-mix weights are applied to CY 2017 utilization data. The case-mix budget neutrality factor for CY 2019 is 1.0163 as described in section III.B of this proposed rule.

Next, we would update the payment rates by the CY 2019 home health payment update percentage of 2.1 percent as described in section III.C.2 of this proposed rule. The CY 2019 national, standardized 60-day episode payment rate is calculated in Table 18.

TABLE 18—CY 2019 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2018 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	CY 2019 HH payment update	CY 2019 National, standardized 60-day episode payment
\$3,039.64	× 0.9991	× 1.0163	× 1.021	\$3,151.22

The CY 2019 national, standardized 60-day episode payment rate for an HHA that does not submit the required

quality data is updated by the CY 2019 home health payment update of 2.1

percent minus 2 percentage points and is shown in Table 19.

TABLE 19—CY 2019 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2018 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	CY 2019 HH payment update minus 2 percentage points	CY 2019 National, standardized 60-day episode payment
\$3,039.64	× 0.9991	× 1.0163	× 1.001	\$3,089.49

c. CY 2019 National Per-Visit Rates

The national per-visit rates are used to pay LUPAs (episodes with four or fewer visits) and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the CY 2019 national per-visit rates, we started with the CY 2018 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-

visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA episodes using the CY 2019 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2018 wage index. By dividing the total payments for LUPA episodes using the CY 2019 wage index by the total payments for LUPA episodes using the CY 2018 wage index, we obtained a wage index budget neutrality factor of 1.0000. We apply the wage index budget neutrality factor of 1.0000 in order to calculate the CY 2019 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weights budget

neutrality factor is needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the CY 2019 home health payment update percentage of 2.1 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2019 national per-visit rates for HHAs that submit the required quality data are updated by the CY 2019 HH payment update percentage of 2.1 percent and are shown in Table 20.

TABLE 20—CY 2019 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2018 per-visit payment	Wage index budget neutrality factor	CY 2019 HH payment update	CY 2019 per-visit payment
Home Health Aide	\$64.94	× 1.0000	× 1.021	\$66.30
Medical Social Services	229.86	× 1.0000	× 1.021	234.69
Occupational Therapy	157.83	× 1.0000	× 1.021	161.14
Physical Therapy	156.76	× 1.0000	× 1.021	160.05
Skilled Nursing	143.40	× 1.0000	× 1.021	146.41
Speech-Language Pathology	170.38	× 1.0000	× 1.021	173.96

The CY 2019 per-visit payment rates for HHAs that do not submit the

required quality data are updated by the CY 2019 HH payment update percentage

of 2.1 percent minus 2 percentage points and are shown in Table 21.

TABLE 21—CY 2019 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2018 per-visit rates	Wage index budget neutrality factor	CY 2019 HH payment update minus 2 percentage points	CY 2019 per-visit rates
Home Health Aide	\$64.94	× 1.0000	× 1.001	\$65.00
Medical Social Services	229.86	× 1.0000	× 1.001	230.09
Occupational Therapy	157.83	× 1.0000	× 1.001	157.99
Physical Therapy	156.76	× 1.0000	× 1.001	156.92
Skilled Nursing	143.40	× 1.0000	× 1.001	143.54
Speech-Language Pathology	170.38	× 1.0000	× 1.001	170.55

d. Low-Utilization Payment Adjustment (LUPA) Add-On Factors

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent

episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, in the case of HHAs that do submit the required quality data, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit will be \$270.14 (1.8451 multiplied by \$146.41), subject to area wage adjustment.

e. CY 2019 Non-Routine Medical Supply (NRS) Payment Rates

All medical supplies (routine and nonroutine) must be provided by the HHA while the patient is under a home health plan of care. Examples of supplies that can be considered non-

routine include dressings for wound care, I.V. supplies, ostomy supplies, catheters, and catheter supplies. Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2019 NRS conversion factor, we updated the CY 2018 NRS conversion factor (\$53.03) by the CY 2019 home health payment update percentage of 2.1 percent. We did not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The proposed NRS conversion factor for CY 2019 is shown in Table 22.

TABLE 22—CY 2019 NRS CONVERSION FACTOR FOR HHAs THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2018 NRS conversion factor	CY 2019 HH payment update	CY 2019 NRS conversion factor
\$53.03	× 1.021	\$54.14

Using the CY 2019 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 23.

TABLE 23—CY 2019 NRS PAYMENT AMOUNTS FOR HHAs THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2019 NRS payment amounts
1	0	0.2698	\$ 14.61
2	1 to 14	0.9742	52.74
3	15 to 27	2.6712	144.62
4	28 to 48	3.9686	214.86
5	49 to 98	6.1198	331.33
6	99+	10.5254	569.85

For HHAs that do not submit the required quality data, we updated the CY 2018 NRS conversion factor (\$53.03)

by the CY 2019 home health payment update percentage of 2.1 percent minus 2 percentage points. The proposed CY

2019 NRS conversion factor for HHAs that do not submit quality data is shown in Table 24.

TABLE 24—CY 2019 NRS CONVERSION FACTOR FOR HHAs THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2018 NRS conversion factor	CY 2019 HH payment update percentage minus 2 percentage points	CY 2019 NRS conversion factor
\$53.03	× 1.001	\$53.08

The payment amounts for the various severity levels based on the updated

conversion factor for HHAs that do not

submit quality data are calculated in Table 25.

TABLE 25—CY 2019 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2019 NRS payment amounts
1	0	0.2698	\$ 14.32
2	1 to 14	0.9742	51.71
3	15 to 27	2.6712	141.79
4	28 to 48	3.9686	210.65
5	49 to 98	6.1198	324.84
6	99+	10.5254	558.69

D. Proposed Rural Add-On Payments for CYs 2019 Through 2022

1. Background

Section 421(a) of the MMA required, for HH services furnished in a rural areas (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent.

Section 5201 of the DRA amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 50208(a) of the Bipartisan Budget Act of 2018 amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2019. This extension of the rural add-on payments was implemented as

described in CMS Transmittal 2047 published on March 20, 2018.

2. Proposed Rural Add-On Payments for CYs 2019 Through 2022

Section 50208(a)(1)(D) of the BBA of 2018 adds a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes and visits ending during CYs 2019 through 2022. It also mandates implementation of a new methodology for applying those payments. Unlike previous rural add-ons, which were applied to all rural areas uniformly, the extension provides varying add-on amounts depending on the rural county (or equivalent area) classification by classifying each rural county (or equivalent area) into one of three distinct categories.

Specifically, section 421(b)(1) of the MMA, as amended by section 50208 of the BBA of 2018, provides that rural counties (or equivalent areas) would be placed into one of three categories for purposes of HH rural add-on payments: (1) Rural counties and equivalent areas in the highest quartile of all counties and equivalent areas based on the number of Medicare home health episodes furnished per 100 individuals who are entitled to, or enrolled for, benefits under part A of Medicare or enrolled for benefits under part B of Medicare only, but not enrolled in a Medicare Advantage plan under part C of Medicare, as provided in section 421(b)(1)(A) of the MMA (the “High utilization” category); (2) rural counties and equivalent areas with a population density of 6 individuals or fewer per square mile of land area and are not included in the category provided in section 421(b)(1)(A) of the MMA, as provided in section 421(b)(1)(B) of the MMA (the “Low population density” category); and (3) rural counties and equivalent areas not in the categories provided in either sections 421(b)(1)(A) or 421(b)(1)(B) of the MMA, as provided in section 421(b)(1)(C) of the MMA (the “All other” category). The list of counties and equivalent areas used in our analysis is based on the CY 2015 HH PPS wage index file, which includes the

names of the constituent counties for each rural and urban area designation. We used the 2015 HH PPS wage index file as the basis for our analysis because the 2015 HH PPS wage index file already included SSA state and county codes not normally included on the HH PPS wage index files, but were included in the 2015 HH PPS wage index file due to the transition to new OMB geographic area delineations that year. The CY 2015 HH PPS wage index file is available for download at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1611-F.html>. This file includes 3,246 counties and equivalent areas and their urban and rural status and uses the OMB’s geographic area delineations, as described in section III.C.3 of this proposed rule. We updated the information contained in this file to include any revisions to the geographic area delineations as published by the OMB in their publicly available bulletins that would reflect a change in urban and rural status. The states, the District of Columbia, and the U.S. territories of Guam, Puerto Rico, and the U.S. Virgin Islands are included in the analysis file containing 3,246 counties and equivalent areas. Of the 3,246 total counties and equivalent areas that were used in our analysis, 2,006 of these are considered rural for purposes of determining HH rural add-on payments. We identify equivalent areas based on the definition of equivalent entities as defined by the OMB in their most recent bulletin (No. 18–03) available at <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>.¹³ We consider boroughs and a municipality in Alaska, parishes in Louisiana, municipios in Puerto Rico, and independent cities in

¹³ “Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas”. OMB BULLETIN NO. 18–03. April 10, 2018. <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>.

Maryland, Missouri, Nevada, and Virginia as equivalent areas.

Under section 421(b)(1)(A) of the MMA, one category of rural counties and equivalent areas for purposes of the HH rural add-on payment is a category comprised of rural counties or equivalent areas that are in the highest quartile of all counties or equivalent areas based on the number of Medicare home health episodes furnished per 100 Medicare beneficiaries. Section 421(b)(2)(B)(i) of the MMA requires the use of data from 2015 to determine which counties or equivalent areas are in the highest quartile of home health utilization for the category described under section 421(b)(1)(A) of the MMA, that is, the “High utilization” category. Section 421(b)(2)(B)(ii) of the MMA requires that data from the territories are to be excluded in determining which counties or equivalent areas are in the highest quartile of home health utilization and requires that the territories be excluded from the category described by section 421(b)(1)(A) of the MMA. Under section 421(b)(2)(B)(iii) of the MMA, the Secretary may exclude data from counties or equivalent areas in rural areas with a low volume of home health episodes in determining which counties or equivalent areas are in the highest quartile of home health utilization. If data is excluded for a county or equivalent area, section 421(b)(2)(B)(iii) of the MMA requires that the county or equivalent area be excluded from the category described by section 421(b)(1)(A) of the MMA (the “High utilization” category).

We used CY 2015 claims data and 2015 data from the Medicare Beneficiary Summary File to classify rural counties and equivalent areas into the “High utilization” category. We propose to classify a rural county or equivalent area into this category if the county or equivalent area is in the highest quartile (top 25th percentile) of all (urban and rural) counties and equivalent areas based on the ratio of Medicare home health episodes furnished per 100 Medicare enrollees. The Medicare Beneficiary Summary File contained information on the Social Security Administration (SSA) state and county code of the beneficiary’s mailing address and information on enrollment in Medicare Part A, B, and C during 2015. The claims data and information from the Medicare Beneficiary Summary File were pulled from the Chronic Condition Warehouse Virtual Research Data Center during December 2017. We used the claims data to determine how many home health episodes (excluding Requests for Anticipated Payments (RAPs) and zero payment episodes)

occurred in each state and county or equivalent area. We assigned each home health episode to the state and county code of the beneficiary’s mailing address. As stipulated by section 421(b)(2)(B)(ii) of the MMA, we excluded any data from the territories of Guam, Puerto Rico, and the U.S. Virgin Islands for determining which rural counties and equivalent areas belong in the “High utilization” category. We note that the territories of American Samoa and the Northern Mariana Islands were not included in the CY 2015 HH PPS wage index file to identify counties or equivalent areas for these territories so no data from these territories were included in determining the “High utilization” category. As we are not aware of any Medicare home health services being furnished in these two territories in recent years, we will address any application of home health rural add-on payments for these territories in the future should Medicare home health services be furnished in them. Therefore, counties and equivalent areas in the territories of American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands are not included in the “High utilization” category, as required by section 421(b)(2)(B)(ii) of the MMA. In addition, under the authority granted to the Secretary (by section 421(b)(2)(B)(iii) of the MMA) to exclude data from counties or equivalent areas in rural areas with a low volume of home health episodes, we excluded data from rural counties and equivalent areas that had 10 or fewer episodes during 2015 for determining which counties and equivalent areas belong in the “High utilization” category. We believe that using a threshold of 10 or fewer episodes is a reasonable threshold for defining low volume, in accordance with section 421(b)(2)(B)(iii) of the MMA. After excluding data from (1) the territories of Guam, Puerto Rico, and the U.S. Virgin Islands and (2) counties and equivalent areas that had 10 or fewer episodes during 2015, we determined the number of home health episodes furnished per 100 enrollees for the remaining counties and equivalent areas. We determined that the counties or equivalent areas in the highest quartile have a ratio of episodes to beneficiaries that is at or above 17.72487. The highest quartile consisted of 778 counties or equivalent areas. Of those 778 counties or equivalent areas, 510 are rural and, therefore, we propose to classify these 510 rural counties or equivalent areas into the “High utilization” category.

Under section 421(b)(1)(B) of the MMA, another category of rural counties and equivalent areas for purposes of the HH rural add-on payment is a category comprised of rural counties or equivalent areas with a population density of 6 individuals or fewer per square mile of land area and that are not included in the “High utilization” category. Section 421(b)(2)(C) of the MMA requires that data from the 2010 decennial Census be used for purposes of determining population density with respect to the category provided under section 421(b)(1)(B) of the MMA, that is, the “Low population density” category.

We used 2010 Census data gathered from the tables provided at: https://factfinder.census.gov/bkmk/table/1.0/en/DEC/10_SF1/GCTPH1.US05PR and <https://www.census.gov/data/tables/time-series/dec/cph-series/cph-t/cph-t-8.html> to determine which counties and equivalent areas have a population density of six individuals or fewer per square mile of land area.^{14 15} In examining the rural counties and equivalent areas that were not already classified into the “High utilization” category, we identified each rural county or equivalent area that had a population density of six individuals or fewer per square mile of land area. As a result of that analysis, we determined there are 334 rural counties or equivalent areas that have a population density of six individuals or fewer per square mile of land area and that are not already classified into the “High utilization” category. We propose to classify 334 rural counties or equivalent areas into the “Low population density” category.

Lastly, section 421(b)(1)(C) of the MMA provides for a category comprised of rural counties or equivalent areas that are not included in either the “High utilization” or the “Low population density” category. After determining which rural counties and equivalent areas should be classified into the “High utilization” and “Low population density” categories, we have determined that there are 1,162 remaining rural counties and equivalent areas that do not meet the criteria for inclusion in the “High utilization” or “Low population density” categories. We propose to classify these 1,162 rural counties and

¹⁴ “Population, Housing Units, Area, and Density: 2010—United States—County by State; and for Puerto Rico 2010 Census Summary File 1”. https://factfinder.census.gov/bkmk/table/1.0/en/DEC/10_SF1/GCTPH1.US05PR.

¹⁵ “Population, Housing Units, Land Area, and Density for U.S. Island Areas: 2010 (CPH-T-8)”. 10/28/2013. <https://www.census.gov/data/tables/time-series/dec/cph-series/cph-t/cph-t-8.html>.

equivalent areas into the “All other” category.

Section 421(b)(1) of the MMA specifies varying rural add-on payment percentages and varying durations of rural add-on payments for home health services furnished in a rural county or equivalent area according to which category described in section 421(b)(1)(A), 421(b)(1)(B), or

421(b)(1)(C) of the MMA that the rural county or equivalent area is classified into. The rural add-on payment percentages and duration of rural add-on payments are shown in Table 26. The national standardized 60-day episode payment rate, the national per-visit rates, and the NRS conversion factor will be increased by the rural add-on

payment percentages as noted in Table 26 when services are provided in rural areas. The HH Pricer module, located within CMS’ claims processing system, will increase the base payment rates provided in Tables 18 through 25 by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments.

TABLE 26—HH PPS RURAL ADD-ON PERCENTAGES, CYs 2019–2022

Category	CY 2019 (%)	CY 2020 (%)	CY 2021 (%)	CY 2022 (%)
High utilization	1.5	0.5
Low population density	4.0	3.0	2.0	1.0
All other	3.0	2.0	1.0

Section 421(b)(2)(A) of the MMA provides that the Secretary shall make a determination only for a single time as to which category under sections 421(b)(1)(A), 421(b)(1)(B), or 421(b)(1)(C) of the MMA that a rural county or equivalent area is classified into, and that the determination applies for the entire duration of the period for which rural add-on payments are in place under section 421(b) of the MMA. We propose that our proposed classifications of rural counties and equivalent areas in the “High utilization”, “Low population density”, and “All other” categories would be applicable throughout the period of rural add-on payments established under section 421(b) of the MMA and there would be no changes in classifications. This would mean that a rural county or equivalent area classified into the “High utilization” category would remain in that category through CY 2022 even after rural add-on payments for that category ends after CY 2020. Similarly, a rural county or equivalent area classified into the “All other” category would remain in that category through CY 2022 even after rural add-on payments for that category ends after CY 2021. A rural county or equivalent area classified into the “Low population density” category would remain in that category through CY 2022.

Section 421(b)(3) of the MMA provides that there shall be no administrative or judicial review of the classification determinations made for the rural add-on payments under section 421(b)(1) of the MMA.

Section 50208(a)(2) of the Bipartisan Budget Act of 2018 amended section 1895(c) of the Act by adding a new requirement set out at section 1895(c)(3) of the Act. This requirement states that no claim for home health services may

be paid unless “in the case of home health services furnished on or after January 1, 2019, the claim contains the code for the county (or equivalent area) in which the home health service was furnished.” This information will be necessary in order to calculate the rural add-on payments. We are proposing that HHAs enter the FIPS state and county code, rather than the SSA state and county code, on the claim. Many HHAs are more familiar with using FIPS state and county codes since HHAs in a number of States are already using FIPS state and county codes for State-mandated reporting programs. Our analysis is based entirely on the SSA state and county codes as these are the codes that are included in the Medicare Beneficiary Summary File. We cross-walked the SSA state and county codes used in our analysis to the FIPS state and county codes in order to provide HHAs with the corresponding FIPS state and county codes that should be reported on their claims.

The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of this proposed rule at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1689-P.html>. In addition, an Excel file containing the rural county or equivalent area names, their FIPS state and county codes, and their designation into one of the three rural add-on categories is available for download.

We are soliciting comments regarding our application of the methodology specified by section 50208 of the Bipartisan Budget Act of 2018.

E. Proposed Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode’s estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or Partial Episode Payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the HH FDL ratio by a case’s wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, and required the Secretary to reduce the HH PPS payment rates such that aggregate HH PPS payments were

reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act, and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act which capped outlier payments as a percent of total payments for each HHA at 10 percent.

As such, beginning in CY 2011, we reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold; and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the

amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

We plan to publish the cost-per-unit amounts for CY 2019 in the rate update change request, which is issued after the publication of the CY 2019 HH PPS final rule. We note that in the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, we noted that the per-unit rates used to estimate an episode's cost will be updated by the home health update percentage each year, meaning we would start with the national per-visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We note that we will continue to monitor the visit length by discipline as more recent data become available, and we may propose to update the rates as needed in the future.

2. Proposed Fixed Dollar Loss (FDL) Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount.

Simulations based on CY 2015 claims data (as of June 30, 2016) completed for the CY 2017 HH PPS final rule showed that outlier payments were estimated to represent approximately 2.84 percent of total HH PPS payments in CY 2017, and as such, we raised the FDL ratio from 0.45 to 0.55. We stated that raising the FDL ratio to 0.55, while maintaining a loss-sharing ratio of 0.80, struck an effective balance of compensating for high-cost episodes while still meeting the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments (81 FR 76726). The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

For this proposed rule, simulating payments using preliminary CY 2017 claims data (as of March 2, 2018) and the CY 2018 HH PPS payment rates (82 FR 51676), we estimate that outlier payments in CY 2018 would comprise 2.30 percent of total payments. Based on simulations using CY 2017 claims data (as of March 2, 2018) and the proposed CY 2019 payment rates presented in section III.C.4 of this proposed rule, we estimate that outlier payments would constitute approximately 2.32 percent of total HH PPS payments in CY 2019. Our simulations show that the FDL ratio would need to be changed from 0.55 to 0.51 to pay up to, but no more than, 2.5 percent of total payments as outlier payments in CY 2019.

Given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made based under the HH PPS, we are proposing to lower the FDL ratio for CY 2019 from 0.55 to 0.51 to better approximate the 2.5 percent statutory maximum. However, we note that we are not proposing a change to the loss-sharing ratio (0.80) for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.). We note that in the final rule, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2017 claims data as of June 30, 2018 or later) and therefore, we may adjust the final FDL ratio accordingly. We invite public comments on the

proposed change to the FDL ratio for CY 2019.

3. Home Health Outlier Payments: Clinical Example

In recent months, concerns regarding the provision of home health care for Medicare patients with chronic, complex conditions have been raised by stakeholders as well as the press.^{16 17 18 19} News stories and anecdotal reports indicate that Medicare patients with chronic conditions may be encountering difficulty in accessing home health care if the goal of home health care is to maintain or prevent further decline of the patient's condition rather than improvement of the patient's condition. While patients must require skilled care to be eligible to receive services under the Medicare home health benefit, as outlined in regulation at 42 CFR 409.42(c), we note that coverage does not turn on the presence or absence of an individual's potential for improvement, but rather on the beneficiary's need for skilled care. Skilled care is covered where such services are necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely and effectively provided. Additionally, there appears to be confusion among the HHA provider community regarding possible Medicare payment through the HH PPS, as it appears that some perceive that payment is somewhat fixed and not able to account for home health stays with higher costs.

The news stories referenced an individual with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, and the difficulties encountered in finding Medicare home health care. Below we describe a clinical example of how care for a patient with ALS could qualify for an additional outlier payment, which would serve to offset unusually high costs associated with providing home health to a patient with unusual variations in the amount of medically necessary care. This example, using

payment policies in place for CY 2018, is provided for illustrative purposes only. We hope that in providing the example below, which illustrates how HHAs could be paid by Medicare for providing care to patients with higher resource use in their homes, and by reiterating that the patient's condition does not need to improve for home health services to be covered by Medicare, that there will be a better understanding of Medicare coverage policies and how outlier payments promote access to home health services for such patients under the HH PPS.

a. Clinical Scenario

Amyotrophic Lateral Sclerosis (ALS) is a progressive neuromuscular degenerative disease. The incidence rates of ALS have been increasing over the last few decades, and the peak incidence rate occurs at age 75.²⁰ The prevalence rate of ALS in the United States is 4.3 per 100,000 population.²¹ Half of all people affected with ALS live at least 3 or more years after diagnosis. Twenty percent live 5 years or more; up to 10 percent will live more than 10 years.²² Because of the progressive nature of this disease, care needs change and generally intensify as different body systems are affected. As such, patients with ALS often require a multidisciplinary approach to meet their care needs.

The clinical care of a beneficiary with ALS typically includes the ongoing assessment of and treatment for many impacts to the body systems. As a part of a home health episode, a skilled nurse could assess the patient for shortness of breath, mucus secretions, sialorrhea, pressure sores, and pain. From these assessments, the nurse could speak with the doctor about changes to the care plan. A nurse's aide could provide assistance with bathing, dressing, toileting, and transferring. Physical therapy services could also help the patient with range of motion exercises, adaptive transfer techniques, and assistive devices in order to maintain a level of function.

The following is a description of how the provision of services per the home

health plan of care could emerge for a beneficiary with ALS who qualifies for the Medicare home health benefit. We note that this example is provided for illustrative purposes only and does not constitute a specific Medicare payment scenario.

b. Example One: Home Health Episodes 1 and 2

A beneficiary with ALS may be assessed by a physician in the community and subsequently be deemed to require home health services for skilled nursing, physical therapy, occupational therapy, and a home health aide. The beneficiary could receive skilled nursing twice a week for 45 minutes to assess dyspnea when transferring to a bedside commode, stage two pressure ulcer at the sacrum, and pain status. In addition, a home health aide could provide services for three hours in the morning and three hours in the afternoon on Monday, Wednesday, and Friday and two and a half hours in the morning and 2.5 hours in the afternoon on Tuesday and Thursdays to assist with bathing, dressing, and transferring. Physical therapy services twice a week for 45 minutes could be provided for adaptive transfer techniques, and occupational therapy services could be supplied twice a week for 45 minutes for assessment and teaching of assistive devices for activities of daily living to prevent or slow deterioration of the patient's condition. Given the patient's clinical presentation, for the purpose of this specific example, we will assign the patient payment group 40331 (C3F3S1 with 20+ therapy visits).

For the purposes of this example, we assume that services are rendered per week for a total of 8 weeks per home health episode. For both the first and second home health episodes of care, the calculation to determine outlier payment utilizing payment amounts and case mix weights for CY 2018, as described in the CY 2018 HH PPS final rule (82 FR 51676), would be as follows, per 60-day episode:

TABLE 27—CLINICAL SCENARIO CALCULATION TABLE: EPISODES 1 AND 2

HH outlier—CY 2018 illustrative values	Value	Operation	Adjuster	Equals	Output
National, Standardized 60-day Episode Payment Rate	\$3,039.64

¹⁶ <https://www.npr.org/sections/health-shots/2018/01/17/578423012/home-care-agencies-often-wrongly-deny-medicare-help-to-the-chronically-ill>.

¹⁷ <http://www.alsa.org/als-care/resources/fyi/medicare-and-home-health-care.html>.

¹⁸ <https://patientworthy.com/2018/01/31/chronically-ill-are-being-denied-medicare-coverage-by-home-care-agencies/>.

¹⁹ <https://alsnewstoday.com/2018/05/09/als-medicare-cover-home-healthcare/>.

²⁰ Worms PM, The epidemiology of motor neuron diseases: A review of recent studies. *J Neurol Sci.* 2001;191(1-2):3.

²¹ Mehta P, Prevalence of Amyotrophic Lateral Sclerosis—United States, 2012–2013. *MMWR Surveill Summ.* 2016;65(8):1. Epub 2016 Aug 5.

²² <http://www.alsa.org>.

TABLE 27—CLINICAL SCENARIO CALCULATION TABLE: EPISODES 1 AND 2—Continued

HH outlier—CY 2018 illustrative values	Value	Operation	Adjuster	Equals	Output
Case-Mix Weight for Payment Group 4.0331 (for C3F3S1 for 20+ therapy) ..	2.1359
Case-Mix Adjusted Episode Payment Amount	3,039.64	*	2.1359	=	6,492.37
Labor Portion of the Case-Mix Adjusted Episode Payment Amount	6,492.37	*	0.78535	—	5,098.78
Non-Labor Portion of the Case-Mix Adjusted Episode Payment Amount	6,492.37	*	0.21465	=	1,393.59
Wage Index Value (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.2781
Wage-Adjusted Labor Portion of the Case-Mix Adjusted Episode Payment Amount	5,098.78	*	1.2781	=	6,516.75
NRS Payment Amount (Severity Level 2)	51.66	=	51.66
Total Case-Mix and Wage-Adjusted Episode Payment Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Episode Payment Amount plus the NRS Amount)				=	7,962.00
Total Wage-Adjusted Fixed Dollar Loss Amount:					
Fixed Dollar Loss Amount (National, Standardized 60-day Episode Payment Rate * FDL Ratio)	3,039.64	*	0.55	=	1,671.80
Labor Portion of the Fixed Dollar Loss Amount	1,671.80	*	0.78535	=	1,312.95
Non-Labor Amount of the Fixed Dollar Loss Amount	1,671.80	*	0.21465	=	358.85
Wage-Adjusted Fixed Dollar Loss Amount	1,312.95	*	1.2781	=	1,678.08
Total Wage-Adjusted Fixed Dollar Loss Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Fixed Dollar Loss Amount)	1,678.08	+	358.85	=	2,036.93
Total Wage-Adjusted Imputed Cost Amount:					
National Per-Unit Payment Amount—Skilled Nursing	48.01
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48
Imputed Skilled Nursing Visit Costs (National Per-Unit Payment Amount * Number of Units)	48.01	*	48	=	2,304.48
National Per-Unit Payment Amount—Home Health Aide	15.46
Number of 15-minute units (28 hours per week = 112 units per week for 8 weeks)	896
Imputed Home Health Aide Costs (National Per-Unit Payment Amount * Number of Units)	15.46	*	896	=	13,852.16
National Per-Unit Payment Amount—Occupational Therapy (OT)	50.26
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48
Imputed OT Visit Costs (National Per-Unit Payment Amount * Number of Units)	50.26	*	48	=	2,412.48
National Per-Unit Payment Amount—Physical Therapy (PT)	50.46
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48
Imputed PT Visit Costs (National Per-Unit Payment Amount * Number of Units)	50.46	*	48	=	2,422.08
Total Imputed Cost Amount for all Disciplines				=	20,991.20
Labor Portion of the Imputed Costs for All Disciplines	20,991.20	*	0.78535	=	16,485.44
Non-Labor Portion of Imputed Cost Amount for All Disciplines	20,991.20	*	0.21465	=	4,505.76
CBSA Wage Index (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.2781
Wage-Adjusted Labor Portion of the Imputed Cost Amount for All Disciplines	16,485.44	*	1.2781	=	21,070.04
Total Wage-Adjusted Imputed Cost Amount (Wage-Adjusted Labor Portion of the Imputed Cost Amount plus Non-Labor Portion of the Imputed Cost Amount)	21,070.04	+	4,505.76	=	25,575.80
Total Payment Per 60-Day Episode:					
Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Episode Payment Amount)	2,036.93	+	7,962.00	=	9,998.93
Total Wage-Adjusted Imputed Cost Amount—Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Episode Payment Amount)	25,575.80	—	9,998.93	=	15,576.87
Outlier Payment = Imputed Costs Greater Than the Outlier Threshold * Loss-Sharing Ratio (0.80)	15,576.87	*	0.80	=	12,461.50
Total Payment Per 60-Day Episode = Total Case-Mix and Wage-Adjusted Episode Payment Amount + Outlier Payment	7,962.00	+	12,461.50	=	20,423.49

For Episodes 1 and 2 of this clinical scenario, the preceding calculation illustrates how HHAs are paid by Medicare for providing care to patients with higher resource use in their homes.

c. Example Two: Home Health Episodes 3 and 4

ALS is a progressive disease such that the patient would most likely need care beyond a second 60-day HH episode. A beneficiary's condition could become

more complex, such that the patient could require a gastrostomy tube, which could be placed during a hospital stay. The patient could be discharged to home for enteral nutrition to maintain weight and continuing care for his/her stage two pressure ulcer. Given the complexity of the beneficiary's condition in this example, the episode could remain at the highest level of care C3F3S1 and would now fit into equation 4.

For the purposes of this example, we assume that services are rendered per week for a total of 8 weeks per home health episode. For both the third and fourth home health episodes of care, the calculation to determine outlier payment utilizing payment amounts and case mix weights for CY 2018 as described in as described in the CY 2018 HH PPS final rule (82 FR 51676) would be as follows, per 60-day episode:

TABLE 28—CLINICAL SCENARIO CALCULATION: EPISODES 3 AND 4

HH outlier—CY 2018 illustrative values	Value	Operation	Adjuster	Equals	Output
National, Standardized 60-day Episode Payment Rate	\$3,039.64
Case-Mix Weight for Payment Group 4.0331 (for C3F3S1 for 20+ therapy) ...	2.1359
Case-Mix Adjusted Episode Payment Amount	3,039.64	*	2.1359	=	\$6,492.37
Labor Portion of the Case-Mix Adjusted Episode Payment Amount	6,492.37	*	0.78535	=	5,098.78
Non-Labor Portion of the Case-Mix Adjusted Episode Payment Amount	6,492.37	*	0.21465	=	1,393.59
Wage Index Value (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.2781
Wage-Adjusted Labor Portion of the Case-Mix Adjusted Episode Payment Amount	5,098.78	*	1.2781	=	6,516.75
NRS Payment Amount (Severity Level 2)	324.53	=	324.53
Total Case-Mix and Wage-Adjusted Episode Payment Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Episode Payment Amount plus the NRS Amount)	=	8,234.87
Total Wage-Adjusted Fixed Dollar Loss Amount:					
Fixed Dollar Loss Amount (National, Standardized 60-day Episode Payment Rate * FDL Ratio)	3,039.64	*	0.55	=	1,671.80
Labor Portion of the Fixed Dollar Loss Amount	1,671.80	*	0.78535	=	1,312.95
Non-Labor Amount of the Fixed Dollar Loss Amount	1,671.80	*	0.21465	=	358.85
Wage-Adjusted Fixed Dollar Loss Amount	1,312.95	*	1.2781	=	1,678.08
Total Wage-Adjusted Fixed Dollar Loss Amount (Wage-Adjusted Labor Portion plus Non-Labor Portion of the Case-Mix Adjusted Fixed Dollar Loss Amount)	1,678.08	+	358.85	=	2,036.93
Total Wage-Adjusted Imputed Cost Amount:					
National Per-Unit Payment Amount—Skilled Nursing	48.01
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48
Imputed Skilled Nursing Visit Costs (National Per-Unit Payment Amount * Number of Units)	48.01	*	48	=	2,304.48
National Per-Unit Payment Amount—Home Health Aide	15.46
Number of 15-minute units (28 hours per week = 112 units per week for 8 weeks)	896
Imputed Home Health Aide Costs (National Per-Unit Payment Amount * Number of Units)	15.46	*	896	=	13,852.16
National Per-Unit Payment Amount—Occupational Therapy (OT)	50.26
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48
Imputed OT Visit Costs (National Per-Unit Payment Amount * Number of Units)	50.26	*	48	=	2,412.48
National Per-Unit Payment Amount—Physical Therapy (PT)	50.46
Number of 15-minute units (45 minutes = 3 units twice per week for 8 weeks)	48
Imputed PT Visit Costs (National Per-Unit Payment Amount * Number of Units)	50.46	*	48	=	2,422.08
Total Imputed Cost Amount for all Disciplines	=	20,991.20
Labor Portion of the Imputed Costs for All Disciplines	20,991.20	*	0.78535	=	16,485.44
Non-Labor Portion of Imputed Cost Amount for All Disciplines	20,991.20	*	0.21465	=	4,505.76
CBSA Wage Index (Beneficiary resides in 31084, Los Angeles-Long Beach-Glendale, CA)	1.2781
Wage-Adjusted Labor Portion of the Imputed Cost Amount for All Disciplines	16,485.44	*	1.2781	=	21,070.04
Total Wage-Adjusted Imputed Cost Amount (Wage-Adjusted Labor Portion of the Imputed Cost Amount plus Non-Labor Portion of the Imputed Cost Amount)	21,070.04	+	4,505.76	=	25,575.80
Total Payment Per 60-Day Episode:					

TABLE 28—CLINICAL SCENARIO CALCULATION: EPISODES 3 AND 4—Continued

HH outlier—CY 2018 illustrative values	Value	Operation	Adjuster	Equals	Output
Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Episode Payment Amount)	2,036.93	+	8,234.87	=	10,271.80
Total Wage-Adjusted Imputed Cost Amount – Outlier Threshold Amount (Total Wage-Adjusted Fixed Dollar Loss Amount + Total Case-Mix and Wage-Adjusted Episode Payment Amount)	25,575.80	–	10,271.80	=	15,304.00
Outlier Payment = Imputed Costs Greater Than the Outlier Threshold * Loss-Sharing Ratio (0.80)	15,304.00	*	0.80	=	12,243.20
Total Payment Per 60-Day Episode = Total Case-Mix and Wage-Adjusted Episode Payment Amount + Outlier Payment	12,243.20	+	8,234.87	=	20,478.07

For Episodes 3 and 4 of this clinical scenario, the above calculation demonstrates how outlier payments could be made for patients with chronic, complex conditions under the HH PPS. We reiterate that outlier payments could provide payment to HHAs for those patients with higher resource use and that the patient’s condition does not need to improve for home health services to be covered by Medicare. We appreciate the feedback we have received from the public on the outlier policy under the HH PPS and look forward to ongoing collaboration with stakeholders on any further refinements that may be warranted. We note that this example is presented for illustrative purposes only, and is not intended to suggest that all diagnoses of ALS should receive the grouping assignment or number of episodes described here. The CMS Grouper assigns these groups based on information in the OASIS.

F. Implementation of the Patient-Driven Groupings Model (PDGM) for CY 2020

1. Background and Legislation, Overview, Data, and File Construction

a. Background and Legislation

In the CY 2018 HH PPS proposed rule, we proposed an alternative case mix-adjustment methodology (known as the Home Health Groupings Model or HHGM), to be implemented for home health periods of care beginning on or after January 1, 2019. Ultimately this proposed alternative case-mix adjustment methodology, including a proposed change in the unit of payment from 60 days to 30 days, was not finalized in the CY 2018 HH PPS final rule in order to allow us additional time to consider public comments for potential refinements to the methodology (82 FR 51676).

On February 9, 2018, the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) was signed into law. Section 51001(a)(1) of the BBA of 2018 amended section 1895(b)(2) of the Act by adding a new subparagraph (B) to

require the Secretary to apply a 30-day unit of service for purposes of implementing the HH PPS, effective January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service that end during the 12-month period beginning January 1, 2020 in a budget neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before, and not affect the application of, the provisions of section 1895(b)(3)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act additionally requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavioral changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavioral assumptions made in notice and comment rulemaking.

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary to annually determine the impact of differences between assumed behavior changes as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020

and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year.

Section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for 2020 and subsequent years. Lastly, section 51001(b)(4) of the BBA of 2018 requires the Secretary to pursue notice and comment rulemaking no later than December 31, 2019 on a revised case-mix system for payment of home health services under the HH PPS

b. Overview

To meet the requirement under section 51001(b)(4) of the BBA of 2018 to engage in notice and comment rulemaking on a HH PPS case-mix system and to better align payment with

patient care needs and better ensure that clinically complex and ill beneficiaries have adequate access to home health care, we are proposing case-mix methodology refinements through the implementation of the Patient-Driven Groupings Model (PDGM). The proposed PDGM shares many of the features included in the alternative case mix-adjustment methodology proposed in the CY 2018 HH PPS proposed rule. We propose to implement the PDGM for home health periods of care beginning on or after January 1, 2020. The implementation of the PDGM will require provider education and training, updating and revising relevant manuals, and changing claims processing systems. Implementation starting in CY 2020 would provide opportunity for CMS, its contractors, and the agencies themselves to prepare. This patient-centered model groups periods of care in a manner consistent with how clinicians differentiate between patients and the primary reason for needing home health care. As required by section 1895(b)(2)(B) of the Act, we propose to use 30-day periods rather than the 60-day episode used in the current payment system. In addition, section 1895(b)(4)(B)(ii) of the Act eliminates the use of therapy thresholds in the case-mix adjustment for determining payment. The proposed PDGM does not use the number of therapy visits in determining payment. The change from the current case-mix adjustment methodology for the HH PPS, which relies heavily on therapy thresholds as a major determinant for payment and thus provides a higher payment for a higher volume of therapy provided, to the PDGM would remove the financial incentive to overprovide therapy in order to receive a higher payment. The PDGM would base case-mix adjustment for home health payment solely on patient characteristics, a more patient-focused approach to payment. Finally, the PDGM relies more heavily on clinical characteristics and other patient information (for example, diagnosis, functional level, comorbid conditions, admission source) to place patients into clinically meaningful payment categories. In total, there are 216 different payment groups in the PDGM.

Costs during an episode/period of care are estimated based on the concept of resource use, which measures the costs associated with visits performed during a home health episode/period. For the current HH PPS case-mix weights, we use Wage Weighted Minutes of Care (WWMC), which uses data from the Bureau of Labor Statistics

(BLS) reflecting the Home Health Care Service Industry. For the PDGM, we propose shifting to a Cost-Per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from the Medicare Cost Report. The CPM + NRS approach incorporates a wider variety of costs (such as transportation) compared to the BLS estimates and the costs are available for individual HHA providers while the BLS costs are aggregated for the Home Health Care Service industry.

Similar to the current payment system, 30-day periods under the PDGM would be classified as “early” or “late” depending on when they occur within a sequence of 30-day periods. Under the current HH PPS, the first two 60-day episodes of a sequence of adjacent 60-day episodes are considered early, while the third 60-day episode of that sequence and any subsequent episodes are considered late. Under the PDGM, the first 30-day period is classified as early. All subsequent 30-day periods in the sequence (second or later) are classified as late. We propose to adopt this timing classification for 30-day periods with the implementation of the PDGM for CY 2020. Similar to the current payment system, we propose that a 30-day period could not be considered early unless there was a gap of more than 60 days between the end of one period and the start of another. The comprehensive assessment would still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, Condition of participation: Comprehensive assessment of patients. In addition, the plan of care would still be reviewed and revised by the HHA and the physician responsible for the home health plan of care no less frequently than once every 60 days, beginning with the start of care date, as currently required by § 484.60(c), Condition of participation: Care planning, coordination of services, and quality of care.

Under the PDGM, we propose that each period would be classified into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health. The 30-day period would be categorized as institutional if an acute or post-acute care stay occurred in the 14 days prior to the start of the 30-day period of care. The 30-day period would be categorized as community if there was no acute or post-acute care stay in the 14 days prior to the start of the 30-day period of care.

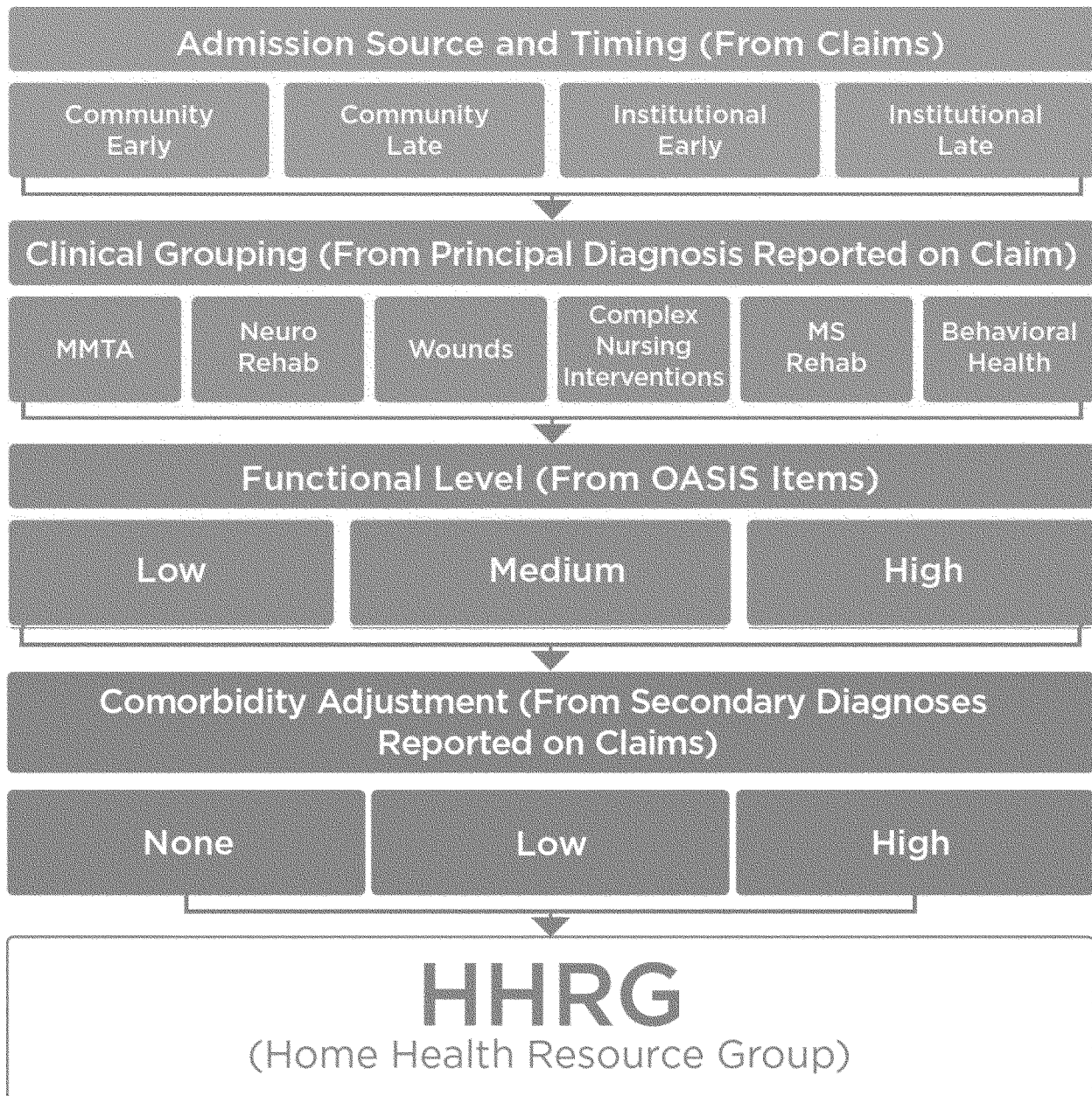
The PDGM would group 30-day periods into categories based on a variety of patient characteristics. We propose grouping periods into one of six clinical groups based on the principal diagnosis. The principal diagnosis reported would provide information to describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The proposed six clinical groups, are as follows:

- Musculoskeletal Rehabilitation.
- Neuro/Stroke Rehabilitation.
- Wounds—Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care.
- Complex Nursing Interventions.
- Behavioral Health Care (including Substance Use Disorders).
- Medication Management, Teaching and Assessment (MMTA).

Under the PDGM, we propose that each 30-day period would be placed into one of three functional levels. The level would indicate if, on average, given its responses on certain functional OASIS items, a 30-day period is predicted to have higher costs or lower costs. We are proposing to assign roughly 33 percent of periods within each clinical group to each functional level. The criteria for assignment to each of the three functional levels may differ across each clinical group. The proposed functional level assignment under the PDGM is very similar to the functional level assignment in the current payment system. Finally, the PDGM includes a comorbidity adjustment category based on the presence of secondary diagnoses. We propose that, depending on a patient’s secondary diagnoses, a 30-day period may receive “no” comorbidity adjustment, a “low” comorbidity adjustment, or a “high” comorbidity adjustment. For low-utilization payment adjustments (LUPAs) under the PDGM, we propose that the LUPA threshold would vary for a 30-day period under the PDGM depending on the PDGM payment group to which it is assigned. For each payment group, we propose to use the 10th percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 for each group.

Figure BBB1 represents how each 30-day period of care would be placed into one of the 216 home health resource groups (HHRGs) under the proposed PDGM for CY 2020.

BILLING CODE 4210-01-P

FIGURE 4: STRUCTURE OF THE PDGM

Under the Patient Driven Groupings Model, a 30-day period is grouped into one (and only one) subcategory under each larger colored category. A 30-day period's combination of subcategories places the 30-day period into one of 216 different payment groups.

BILLING CODE 4210-01-C**c. Data and File Construction**

To create the PDGM proposed model and related analyses, a data file based on home health episodes of care as reported in Medicare home health claims was utilized. The claims data provide episode-level data (for example, episode From and Through Dates, total number of visits, HHRG, diagnoses), as

well as visit-level data (visit date, visit length in 15-minute units, discipline of the staff, etc.). The claims also provide data on whether NRS was provided during the episode and total charges for NRS.

The core file for most of the analyses for this proposed rule includes 100 percent of home health episode claims with Through Dates in Calendar Year (CY) 2017, processed by March 2, 2018,

accessed via the Chronic Conditions Data Warehouse (CCW). Original or adjustment claims processed after March 2, 2018, would not be reflected in the core file. The claims-based file was supplemented with additional variables that were obtained from the CCW, such as information regarding other Part A and Part B utilization.

The data were cleaned by processing any remaining adjustments and by

excluding duplicates and claims that were Requests for Anticipated Payment (RAP). In addition, visit-level variables needed for the analysis were extracted from the revenue center trailers (that is, the line items that describe the visits) and downloaded as a separate visit-level file, with selected episode-level variables merged onto the records for visits during those episodes. To account for potential data entry errors, the visit-level variables for visit length were top-censored at 8 hours.²³

A set of data cleaning exclusions were applied to the episode-level file, which resulted in the exclusion of the following:

- Episodes that were RAPs.
- Episodes with no covered visits.
- Episodes with any missing units or visit data.
- Episodes with zero payments.
- Episodes with no charges.
- Non-LUPA episodes missing an HHRG.

The analysis file also includes data on patient characteristics obtained from the OASIS assessments conducted by home health agency (HHA) staff at the start of each episode. The assessment data are electronically submitted by HHAs to a central CMS repository. In constructing the core data file, 100 percent of the OASIS assessments submitted October 2016 through December 2017 from the CMS repository were uploaded by CMS to the CCW. A CCW-derived linking key

(Bene ID) was used to match the OASIS data with CY 2017 episodes of care. Episodes that could not be linked with an OASIS assessment were excluded from the analysis file, as they included insufficient patient-level data to create the PDGM.

To construct measures of resource use, a variety of data sources were used (see section III.F.2 of this proposed rule for the proposed methodology used to calculate the cost of care under the PDGM). First, BLS data on average wages and fringe benefits were used to produce wage-weighted minutes of care (WWMC), the approach used in the current system to calculate the cost of care. The wage data are for North American Industry Classification System (NAICS) 621600—Home Health Care Services (see Table 29).

TABLE 29—BLS STANDARD OCCUPATION CLASSIFICATION (SOC) CODES FOR HOME HEALTH PROVIDERS

Standard Occupation Code (SOC) No.	Occupation title
29-1141	Registered Nurses.
29-2061	Licensed Practical and Licensed Vocational Nurses.
29-1123	Physical Therapists.
31-2021	Physical Therapist Assistants.
31-2022	Physical Therapist Aides.
29-1122	Occupational Therapists.
31-2011	Occupational Therapist Assistants.
31-2012	Occupational Therapist Aides.

TABLE 29—BLS STANDARD OCCUPATION CLASSIFICATION (SOC) CODES FOR HOME HEALTH PROVIDERS—Continued

Standard Occupation Code (SOC) No.	Occupation title
29-1127	Speech-Language Pathologists.
21-1022	Medical and Public Health Social Workers.
21-1023	Mental Health and Substance Abuse Social Workers.
31-1011	Home Health Aides.

The WWMC approach determines resource use for each episode by multiplying utilization (in terms of the number of minutes of direct patient care provided by each discipline) by the corresponding opportunity cost of that care (represented by wage and fringe benefit rates from the BLS).²⁴ Table 30 shows the occupational titles and corresponding mean hourly wage rates from the BLS. The employer cost per hour worked shown in the fifth column is calculated by adding together the mean hourly wage rates and the fringe benefit rates from the BLS. For home health disciplines that include multiple occupations (such as skilled nursing), the opportunity cost is generated by weighting the employer cost by the proportions of the labor mix.²⁵ Otherwise, the opportunity cost is the same as the employer cost per hour.

TABLE 30—OCCUPATIONAL EMPLOYMENT AND WAGES PROVIDED BY THE FEDERAL BUREAU OF LABOR STATISTICS

Occupation title	National employment counts	Mean hourly wage	Estimate of benefits as a % of wages	Estimated employer cost per hour worked	Labor mix	Home health discipline	Opportunity cost
Registered Nurses	179,280	\$33.34	43.85	\$47.96	0.66	Skilled Nursing	\$42.42
Licensed Practical and Licensed Vocational Nurses.	85,410	22.03	43.85	31.69	0.34		
Physical Therapists	24,810	47.23	40.92	66.55	0.66	Physical Therapy	58.55
Physical Therapist Assistants.	7,330	31.43	35.79	42.68	0.34		
Occupational Therapists	10,760	45.27	40.92	63.79	0.79	Occupational Therapy	59.97
Occupational Therapist Assistants.	2,270	33.83	35.79	45.94	0.21		
Speech-Language Pathologists.	5,360	47.08	40.92	66.34	Speech Therapy	66.34
Medical and Public Health Social Workers.	18,930	28.76	40.92	40.53	0.97	Medical Social Service	40.42
Mental Health and Substance Abuse Social Workers.	500	25.85	40.92	36.43	0.03		
Home Health Aides	408,920	11.25	35.79	15.28	Home Health Aide	15.28

Source: May 2016 National Industry-Specific Occupational Employment and Wage Estimates—NAICS 621600—Home Health Care Services.

²³ Less than 0.1 percent of all visits were recorded as having greater than 8 hours of service.

²⁴ Opportunity costs represent the foregone resources from providing each minute of care versus using the resources for another purpose (the next best alternative). Generally, opportunity costs

represent more than the monetary costs, but in these analyses, they are proxied using hourly wage rates.

²⁵ Labor mix represents the percentage of employees with a particular occupational title (as obtained from claims) within a home health

discipline. Physical therapist aides and occupational therapist aides were not included in the labor mix.

Home Health Agency Medicare Cost Report (MCR) data for FY 2016 were also used to construct a measure of resource use after trimming out HHAs whose costs were outliers (see section III.F.2 of this proposed rule). These data are used to provide a representation of the average costs of visits provided by HHAs in the six Medicare home health disciplines: Skilled nursing; physical therapy; occupational therapy; speech-language pathology; medical social services; and home health aide services. Cost report data are publicly available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/>. More details regarding how HHA MCR data were used in constructing the CPM+NRS measure of resource use can be found in section III.F.2 of this proposed rule.

A comment submitted in response to the CY 2018 HH PPS proposed rule questioned the trimming process for the Medicare cost report data used to calculate the cost-per-minute plus non-routine supplies (CPM+NRS) methodology used to estimate resource use (outlined in section III.F.2 of this rule). The commenter stated that for rebasing, CMS audited 100 cost reports and the findings of such audits found that costs were overstated by 8 percent and that finding was attributed to the entire population of HHA Medicare cost reports. The commenter questioned if CMS applied the 8 percent “adjustment factor” in last year’s proposed rule, requested CMS provide the number of cost reports used for the proposed rule, asked if only cost reports of freestanding HHAs were used, and requested that CMS describe what percentage of cost reports did not list any costs for NRS, yet listed NRS charges.

For the calculations in the CY 2018 HH PPS proposed rule, CMS applied the trimming methodology described in detail in the “Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates” Report available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf>. This is also the trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284). Of note, for each discipline and for NRS, we also followed the methodology laid out in the “Rebasing Report” by trimming out values that fell in the top or bottom 1 percent of the distribution across all HHAs. This included the cost-per-visit values for each discipline and NRS cost-to-charge ratios that fell in the top or bottom 1

percent of the distribution across all HHAs. For this proposed rule, we applied the same trimming methodology.

We included both freestanding and facility-based HHA Medicare cost report data in our rebasing calculations as outlined in the CY 2014 HH PPS proposed and final rules and in our analysis of FY 2015 HHA Medicare cost report data for the CY 2018 HH PPS proposed rule. We similarly included both freestanding and facility-based HHA Medicare cost report data in our analysis of FY 2016 cost report data for this proposed rule. We note that although we found an 8 percent overstatement of costs from the Medicare cost reports audits performed to support the rebasing adjustments, we did not apply an 8 percent adjustment to HHA costs in the CY 2014 HH PPS proposed or final rules. We also did not apply an 8 percent adjustment to the costs in the CY 2018 HH PPS proposed rule or in this proposed rule. The 8 percent overstatement was determined using a small sample size of HHA Medicare cost reports and the CY 2014 HH PPS proposed rule included this information as illustrative only. The information was not used in any cost calculations past or present.

Before trimming, there were 10,394 cost reports for FY 2016. In this proposed rule, we used 7,458 cost reports. Of the 7,458 cost reports, 5,447 (73.4 percent) had both NRS charges and costs, 1,672 (22.4 percent) had neither NRS charges or costs, and 339 (4.5 percent) had NRS charges but no NRS costs. There were no cost reports with NRS costs, but no NRS charges.

The initial 2017 analytic file included 6,771,059 episodes. Of these, 959,410 (14.2 percent) were excluded because they could not be linked to OASIS assessments or because of the claims data cleaning process reasons listed above. This yielded a final analytic file that included 5,811,649 episodes. Those episodes are 60-day episodes under the current payment system, but for the PDGM those 60-day episodes were converted into two 30-day periods. This yielded a final PDGM analytic file that included 10,160,226, 30-day periods. Certain 30-day periods were excluded for the following reasons:

- Inability to merge to certain OASIS items to create the episode’s functional level that is used for risk adjustment. For all the periods in the analytic file, there was a look-back through CY 2016 for a period with a Start of Care or Resumption of Care assessment that preceded the period being analyzed and was in the same sequence of periods. If such an assessment was found, it was

used to impute responses for OASIS items that were not included in the follow-up assessment. Periods that were linked to a follow-up assessment which did not link to a Start of Care or Resumption of Care assessment using the process described above were dropped (after exclusions, n = 9,471,529).

- No nursing visits or therapy visits (after exclusions, n = 9,287,622).

- LUPAs were excluded from the analysis. Periods that are identified as LUPAs in the current payment system were excluded in the creation of the functional score. Following the creation of the score (and the corresponding levels), case-mix group specific LUPA thresholds were created and episodes/periods were excluded that were below the new LUPA threshold when computing the case-mix weights.²⁶ Therefore, the final analytic sample included 8,624,776 30-day periods that were used for the analyses in the PDGM.

In response to the CY 2018 HH PPS proposed rule, we received many comments stating there was limited involvement with the industry in the development of the alternative case-mix adjustment methodology. Commenters also stated that they were unable to obtain the necessary data in order to replicate and model the effects on their business. We note that, through notice and comment rulemaking and other processes, stakeholders always have the opportunity to reach out to CMS and provide suggestions for improvement in the payment methodology under the HH PPS. In the CY 2014 HH PPS final rule, we noted that we were continuing to work on improvements to our case-mix adjustment methodology and welcomed suggestions for improving the case-mix adjustment methodology as we continued in our case-mix research (78 FR 72287). The analyses and the ultimate development of an alternative case-mix adjustment methodology was shared with stakeholders via technical expert panels, clinical workgroups, and special open door forums. We also provided high-level summaries on our case-mix methodology refinement work in the HH PPS proposed rules for CYs 2016 and 2017 (80 FR 39839, and 81 FR 76702). A detailed technical report was posted on the CMS website in December of 2016, additional technical expert panel and clinical workgroup webinars were held after the posting of the technical report, and a National Provider call occurred in January 2017

²⁶ The case-mix group specific LUPA thresholds were determined using episodes that were considered LUPAs under the current payment system.

to further solicit feedback from stakeholders and the general public.^{27 28} As noted above, the CY 2018 HH PPS proposed rule further solicited comments on an alternative case-mix adjustment methodology. Ultimately the proposed alternative case-mix adjustment methodology, including a proposed change in the unit of payment from 60 days to 30 days, was not finalized in the CY 2018 HH PPS final rule in order to allow CMS additional time to consider public comments for potential refinements to the model (82 FR 51676).

On February 1, 2018, CMS convened another TEP, to gather perspectives and identify and prioritize recommendations from industry leaders, clinicians, patient representatives, and researchers with experience with home health care and/or experience in home health agency management regarding the case-mix adjustment methodology refinements described in the CY 2018 HH PPS proposed rule (82 FR 35270), and alternative case-mix models submitted during 2017 as comments to the CY 2018 HH PPS proposed rule. During the TEP, there was a description and solicitation of feedback on the components of the proposed case-mix methodology refinement, such as resource use, 30-day periods, clinical groups, functional levels, comorbidity groups, and other variables used to group periods into respective case-mix groups. Also discussed were the comments received from the CY 2018 HH PPS proposed rule, the creation of case-mix weights, and an open discussion to solicit feedback and recommendations for next steps. This TEP satisfied the requirement set forth in section 51001(b)(1) of the BBA of 2018, which requires that at least one session of such a TEP be held between January 1, 2018 and December 31, 2018. Lastly, section 51001(b)(3) of the BBA of 2018 requires the Secretary to issue a report to the Committee on Ways and Means and Committee on Energy and Commerce of the House of Representatives and the Committee on

Finance of the Senate on the recommendations from the TEP members, no later than April 1, 2019. This report is available on the CMS HHA Center web page at: <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html> and satisfies the requirement of section 51001(b)(3) of the BBA of 2018.

Finally, with respect to comments regarding the availability of data to replicate and model the effects of the PDGM on HHAs, we note that generally the data needed to replicate and model the effects of the proposed PDGM are available by request through the CMS Data Request Center.²⁹ Although claims data for home health are available on a quarterly and annual basis as Limited Data Set (LDS) files and Research Identifiable Files (RIFs); we note that assessment data (OASIS) are not available as LDS files through the CMS Data Request Center. While CMS is able to provide LDS files in a more expedited manner, it may take several months for CMS to provide RIFs. Therefore, we will provide upon request a Home Health Claims-OASIS LDS file to accompany the CY 2019 HH PPS proposed and final rules. We believe that in making a Home Health Claims-OASIS LDS file available upon request in conjunction with the CY 2019 HH PPS proposed and final rules, this would address concerns from stakeholders regarding data access and transparency in annual ratesetting.

The Home Health Claims-OASIS LDS file can be requested by following the instructions on the following CMS website: https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures/Data-Agreements/DUA_-_NewLDS.html and a file layout will be available. This file will contain information from claims data matched with assessment data for CY 2017, both obtained from the Chronic Conditions Data Warehouse (CCW), and each observation in the file will represent a 30-day period of care with variables created that provide information corresponding to both the 30-day period of care and the 60-day episode of care. The file will also contain variables that show the case-mix group that a particular claim would be grouped into under both the new PDGM case-mix methodology and the current case-mix adjustment methodology as well as variables for all the assessment items used for grouping the claim into its appropriate case-mix group under the PDGM and variables used for calculating resource use. Because this Home Health Claims-OASIS LDS file

includes variables used for calculating resource use, this file will also include publically available data from home health cost reports and the BLS. Some of the cost data in this file is trimmed and imputed before being used as outlined above. We note that much of the content of the Home Health Claims-OASIS LDS file will be derived from CMS data sources. That is, many elements of claims or elements of OASIS will not be copied to the LDS file as is. For example, we will have variables in the data files that will record the aggregated number of visits and minutes of service by discipline type. We will need to create those aggregates from the line item data available on the claims data. Because we will be taking data from different sources (claims, OASIS, and cost reports/BLS), we will match the data across those sources. Information from claims and costs reports will be linked using the CCN. OASIS assessment data will be linked to those sources using information available both on the claim and OASIS. As noted earlier in this section, any episodes that could not be linked with an OASIS assessment were excluded from the analysis file, as they included insufficient patient-level data to re-group such episodes into one of the 216 case-mix groups under the PDGM.

In addition, similar to the CY 2018 HH PPS proposed rule, we will again provide a PDGM Grouper Tool in conjunction with this proposed rule on CMS' HHA Center web page to allow HHAs to replicate the PDGM methodology using their own internal data.³⁰ In addition, in conjunction with this proposed rule, we will post a file on the HHA Center web page that contains estimated Home Health Agency-level impacts as a result of the proposed PDGM.

2. Methodology Used To Calculate the Cost of Care

To construct the case-mix weights for the PDGM proposal, the costs of providing care needed to be determined. A Wage-Weighted Minutes of Care (WWMC) approach is used in the current payment system based on data from the BLS. However, we are proposing to adopt a Cost-per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from HHA Medicare Cost Reports and Home Health Claims.

- *Home Health Medicare Cost Report Data:* All Medicare-certified HHAs must report their own costs through publicly-

²⁷ Abt Associates. "Overview of the Home Health Groupings Model." *Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements*. Cambridge, MA, November 18, 2016. Available at <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

²⁸ Centers for Medicare & Medicaid Services (CMS). "Certifying Patients for the Medicare Home Health Benefit." MLN Connects™ National Provider Call. Baltimore, MD, December 16, 2016. Slides, examples, audio recording and transcript available at <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-01-18-Home-Health.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending>.

²⁹ <https://www.resdac.org/cms-data/request/cms-data-request-center>.

³⁰ <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>.

available home health cost reports maintained by the Healthcare Cost Report Information System (HCRIS). Freestanding HHAs report using a HHA-specific cost report while HHAs that are hospital-based report using the HHA component of the hospital cost reports. These cost reports enable estimation of the cost per visit by provider and the estimated NRS cost to charge ratios. To obtain a more robust estimate of cost, a trimming process was applied to remove cost reports with missing or questionable data and extreme values.³¹

• *Home Health Claims Data:*

Medicare home health claims data are used in both the previous WWMC approach and in the CPM+NRS method to obtain minutes of care by discipline of care.

Under the proposed PDGM, we group 30-day periods of care into their case-mix groups taking into account admission source, timing, clinical group, functional level, and comorbidity adjustment. From there, the average resource use for each case-mix group dictates the group's case-mix weight. We propose that resource use be estimated with the cost of visits recorded on the home health claim plus the cost of NRS recorded on the claims. The cost of NRS is generated by taking NRS charges on claims and converting them to costs using a NRS cost to charge ratio that is specific to each HHA. NRS costs are then added to the resource use estimates. That overall resource use estimate is then used to establish the case-mix weights. Similar to the current system, NRS would still be paid prospectively under the PDGM, but the PDGM eliminates the separate case-mix adjustment model for NRS.

Under the proposed alternative case-mix methodology discussed in the CY 2018 HH PPS proposed rule, we proposed to calculate resource use using the CPM+NRS approach (82 FR 35270). In response to the CY 2018 HH PPS proposed rule, several commenters expressed support for the proposed change to the CPM+NRS methodology used to measure resource use, noting that such an approach incorporates a wider variety of costs (such as transportation) compared to the current WWMC approach. Alternatively, other commenters responding to last year's proposed rule objected to using

Medicare cost report data rather than Wage-Weighted Minutes of Care (WWMC) to calculate resource use. The commenters indicated that the strength and utility of period-specific cost depends on the accuracy and consistency of agencies' reported charges, cost-to-charge ratios, and period minutes and indicated that they believe there are no incentives for ensuring the accuracy of HHA cost reports, which they believe may result in erroneous data. Several commenters also indicated that the use of cost report data in lieu of WWMC favors facility-based agencies because they believe that facility-based agencies have the ability to allocate indirect overhead costs from their parent facilities to their service cost and argued that the proposed alternative case-mix methodology would reward inefficient HHAs with historically high costs. A few commenters stated that Non-Routine Supplies (NRS) should not be incorporated into the base rate and then wage-index adjusted (as would be the case if CMS were to use the CPM+NRS approach to estimate resource use). The commenters stated that HHAs' supply costs are approximately the same nationally, regardless of rural or urban locations and regardless of the wage-index, and including NRS in the base rate will penalize rural providers and unnecessarily overpay for NRS in high wage-index areas. We note that in accordance with the requirement of section 51001 of the BBA of 2018, a Technical Expert Panel (TEP) convened in February 2018 to solicit feedback and identify and prioritize recommendations from a wide variety of industry experts and patient representatives regarding the public comments received on the proposed alternative case-mix adjustment methodology. We received similar comments on the approach to calculating resource use using the CPM+NRS approach, versus the WWMC approach, both in response to the CY 2018 HH PPS proposed rule and those provided by the TEP participants.

We believe that using HHA Medicare cost report data, through the CPM+NRS approach, to calculate the costs of providing care better reflects changes in utilization, provider payments, and supply amongst Medicare-certified HHAs. Using the BLS average hourly wage rates for the entire home health care service industry does not reflect changes in Medicare home health utilization that impact costs, such as the allocation of overhead costs when Medicare home health visit patterns change. Utilizing data from HHA Medicare cost reports better represents

the total costs incurred during a 30-day period (including, but not limited to, direct patient care contract labor, overhead, and transportation costs), while the WWMC method provides an estimate of only the labor costs (wage and fringe benefit costs) related to direct patient care from patient visits that are incurred during a 30-day period. With regards to accuracy, we note that each HHA Medicare cost report is required to be certified by the Officer or Director of the home health agency as being true, correct, and complete with potential penalties should any information in the cost report be a misrepresentation or falsification of information.

As noted above, and in the CY 2018 HH PPS proposed rule, we applied the trimming methodology described in detail in the "Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates" Report. This is also the trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) in determining the rebased national, standardized 60-day episode payment amount. For each discipline and for NRS used in calculating resource use using the CPM+NRS approach, we also followed the methodology laid out in the "Rebasing Report" by trimming out values that fall in the top or bottom 1 percent of the distribution across all HHAs. This included the cost per visit values for each discipline and NRS cost-to-charge ratios that fall in the top or bottom 1 percent of the distribution across all HHAs. Normalizing data by trimming out missing or extreme values is a widely accepted methodology both within CMS and amongst the health research community and provides a more robust measure of average costs per visit that is reliable for the purposes of establishing base payment amounts and case-mix weights under the HH PPS. Using HHA Medicare cost report data to establish the case-mix weight aligns with the use of this data in determining the national, standardized 60-day episode payment amount under the HH PPS.

In response to commenters' concerns regarding the allocation of overhead costs by facility-based HHAs, we note that a single HHA's costs impact only a portion of the calculation of the weights and costs are blended together across all HHAs. The payment regression was estimated using 8,624,776 30-day periods from 10,480 providers. On average, each provider contributed 823 30-day periods to the payment regression, which is only 0.010 percent of all 30-day periods. Therefore, including or excluding any single HHA, on average, would not dramatically

³¹ The trimming methodology is described in the report "Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates" (Morefield, Christian, and Goldberg 2013). See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf>.

impact the results of the payment regression. Further, facility-based HHAs are only 8 percent of HHAs whereas 92 percent of HHAs are freestanding, and coincidentally the percentage of 30-day periods furnished by facility-based versus freestanding HHAs is also 8 and 92 percent, respectively. Additionally, in the PDGM, we estimate the payment regression using provider-level fixed effects; therefore we are looking at the within provider variation in resource use.

In the CY 2008 HH PPS final rule, CMS noted that use of non-routine medical supplies is unevenly distributed across episodes of care in home health. In addition, the majority of episodes do not incur any NRS costs and, at that time, the current payment system overcompensated for episodes with no NRS costs. In the CY 2008 HH PPS proposed rule, we stated that patients with certain conditions, many of them related to skin conditions, were more likely to require high non-routine medical supply utilization (72 FR 49850), and that we would continue to look for ways to improve our approach to account for NRS costs and payments in the future (72 FR 25428). We believe that the proposed PDGM offers an alternative method for accounting for NRS costs and payments by grouping patients more likely to require high NRS utilization. For example, while the Wound group and Complex Nursing Interventions groups comprise about 9 percent and 4 percent of all 30-day periods of care, respectively; roughly 27 percent of periods where NRS was supplied were assigned to the Wound and Complex Nursing Interventions groups and 44 percent of NRS costs fall into the Wound and Complex Nursing groups. We note that CY 2017 claims data indicates that about 60 percent of 60-day episodes did not provide any NRS.

In using the CPM + NRS approach to calculate the cost of providing care (resource use), NRS costs are reflected in the average resource use that drives

the case-mix weights. If there is a high amount of NRS cost for all periods in a particular group (holding all else equal), the resource use for those periods will be higher relative to the overall average and the case-mix weight will correspondingly be higher. Similar to the current system, NRS would still be paid prospectively under the PDGM, but the PDGM eliminates the separate case-mix adjustment model for NRS. Incorporating the NRS cost into the measure of overall resource use (that is, the dependent variable of the payment model) requires adjusting the NRS charges submitted on claims based on the NRS cost-to-charge ratio from cost report data.

The following steps would be used to generate the measure of resource use under this CPM + NRS approach:

- (1) From the cost reports, obtain total costs for each of the six home health disciplines for each HHA.
- (2) From the cost reports, obtain the number of visits by each of the six home health disciplines for each HHA.
- (3) Calculate discipline-specific cost per visit values by dividing total costs [1] by number of visits [2] for each discipline for each HHA. For HHAs that did not have a cost report available (or a cost report that was trimmed from the sample), imputed values were used as follows:

- A state-level mean was used if the HHA was not hospital-based. The state-level mean was computed using all non-hospital based HHAs in each state.
- An urban nationwide mean was used for all hospital-based HHAs located in a Core-based Statistical Area (CBSA). The urban nation-wide mean was computed using all hospital-based HHAs located in any CBSA.
- A rural nationwide mean was used for all hospital-based HHAs not in a CBSA. The rural nation-wide mean was computed using all hospital-based HHAs not in a CBSA.

(4) From the home health claims data, obtain the average number of minutes of care provided by each discipline across all episodes for a HHA.

(5) From the home health claims data, obtain the average number of visits provided by each discipline across all episodes for each HHA.

(6) Calculate a ratio of average visits to average minutes by discipline by dividing average visits provided [5] by average minutes of care [4] by discipline for each HHA.

(7) Calculate costs per minute by multiplying the HHA's cost per visit [3] by the ratio of average visits to average minutes [6] by discipline for each HHA.

(8) Obtain 30-day period costs by multiplying costs per minute [7] by the total number of minutes of care provided during a 30-day period by discipline. Then, sum these costs across the disciplines for each period.

This approach accounts for variation in the length of a visit by discipline. NRS costs are added to the resource use calculated in [8] in the following way:

(9) From the cost reports, determine the NRS cost-to-charge ratio for each HHA. The NRS ratio is trimmed if the value falls in the top or bottom 1 percent of the distribution across all HHAs from the trimmed sample. Imputation for missing or trimmed values is done in the same manner as it was done for cost per visit (see [3] above).

(10) From the home health claims data, obtain NRS charges for each period.

(11) Obtain NRS costs for each period by multiplying charges from the home health claims data [10] by the cost-to-charge ratio from the cost reports [9] for each HHA.

Resource use is then obtained by:

(12) Summing costs from [8] with NRS costs from [11] for each 30-day period.

Table 31 shows these costs for 30-day periods in CY 2017 (n = 8,624,776). On average, total 30-day period costs as measured by resource use are \$1,570.68. The distribution ranges from a 5th percentile value of \$296.66 to a 95th percentile value of \$3,839.91.

TABLE 31—DISTRIBUTION OF AVERAGE RESOURCE USE USING CPM + NRS APPROACH
[30 Day periods]

Statistics	Mean	N	5th Percentile	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile	95th Percentile
Average Resource Use (CPM + NRS)	\$1,570.68	8,624,776	\$296.66	\$394.31	\$679.12	\$1,272.18	\$2,117.47	\$3,107.93	\$3,839.91

The distributions and magnitude of the estimates of costs for the CPM + NRS method versus the WWMC method are very different. The differences arise because the CPM + NRS method

incorporates HHA-specific costs that represent the total costs incurred during a 30-day period (including overhead costs), while the WWMC method provides an estimate of only the labor

costs (wage + fringe) related to direct patient care from patient visits that are incurred during a 30-day period. Those costs are not HHA-specific and do not account for any non-labor costs (such as

transportation costs) or the non-direct patient care labor costs (such as, administration and general labor costs). Because the costs estimated using the two approaches are measuring different items, they cannot be directly compared. However, if the total cost of a 30-day period is correlated with the labor that is provided during visits, the two approaches should be highly correlated. The correlation coefficient

(estimated by comparing a 30-day period's CPM + NRS resource use to the same period's WWMC resource use) between the two approaches to calculating resource use is equal to 0.8512 (n = 8,624,776). Therefore, the relationship in relative costs is similar between the two methods.

Using cost report data to develop case-mix weights more evenly weights skilled nursing services and therapy

services than the BLS data. Table 32 shows the ratios between the estimated costs per hour for each of the home health disciplines compared with skilled nursing resulting from the CPM + NRS versus WWMC methods. Under the CPM + NRS methodology, the ratio for physical therapy costs per hour to skilled nursing is 1.14 compared with 1.36 using the WWMC method.

TABLE 32—RELATIVE VALUES IN COSTS PER HOUR BY DISCIPLINE
[Skilled nursing is base]

Estimated cost per hour	Skilled nursing	Physical therapy	Occupational therapy	Speech therapy	Medical social service	Home health aide
CPM + NRS	1.00	1.14	1.15	1.25	1.39	0.40
WWMC	1.00	1.36	1.38	1.56	0.94	0.35

In response to the CY 2018 HH PPS proposed rule (82 FR 35270), a few commenters, stated that based on their operational experiences with clinical staffing labor costs, HHA cost report data suggests more parity exists between skilled nursing (“SN”) versus physical therapist (“PT”) costs than in fact exists. Commenters stated that BLS data showing a 40 percent difference between SN and PT costs are more reflective of the human resources experiences in the markets where they operate. As such, commenters believe the use of cost report data would cause the proposed alternative case-mix methodology to overpay for nursing services and underpay for therapy services, although it was not clear from the comments why the relative relationship in cost between disciplines would necessarily mean that nursing would be overpaid or underpaid relative to therapy.

We note that the HHA Medicare cost report data reflects all labor costs, including contract labor costs. The BLS data only reflects employed staff. This may partially explain why a 40 percent variation between SN and PT costs is not evident in the cost report data. However, the comparison is somewhat inappropriate because the BLS data only reflects labor costs whereas the HHA Medicare cost report data includes labor and non-labor costs. As noted earlier in Table 32, there is only a 14 percent variation using the CPM + NRS methodology. Moreover, in aggregate, about 15 percent of compensation costs are contract labor costs and this varies among the disciplines with contract labor costs accounting for a much higher proportion of therapy visit costs compared to skilled nursing visit costs. Utilization also varies among freestanding providers with smaller

providers having a higher proportion of contract labor costs, particularly for therapy services compared to larger providers. The decision of whether to/ or what proportion of contract labor to use is at the provider’s discretion. Finally, we note that in order to be eligible for Medicare HH PPS payments, providers must complete the HHA Medicare cost report and certify the report by the Officer or Director of the home health agency as being true, correct, and complete; therefore, such data can and should be used to calculate the cost of care.

We have determined that using cost report data to calculate the cost of home health care better aligns the case-mix weights with the total relative cost for treating various patients. In addition, using cost report data allows us to incorporate NRS into the case-mix system, rather than maintaining a separate payment system. Therefore, we are re-proposing to calculate the cost of a 30-day period of home health care under the proposed PDGM using the cost per minute plus non-routine supplies (CPM + NRS) approach outlined above, as also outlined in the CY 2018 proposed rule. We invite comments on the proposed methodology for calculating the cost of a 30-day period of care under the PDGM.

3. Change From a 60-Day to a 30-Day Unit of Payment

a. Background

Currently, HHAs are paid for each 60-day episode of home health care provided. In the CY 2018 HH PPS proposed rule, CMS proposed a change from making payment based on 60-day episodes to making payment based on 30-day periods, effective for January 1,

2019. Examination of the resources used within a 60-day episode of care identified differences in resources used between the first 30-day period within a 60-day episode and the second 30-day period within a 60-day episode. Episodes have more visits, on average, during the first 30 days compared to the last 30 days and costs are much higher earlier in the episode and lesser later on; therefore, dividing a single 60-day episode into two 30-day periods more accurately apportioned payments. In addition, with the proposed removal of therapy thresholds from the case-mix adjustment methodology under the HH PPS, a shorter period of care reduced the variation and improved the accuracy of the case-mix weights generated under the PDGM. CMS did not finalize the implementation of a 30-day unit of payment in the CY 2018 HH PPS final rule (82 FR 51676).

Section 1895(b)(2)(B) of the Act, as added by section 51001(a)(1) of the BBA of 2018, requires the Secretary to apply a 30-day unit of service for purposes of implementing the HH PPS, effective January 1, 2020. We note that we interpret the term “unit of service” to be synonymous with “unit of payment” and will henceforth refer to “unit of payment” in this proposed rule with regards to payment under the HH PPS. We propose to make HH payments based on a 30-day unit of payment effective January 1, 2020. While we are proposing to change to a 30-day unit of payment, we note that the comprehensive assessment would still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, Condition of participation: Comprehensive assessment of patients.

In addition, the plan of care would still be reviewed and revised by the HHA and the physician responsible for the home health plan of care no less frequently than once every 60 days, beginning with the start of care date, as currently required by § 484.60(c), Condition of participation: Care planning, coordination of services, and quality of care.

b. 30-Day Unit of Payment

Under section 1895(b)(3)(A)(iv) of the Act, we are required to calculate a 30-day payment amount for CY 2020 in a budget neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of payment. Furthermore, as also required by section 1895(b)(3)(A)(iv) of the Act, to calculate a 30-day payment amount in a budget-neutral manner, we are required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment. In addition, in calculating a 30-day payment amount in a budget-neutral manner, we must take into account behavior changes that could occur as a result of the case-mix adjustment factors that are implemented in CY 2020. We are also required to calculate a budget-neutral 30-day payment amount before the provisions of section 1895(b)(3)(B) of the Act are applied, that is, the home health applicable percentage increase, the adjustment for case-mix changes, the adjustment if quality data is not reported, and the productivity adjustment.

In calculating the budget-neutral 30-day payment amount, we propose to make three assumptions about behavior change that could occur in CY 2020 as a result of the implementation of the 30-day unit of payment and the implementation of the PDGM case-mix adjustment methodology outlined in this proposed rule:

- *Clinical Group Coding:* A key component of determining payment under the PDGM is the 30-day period's clinical group assignment, which is based on the principal diagnosis code for the patient as reported by the HHA on the home health claim. Therefore, we assume that HHAs will change their documentation and coding practices and would put the highest paying diagnosis code as the principal diagnosis code in order to have a 30-day period be placed into a higher-paying clinical group. While we do not support or condone coding practices or the

provision of services solely to maximize payment, we often take into account expected behavioral effects of policy changes related to the implementation of the proposed rule.

- *Comorbidity Coding:* The PDGM further adjusts payments based on patients' secondary diagnoses as reported by the HHA on the home health claim. While the OASIS only allows HHAs to designate 1 primary diagnosis and 5 secondary diagnoses, the home health claim allows HHAs to designate 1 principal diagnosis and 24 secondary diagnoses. Therefore, we assume that by taking into account additional ICD-10-CM diagnosis codes listed on the home health claim (beyond the 6 allowed on the OASIS), more 30-day periods of care will receive a comorbidity adjustment than periods otherwise would have received if we only used the OASIS diagnosis codes for payment. The comorbidity adjustment in the PDGM can increase payment by up to 20 percent.

- *LUPA Threshold:* Rather than being paid the per-visit amounts for a 30-day period of care subject to the low-utilization payment adjustment (LUPA) under the proposed PDGM, we assume that for one-third of LUPAs that are 1 to 2 visits away from the LUPA threshold HHAs will provide 1 to 2 extra visits to receive a full 30-day payment.³² LUPAs are paid when there are a low number of visits furnished in a 30-day period of care. Under the PDGM, the LUPA threshold ranges from 2–6 visits depending on the case-mix group assignment for a particular period of care (see section F.9 of this proposed rule for the LUPA thresholds that correspond to the 216 case-mix groups under the PDGM).

Table 33 includes estimates of what the 30-day payment amount would be for CY 2019 (using CY 2017 home health utilization data) in order to achieve budget neutrality both with and without behavioral assumptions and including the application of the proposed home health payment update percentage of 2.1 percent outlined in section C.2 of this proposed rule. We note that these are only estimates to illustrate the 30-day payment amount if we had proposed to implement the 30-day unit of payment and the proposed PDGM for CY 2019. However, because we are proposing to implement the 30-day unit of payment and proposed

³² Current data suggest that what would be about 1/3 of the LUPA episodes with visits near the LUPA threshold move up to become non-LUPA episodes. We assume this experience will continue under the PDGM, with about 1/3 of those episodes 1 or 2 visits below the thresholds moving up to become non-LUPA episodes.

PDGM for CY 2020, we would propose the actual 30-day payment amount in the CY 2020 HH PPS proposed rule calculated using CY 2018 home health utilization data, and we would calculate this amount before application of the proposed home health update percentage required for CY 2020 (as required by section 1895(b)(3)(iv) of the Act). In order to calculate the budget neutral 30-day payment amounts in this proposed rule, both with and without behavioral assumptions, we first calculated the total, aggregate amount of expenditures that would occur under the current case-mix adjustment methodology (as described in section III.B. of this rule) and the 60-day episode unit of payment using the proposed CY 2019 payment parameters (e.g., proposed 2019 payment rates, proposed 2019 case-mix weights, and outlier fixed-dollar loss ratio). That resulted in a total aggregate expenditures target amount of \$16.1 billion.³³ We then calculated what the 30-day payment amount would need to be set at in CY 2019, with and without behavior assumptions, while taking into account needed changes to the outlier fixed-dollar loss ratio under the PDGM in order to pay out no more than 2.5 percent of total HH PPS payments as outlier payments (refer to section III.F.12 of this proposed rule) and in order for Medicare to pay out \$16.1 billion in total expenditures in CY 2019 with the application of a 30-day unit of payment under the PDGM.

³³ The initial 2017 analytic file included 6,771,059 60-day episodes (\$18.2 billion in total expenditures). Of these, 959,410 (14.2 percent) were excluded because they could not be linked to OASIS assessments or because of the claims data cleaning process reasons listed in section III.F.1 of this proposed rule. We note that of the 959,410 claims excluded, 620,336 were excluded because they were RAPs without a final claim or they were claims with zero payment amounts, resulting in \$17.4 billion in total expenditures. After removing all 959,410 excluded claims, the 2017 analytic file consisted of 5,811,649 60-day episodes (\$16.4 billion in total expenditures). 60-day episodes of duration longer than 30 days were divided into two 30-day periods in order to calculate the 30-day payment amounts. As noted in section III.F.1 of this proposed rule, there were instances where 30-day periods were excluded from the 2017 analytic file (for example, we could not match the period to a start of care or resumption of care OASIS to determine the functional level under the PDGM, the 30-day period did not have any skilled visits, or because information necessary to calculate payment was missing from claim record). The final 2017 analytic file used to calculate budget neutrality consisted of 9,285,210 30-day periods (\$16.1 billion in total expenditures) drawn from 5,456,216 60-day episodes.

TABLE 33—ESTIMATES OF 30-DAY BUDGET-NEUTRAL PAYMENT AMOUNTS

Behavioral assumption	30-day budget neutral (BN) standard amount	Percent change from no behavioral assumptions
No Behavioral Assumptions	\$1,873.91
LUPA Threshold (1/3 of LUPAs 1–2 visits away from threshold get extra visits and become case-mix adjusted)	1,841.05	– 1.75
Clinical Group Coding (among available diagnoses, one leading to highest payment clinical grouping classification designated as principal)	1,793.69	– 4.28
Comorbidity Coding (assigns comorbidity level based on comorbidities appearing on HHA claims and not just OASIS)	1,866.76	– 0.38
Clinical Group Coding + Comorbidity Coding	1,786.54	– 4.66
Clinical Group Coding + Comorbidity Coding + LUPA Threshold	1,753.68	– 6.42

If no behavioral assumptions were made, we estimate that the 30-day payment amount needed to achieve budget neutrality would be \$1,873.91. The clinical group and comorbidity coding assumptions would result in the need to decrease the budget-neutral 30-day payment amount to \$1,786.54 (a 4.66 percent decrease from \$1,873.91). Adding the LUPA assumption would require us to further decrease that amount to \$1,753.68 (a 6.42 percent decrease from \$1,873.91).

We note that we are also required under section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology, to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. We interpret actual behavior change to encompass both behavior changes that were outlined above, as assumed by CMS when determining the budget-neutral 30-day payment amount for CY 2020, and other behavior changes not identified at the time the 30-day payment amount for CY 2020 is determined. The data from CYs 2020 through 2026 will be available to determine whether a prospective adjustment (increase or decrease) is needed no earlier than in years 2022 through 2028 rulemaking. As noted previously, under section 1895(b)(3)(D)(ii) of the Act, we are required to provide one or more permanent adjustments to the 30-day payment amount on a prospective basis, if needed, to offset increases or decreases in estimated aggregate expenditures as calculated under section 1895(b)(3)(D)(i) of the Act. Clause (iii) of section 1895(b)(3)(D) of the Act requires the Secretary to make temporary adjustments to the 30-day payment amount, on a prospective basis, in order to offset increases or decreases in estimated aggregate

expenditures, as determined under clause (i) of such section. The temporary adjustments allow us to recover excess spending or give back the difference between actual and estimated spending (if actual is less than estimated) not addressed by permanent adjustments. For instance, if expenditures are estimated to be \$18 billion in CY 2020, but expenditures are actually \$18.25 billion in CY 2020, then we can reduce payments (temporarily) in the future to recover the \$250 million.

As noted above, section 1895(b)(3)(A)(iv) of the Act requires the Secretary to calculate a budget-neutral 30-day payment amount to be paid for home health units of service that are furnished and end during the 12-month period beginning January 1, 2020. For implementation purposes, we propose that the 30-day payment amount would be paid for home health services that start on or after January 1, 2020. More specifically, for 60-day episodes that begin on or before December 31, 2019 and end on or after January 1, 2020 (episodes that would span the January 1, 2020 implementation date), payment made under the Medicare HH PPS would be the CY 2020 national, standardized 60-day episode payment amount. For home health units of service that begin on or after January 1, 2020, the unit of service would now be a 30-day period and payment made under the Medicare HH PPS would be the CY 2020 national, standardized prospective 30-day payment amount. For home health units of service that begin on or after December 2, 2020 through December 31, 2020 and end on or after January 1, 2021, the HHA would be paid the CY 2021 national, standardized prospective 30-day payment amount.

We are soliciting comments on our proposals, including the proposed behavior change assumptions outlined above to be used in determining the 30-day payment amount for CY 2020 and the corresponding regulation text

changes outlined in section III.F.13 and IX. of this proposed rule.

c. Split Percentage Payment Approach for a 30-Day Unit of Payment

In the current HH PPS, there is a split percentage payment approach to the 60-day episode. The first bill, a Request for Anticipated Payment (RAP), is submitted at the beginning of the initial episode for 60 percent of the anticipated final claim payment amount. The second, final bill is submitted at the end of the 60-day episode for the remaining 40 percent. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes are paid at a 50/50 percentage payment split.

In the CY 2018 HH PPS proposed rule (82 FR 35270), we solicited comments as to whether the split payment approach would still be needed for HHAs to maintain adequate cash flow if the unit of payment changes from 60-day episodes to 30-day periods of care. In addition, we solicited comments on ways to phase-out the split percentage payment approach in the future. Specifically, we solicited comments on reducing the percentage of the upfront payment over a period of time and if in the future the split percentage approach was eliminated, we solicited comments on the need for HHAs to submit a notice of admission (NOA) within 5 days of the start of care to assure being established as the primary HHA for the beneficiary and so that the claims processing system is alerted that a beneficiary is under a HH period of care to enforce the consolidating billing edits as required by law. Commenters generally expressed support for continuing the split percentage payment approach in the future under the proposed alternative case-mix model. While we solicited comments on the possibility of phasing-out the split percentage payment approach in the future and the need for a NOA, commenters did not provide suggestions for a phase-out approach, but stated that they did not agree with requiring a NOA given the

experience with such a process under the Medicare hospice benefit.

While CMS did not finalize the implementation of a 30-day unit of payment in the CY 2018 HH PPS final rule (82 FR 51676), the BBA of 2018 now requires a change to the unit of payment from a 60-day episode to a 30-day period of care, as outlined in section F.3.b above, effective January 1, 2020. We continue to believe that as a result of the reduced timeframe for the unit of payment, that a split percentage approach to payment may not be needed for HHAs to maintain adequate cash flow. Currently, about 5 percent of requests for anticipated payment are not submitted until the end of a 60-day episode of care and the median length of days for RAP submission is 12 days from the start of the 60-day episode. As such, we are reevaluating the necessity of RAPs for existing and newly-certified HHAs versus the risks they pose to the Medicare program.

RAP payments can result in program integrity vulnerabilities. For example, a final claim was never submitted for \$321 million worth of RAP payments between July 1, 2015 and July 31, 2016. While CMS typically can recoup RAP overpayments from providers that continue to submit final claims to the Medicare program, some fraud schemes have involved collecting these RAP payments, never submitting final claims, and closing the HHA before Medicare can take action. Below are two examples of HHAs that were identified for billing large amounts of RAPs with no final claim:

- Provider 1 is a Home Health Agency located in Michigan. It was identified for submitting home health claims for beneficiaries located in California and Florida. Further analysis found that the HHA was submitting RAPs with no final claims. CMS discovered that the address on record for the HHA was vacant for an extended period of time. In addition, CMS determined that although Provider 1 had continued billing and receiving payments for RAP claims, it had not submitted a final claim in 10 months. Ultimately, the HHA submitted a total of \$50,234,430.36 in RAP payments and received \$37,204,558.80 in RAP payments. In addition to the large amount of money paid to the HHA, Medicare beneficiaries were also impacted by the HHA's billing behavior. For example, a Florida beneficiary who needed home health services was unable to receive the care required due to the RAP submission by this Provider.

- Provider 2 is a Home Health Agency that is also located in Michigan that submitted a significant number of RAPs with no final claim. While the majority

of these beneficiaries were located in Michigan, data analysis identified beneficiaries who were not likely homebound or qualified for home health services. CMS discovered that the address on record for the HHA was vacant. Provider 2 had not submitted any final claims in more than one year and was no longer billing the Medicare program. However, the HHA was paid a total of \$5,765,261.04 in RAP payments that had no final claim.

Given the program integrity concerns outlined above and the reduced timeframe for the unit of payment (30-days rather than 60-days), we are proposing not to allow newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, to receive RAP payments beginning in CY 2020. This would allow newly-enrolled HHAs to structure their operations without becoming dependent on a partial, advanced payment and take advantage of receiving full payments for every 30-day period of care. We are proposing that HHAs, that are certified for participation in Medicare effective on or after January 1, 2019, would still be required to submit a "no pay" RAP at the beginning of care in order to establish the home health episode, as well as every 30-days thereafter. RAP submissions are currently operationally significant as the RAP establishes the HHA as the primary HHA for the beneficiary during that timeframe and alerts the claims processing system that a beneficiary is under the care of an HHA to enforce the consolidating billing edits required by law under section 1842(b)(6)(F) of the Act. Without such notification, there would be an increase in denials of claims subject to the home health consolidated billing edits that are prevented when an episode/period is established in the common working file (CWF) by the RAP, potentially resulting in increases in appeals, and increases in situations where other providers, including other HHAs, would not have easy information on whether a patient was already being served by an HHA. CMS invites comments on whether the burden of submitting a "no-pay" RAP by newly-enrolled HHAs outweighs the risks to the Medicare program and providers associated with not submitting them.

We propose that existing HHAs, that is HHAs certified for participation in Medicare with effective dates prior to January 1, 2019, would continue to receive RAP payments upon implementation of the 30-day unit of payment and the proposed PDGM case-mix adjustment methodology in CY 2020. However, we are again soliciting

comments on ways to phase-out the split percentage payment approach in the future given that CMS is required to implement a 30-day unit of payment beginning on January 1, 2020 as outlined above. Specifically, we are soliciting comments on reducing the percentage of the upfront payment incrementally over a period of time. If in the future the split percentage approach was eliminated, we are also soliciting comments on the need for HHAs to submit a NOA within 5 days of the start of care to assure being established as the primary HHA for the beneficiary during that timeframe and so that the claims processing system is alerted that a beneficiary is under a HH period of care to enforce the consolidating billing edits as required by law. As outlined above, there are significant drawbacks to both Medicare and providers of not establishing a NOA process upon elimination of RAPs.

In summary, we invite comments on the change in the unit of payment from a 60-day episode of care to a 30-day period of care; the proposed calculation of the 30-day payment amount in a budget-neutral manner and behavior change assumptions for CY 2020; the proposed interpretation of the statutory language regarding actual behavior change; the proposal not to allow newly-enrolled HHAs (HHAs certified for participation in Medicare effective on or after January 1, 2019) to receive RAP payments upon implementation of the 30-day unit of payment in CY 2020, yet still require the submission of a "no pay" RAP at the beginning of care; the proposal to maintain the split percentage payment approach for existing HHAs and applying such policy to 30-day periods of care; and the associated regulations text changes outlined in section III.F.13 and IX of this proposed rule. We are also soliciting comments on ways the split percentage payment approach could be phased-out and whether to implement a NOA process if the split percentage payment approach is eliminated in the future.

4. Timing Categories

In the CY 2018 HH PPS proposed rule, we described analysis showing the impact of timing on home health resource use and proposed to classify the 30-day periods under the proposed alternative case-mix adjustment methodology as "early" or "late" depending on when they occur within a sequence of 30-day periods (82 FR 35307). Under the current HH PPS, the first two 60-day episodes of a sequence of adjacent 60-day episodes are considered early, while the third 60-day

episode of that sequence and any subsequent episodes are considered late. Under the alternative case-mix adjustment methodology, we proposed that the first 30-day period would be classified as early and all subsequent 30-day periods in the sequence (second or later) would be classified as late. Similar to the current payment system, we proposed that a 30-day period could not be considered early unless there was a gap of more than 60 days between the end of one period and the start of another, or it was the first period in a sequence of periods in which there was no more than 60 days between the end of that period and the start of the next period.

In response to the CY 2018 HH PPS proposed rule, several commenters were supportive of the inclusion of the timing category in the alternative case-mix adjustment methodology, stating that this differentiation would reflect that HHA costs are typically highest during the first 30 days of care. However, other commenters expressed concerns regarding timing, stating that HHAs may modify the ways in which they provide

care, that the change would cause a decrease in overall payment to HHAs and an increase in hospital readmissions, and that the categories would not account for increased costs in the later periods of care. Several commenters described concerns regarding the potential for problematic provider behavior due to financial incentives as well as the potential for problems with operational aspects of the timing element of the alternative case-mix adjustment methodology. Additionally, some commenters suggested that we modify the definition of an “early” 30-day period to either the first two 30-day periods or the first four 30-days of care, stating that those definitions would more closely mirror the current payment system’s definition of “early” and that HHAs would otherwise experience a payment decrease when compared to the current 60-day episode payment amount.

As described in detail in the CY 2018 HH PPS proposed rule, our proposal regarding the timing element of the alternative case-mix adjustment methodology was intended to refine and

to better fit costs incurred by agencies for patients with differing characteristics and needs under the HH PPS (82 FR 35270). Analysis of home health data demonstrates that under the current payment system, when analyzed by 30-day periods, HHAs provide more resources in the first 30-day period of home health (“early”) than in later periods of care. The differences in the average resource use during early and late home health episodes when divided into 30-day periods are presented in Table 34, and shows the first 30-day periods in a home health sequence have significantly higher average resource use at \$2,113.66 as compared with subsequent 30-day periods. Specifically, the later 30-day periods showed an average resource use of \$1,311.73, a difference of more than \$800 or a 38 percent decrease. Table 34 also shows a significant difference between the early and late median values of resource use. The median for the first 30-day period is \$1,866.79, while the median for subsequent 30-day periods is \$987.94, a difference of more than \$878 or an approximately 47 percent decrease.

TABLE 34—AVERAGE RESOURCE USE BY TIMING
[30-Day periods]

Timing	Average resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Early 30-Day Periods	\$2,113.66	2,785,039	32.3	\$1,236.30	\$1,232.23	\$1,866.79	\$2,707.04
Late 30-Day Periods	1,311.73	5,839,737	67.7	1,125.44	534.82	987.94	1,735.69
Total	1,570.68	8,624,776	100.0	1,221.38	679.12	1,272.18	2,117.47

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

There is significant difference in the resource utilization between early and late 30-day periods as demonstrated in Table 34. Moreover, the predictive power of the proposed PDGM in terms of estimating resource utilization improved when separating episodes into 30-day periods rather than 60-day periods (that is, the first and second 30-day periods). We believe that a PDGM that accounts for the demonstrated increase in resource utilization in the first 30-day period better captures the variations in resource utilization and further promotes the goal of payment accuracy within the HH PPS.

Moreover, we note that the resource cost estimates are derived from a very large, representative dataset. Therefore, we expect that the proposal reflects agencies’ average costs for all home health service delivered in the period examined. We have constructed the revised case-mix adjustment model based upon the actual resources expended by home health agencies for

Medicare beneficiaries, which show that typically HHAs provide more visits during the first 30 days of care and utilize less resources thereafter. We reiterate that the timing categories are reflective of the utilization patterns observed in the data analyzed for the purposes of constructing the PDGM. The weights of the two timing categories are driven by the mix of services provided, the costs of services provided as determined by cost report data, the length of the visits, and the number of visits provided. The categorization of 30-day periods as “early” and “late” serves to better align payments with already existing resource use patterns. This alignment of payment with resource use is not to be interpreted as placing a value judgment on particular care patterns or patient populations. Our goal in developing the PDGM is to provide an appropriate payment based on the identified resource use of different patient groups, not to

encourage, discourage, value, or devalue one type of skilled care over another.

For the reasons described above, we are proposing to classify the 30-day periods under the proposed PDGM as “early” or “late” depending on when they occur within a sequence of 30-day periods. For the purposes of defining “early” and “late” periods for the proposed PDGM, we are proposing that only the first 30-day period in a sequence of periods be defined as “early” and all other subsequent 30-day periods would be considered “late”. Additionally, we are proposing that the definition of a “home health sequence” (as currently described in § 484.230) will remain unchanged relative to the current system, that is, 30-day periods are considered to be in the same sequence as long as no more than 60 days pass between the end of one period and the start of the next, which is consistent with the definition of a “home health spell of illness” described at section 1861(tt)(2) of the Act. We note

that because section 1861(tt)(2) of the Act is a definition related to eligibility for home health services as described at section 1812(a)(3) of the Act, it does not affect or restrict our ability to implement a 30-day unit of payment.

At this time, the data do not support the notion that the first two 30-day periods should be defined as early, as only the first 30-day period presents marked increase in resource use. We believe the PDGM's definition of "early" as the first 30-day period most accurately reflects agencies' average costs for patients with characteristics measured on the OASIS and used in defining payment groups and supports the shift from the current "early" category as defined by two 60-day episodes. We continue to believe that a PDGM that accounts for the actual, demonstrated increase in resource utilization in the first 30-day period better captures the variations in resource utilization.

Additionally, in our CY 2008 HH PPS final rule, we implemented an "early" and "late" distinction in the HH PPS in which the late episode groupings were weighted more heavily than those episodes designated as early due to heavier resource use during later episodes (72 FR 49770). At that time, commenters expressed concerns that this heavier weighting for later episodes could lead to gaming by providers, with patients on service longer than would be appropriate, and providers not discharging patients when merited. During our analysis in support of subsequent refinements to the HH PPS in 2015, we analyzed the utilization patterns observed in the CY 2013 claims data and observed that the resource use for later episodes had indeed shifted such that later episodes had less resource use than earlier periods, which was the opposite of the pattern observed prior to CY 2008. Furthermore, in its 2016 Report to Congress, MedPAC noted that, between 2002 and 2014, a pattern in home health emerged where the number of episodes of care provided to home health beneficiaries trended upwards, with the average number of episodes per user increasing by 18 percent, rising from 1.6 to 1.9 episodes per user.³⁴ MedPAC noted that this upward trajectory coincided with, among other changes, higher payments for the third and later episodes in a consecutive spell of home health episodes. Given the longitudinal variation in terms of resource provision during home health episodes, we

believe that restricting the "early" definition to the first 30-day period is most appropriate for this facet of the PDGM. Our analysis of home health resource use as well as comments from the public that confirm that more resources are provided in the first 30 days provide compelling evidence to limit the definition of early to the first 30-day period.

Moreover, the public comments we received in response to the CY 2018 HH PPS proposed rule presented conflicting predictions regarding anticipated provider behavior in response to the implementation of the alternative case-mix adjustment methodology. Several commenters stated that they expected providers to discharge patients after the first 30-days of care, given that the case-mix weights are, on average, higher for the first 30-days of care. Other commenters expressed concern that providers may attempt to keep home health beneficiaries on service for as long as possible. Additionally, meeting the requirement of section 51001 of the BBA of 2018, a Technical Expert Panel (TEP) was convened in February 2018 to solicit feedback and identify and prioritize recommendations from a wide variety of industry experts and patient representatives regarding the public comments received on the proposed alternative case-mix adjustment methodology. Comments on the timing categories and suggestions for refinement to this adjustment were very similar between those received on the CY 2018 HH PPS proposed rule and those made by the TEP participants. We note the PDGM case-mix weights reflect existing patterns of resource use observed in our analyses of CY 2016 home health claims data. Since we propose to recalibrate the PDGM case-mix weights on an annual basis to ensure that the case-mix weights reflect the most recent utilization data available at the time of rulemaking, future recalibrations of the PDGM case-mix weights may result in changes to the case-mix weights for early versus late 30-day periods of care as a result of changes in utilization patterns.

Several commenters responding to the CY 2018 HH PPS proposed rule suggested that we revise the model such that a readmission to home health within the 60-day gap period results in an "early" instead of a "late" 30-day period. However, we note that the PDGM also includes a category determined specifically by source of admission, which would account for any readmission to home health. Under the PDGM we already account for whether the patient was admitted to home health care from the community

or following an institutional stay, including inpatient stays that occur after the commencement of a home health care. For example, if the original home health stay was categorized as community and subsequently the patient experienced an inpatient stay, the subsequent home health stay would reset to institutional upon discharge from the inpatient setting. Similarly, we note that for the purposes of the timing component of the PDGM, an intervening hospital stay would not trigger re-categorization to an "early" period unless there were a 60-day gap in home health care. Therefore, we do not believe that the timing element of the PDGM would create a financial incentive to inappropriately encourage the admission of home health patients to an acute care setting in order to receive a subsequent home health referral in the higher-paid "early" category. Our proposal was intended to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the prospective payment system. Therefore, we expect that the addition of both the source of admission, as well as the timing categories do reflect agencies' average costs for home health patients and used in defining payment groups. We believe that crafting a multi-pronged case-mix adjustment model, which includes adjustments based both on timing within a home health sequence as well as the source of the beneficiary admission, will serve to more accurately account for resources required for Medicare beneficiaries and similarly provide a differentiated payment amount for care.

Several commenters responding to the CY 2018 HH PPS proposed rule expressed concern regarding the operational aspects of the timing element of the alternative case-mix adjustment methodology. As we described in the CY 2018 HH PPS proposed rule, and as we are proposing in this rule, we would use Medicare claims data and not the OASIS assessment in order to determine if a 30-day period is considered "early" or "late" (82 FR 35309). We have developed claims processing procedures to reduce the amount of administrative burden associated with the implementation of the PDGM. Providers would not have to determine whether a 30-day period is early (the first 30-day period) or later (all adjacent 30-day periods beyond the first 30-day period) if they choose not to. Information from Medicare systems would be used during claims processing to automatically assign the appropriate timing category.

³⁴ <http://www.medpac.gov/docs/default-source/reports/chapter-8-home-health-care-services-march-2016-report-.pdf>.

To identify the first 30-day period within a sequence, the Medicare claims processing system would verify that the claim "From date" and "Admission date" match. If this condition were to be met, our systems would send the "early" indicator to the HH Group for the 30-day period of care. When the claim was received by CMS's Common Working File (CWF), the system would look back 60 days to ensure there was not a prior, related 30-day period. If not, the claim would continue to be paid as "early." If another related 30-day period were to be identified, that is an earlier 30-day period in the sequence, the claim would be flagged as "late" and returned to the shared systems for subsequent regrouping and re-pricing. Those periods that are not the first 30-day period in a sequence of adjacent periods, separated by no more than a 60-day gap, would be categorized as "late" periods and placed in corresponding PDGM categories.

Early 30-day periods are defined as the initial 30-day period in a sequence of adjacent 30-day periods. Late 30-day periods are defined as all subsequent adjacent periods beyond the first 30-day period. Periods are considered to be adjacent if they are contiguous, meaning that they are separated by no more than a 60-day period between 30-day periods of care. In determining a gap, we only consider whether the beneficiary was receiving home health care from traditional fee-for-service Medicare.

For example, if the beneficiary has not received home health care through traditional Medicare for at least 60 days, and then receives home health care from agency A, that is an early 30-day period. If that 30-day period receives a PEP adjustment and agency B recertifies the beneficiary for a second 30-day period, that second 30-day period is now considered a late 30-day period. However, the beneficiary could have received home health care from other traditional Medicare providers within 60 days before coming to agency A. The designation of early or late would depend upon how many adjacent periods of care were received prior to coming to agency A. The CWF will examine claims upon receipt in comparison to all previously processed 30-day period to verify that the period is correctly designated as early or later.

The 60-day period to determine a gap that will begin a new sequence of 30-day periods will be counted in most instances from the calculated end date of the 30-day period. That is, in most cases CWF will count from "day 30" of a 30-day period without regard to an earlier discharge date. The exception to this is for 30-day periods that were

subject to PEP adjustment. In PEP cases, CWF will count 60 days from the date of the last billable home health visit provided. Under the current HH PPS, the partial episode payment (PEP) adjustment is a proportion of the episode payment that is based on the span of days, including the start-of-care date or first billable service date, through and including the last billable service date under the original plan of care, before the intervening event in a home health beneficiary's care, which is defined as: A beneficiary elected transfer, or a discharge and return to home health that would warrant, for purposes of payment, a new OASIS assessment, physician certification of eligibility, and a new plan of care. Because PEPs are paid based upon the last billable service date and not necessarily based on the last day of a 60-day episode, we would consider the end of the PEP HH episode as the last billable home health visit provided and begin the count of gap days from the date of the last billable home health visit and not "day 30" of a 30-day period.

Regarding PEP adjustments, consider the following example: A 30-day period is opened on January 1, 2020 which would normally span until January 30, 2020. If this 30-day period were not subject to a PEP adjustment, any 30-day period beginning within 60 days following January 30, 2020 would be considered an adjacent 30-day period. In the case of a PEP adjustment, the determination of an adjacent 30-day period would no longer be based on day 60, but would instead be based on the latest billable visit in the 30-day period. Assume in the example, the patient is transferred to another HHA (triggering the PEP adjustment) on January 15, 2020 but the last billable visit is provided on January 13, 2020. In this case, any 30-day period beginning within 60 days following the January 13, 2020 visit would be considered an adjacent 30-day period.

Intervening stays in inpatient facilities will not create any special considerations in counting the 60-day gap. If an inpatient stay occurred within a period, it would not be a part of the gap, as counting would begin at "day 60" which in this case would be later than the inpatient discharge date. If an inpatient stay occurred within the time after the end of the HH period and before the beginning of the next one, those days would be counted as part of the gap just as any other days would.

If periods are received after a particular claim is paid that change the sequence initially assigned to the paid period (for example, by service dates

falling earlier than those of the paid period, or by falling within a gap between paid periods), Medicare systems will initiate automatic adjustments to correct the payment of any necessary periods.

Upon receipt of a HH period coded to represent the early 30-day period in a sequence, Medicare systems will search the period history records that are maintained for each beneficiary. If an existing 30-day period is found on that history, the claim for the new period will be recoded to represent its sequence correctly and paid according to the changed code. In addition, when any new 30-day period is added to those history records for each beneficiary, the coding representing period sequence on previously paid periods will be checked to see if the presence of the newly added period causes the need for changes to those periods. If the need for changes is found, Medicare systems will initiate automatic adjustments to those previously paid periods.

For example, a given 30-day period is initially determined to be and paid as the early period in a sequence of periods. After some amount of time, a claim is submitted by another HHA that occurs before the previously designated first period in the sequence of adjacent periods and is less than 60 days before the beginning of that previously designated first period. In such a case, the 30-day period corresponding to the newly submitted claim becomes the first 30-day period of this sequence of adjacent 30-day periods and thus is considered to be an early period. The 30-day period previously designated as the first 30-day period in the sequence of periods now becomes the second 30-day period in the sequence of adjacent periods, thus changing its status from that of an early period to that of a late period.

We plan to develop materials regarding timing categories, including such topics as claims adjustments and resolution of claims processing issues. We will also update guidance in the Medicare Claims Processing Manual, as well as the Medicare Benefit Manual as appropriate with detailed procedures. We will also work with our Medicare Administrative Contractors (MACs) to address any concerns regarding the processing of home health claims as well as develop training materials to facilitate all aspects of the transition the PDGM, including the unique aspects of the timing categories.

Several commenters responding to the CY 2018 HH PPS proposed rule had concerns regarding the potential for problematic provider behavior due to financial incentives. We note that we

fully intend to monitor provider behavior in response to the new PDGM. As we receive and evaluate new data related to the provision of Medicare home health care under the PDGM, we will reassess the appropriateness of the payment levels for “early” and “late” periods in a sequence of periods. Additionally, we will share any concerning behavior or patterns with the Medicare Administrative Contracts (MACs) as well as our Center for Program Integrity. We plan to monitor for and identify any variations in the patterns of care provided to home health patients, including both increased and decreased provision of care to Medicare beneficiaries. We note that an increase in the volume of Medicare beneficiaries receiving home health care may, in fact, represent a positive outcome of the PDGM, signaling increased access to care for the Medicare population, so long as said increase in volume of beneficiaries is appropriate and in keeping with eligibility guidelines for the Medicare home health benefit.

We invite public comments on the timing categories in the proposed PDGM and the associated regulations text changes outlined in section III.F.13. of this proposed rule.

5. Admission Source Category

In the CY 2018 HH PPS proposed rule, we described analysis showing the impact of the source of admission on home health resource use and proposed to classify periods into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health (82 FR 35309). We proposed that a 30-day period would be categorized as institutional if an acute or post-acute care (PAC) stay occurred in the 14 days prior to the start of the 30-day period of care. We also proposed that a 30-day period would be categorized as community if there was no acute or PAC stay in the 14 days prior to the start of the 30-day period of care. We proposed

to adopt this categorization by admission source with the implementation of alternative case-mix adjustment methodology refinements.

The proposed admission source category was discussed in detail in the CY 2018 HH PPS proposed rule and we solicited public comments on the admission source component of the proposed alternative case-mix adjustment methodology. Several commenters expressed their support for the admission categories within the framework of the alternative case-mix adjustment methodology refinements, as they believe that these groups would be meaningful and would more appropriately align the cost of Medicare home health care with payments, thereby improving the accuracy of the HH payment system under the alternative case-mix adjustment methodology refinements. Commenters also expressed a variety of concerns regarding admission source, stating that the source of a home health admission may not always correspond with home health beneficiary needs and associated provider costs, that the categories would discourage the admission of community entrants due to lower reimbursement, that the differentiation may encourage HHAs to favor hospitalization during an episode of home health care, that agencies’ ability to provide the care for beneficiaries in the community would be reduced, and that small HHAs with no hospital affiliation would be negatively impacted. Several commenters recommended that CMS consider incorporating other clinical settings into the definition of the institutional category, including hospices and outpatient facilities. Several commenters also expressed concern regarding the operational aspects of the admission source category, requesting guidance for retroactive adjustments, plans for the claims readjustment process due to institutional claim issues, definitions for timely filing, and guidance regarding

when occurrence codes may be utilized. Moreover, in accordance with the requirement of section 51001 of the BBA of 2018, a Technical Expert Panel (TEP) convened in February 2018 to solicit feedback and identify and prioritize recommendations from a wide variety of industry experts and patient representatives regarding the public comments received on the proposed alternative case-mix adjustment methodology. Comments on the admission source categories and suggestions for refinement to this element of the alternative case-mix system were very similar between those received in response to the CY 2018 HH PPS proposed rule and those provided by the TEP participants.

We appreciate commenters’ feedback regarding the admission source element of the alternative case-mix adjustment methodology. The intention of the proposal included in the CY 2018 HH PPS proposed rule, including the admission source component, was to refine and to better fit costs incurred by agencies for patients with differing characteristics and needs under the HH prospective payment system, and we believe that the differing weights for source of admission will serve to promote appropriate alignment between costs and payment within the HH PPS.

As described in the CY 2018 HH PPS proposed rule, our analytic findings demonstrate that institutional admissions have higher average resource use when compared with community admissions, which ultimately led to the inclusion of the admission source category within the framework of the alternative case-mix adjustment methodology refinements (82 FR 35309). The differences in care needs during home health based on admission source are illustrated in the resource utilization figures presented in Table 35, which shows the distribution of admission sources as well as average resource use for 30-day periods by admission source.

TABLE 35—AVERAGE RESOURCE USE BY ADMISSION SOURCE (14 DAY LOOK-BACK; 30 DAY PERIODS) ADMISSION SOURCE, COMMUNITY AND INSTITUTIONAL ONLY

	Average resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Community	\$1,363.11	6,408,805	74.3	\$1,119.20	\$570.26	\$1,062.05	\$1,817.75
Institutional	2,171.00	2,215,971	25.7	1,303.24	1,246.05	1,920.06	2,791.91
Total	1,570.68	8,624,776	100.0	1,221.38	679.12	1,272.18	2,117.47

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

Institutional admissions have significantly higher average resource use

at \$2,171.00 compared with community admissions at \$1,363.11, a difference of

\$807.89. Median values of resource use also show a significant difference

between sources of admission, with institutional resource use at \$1,920.06 while community resource use is at \$1,062.05, a difference of \$858.01. The pattern of higher resource use for institutional admissions as compared to community admissions remains consistent for the 25th and 75th percentiles, with a difference of approximately \$675 and \$974, respectively.

Additionally, we note that we do not show preference to any particular patient profile, but rather aim to better align home health payment with the costs associated with providing care. As discussed in our CY 2018 HH PPS proposed rule, current research around those patients who are discharged from acute and PAC settings shows that these beneficiaries tend to be sicker upon admission, are being discharged rapidly back to the community, and are more likely to be re-hospitalized after discharge due to the acute nature of their illness.³⁵ Additionally, as further described in the CY 2018 HH PPS proposed rule, research studies indicate that patients admitted to home health from institutional settings are vulnerable to adverse effects and injury because of the functional decline that occurs due to their institutional stay, indicating that the patient population referred from an institutional setting requires more concentrated resources and supports to account for and mitigate this functional decline.³⁶ Moreover, as described in the CY 2018 HH PPS proposed rule, research suggests that the reduction in monitoring from the level typically experienced in an inpatient facility to that in the home environment can potentially cause gaps in care and consequently increased risk for adverse events for the newly-admitted home health beneficiary, and any negative impacts of the transition to the home setting can be reduced by an appropriate increase in care for the beneficiary, particularly through more frequent assessment of their condition and ongoing monitoring once transferred to the home environment.³⁷ Furthermore, research discussed in our CY 2018 HH PPS proposed rule shows that

beneficiaries discharged from institutional settings are more vulnerable because of, among other factors, the need to manage new health care issues, major modifications to medication interventions, and the coordination of follow-up appointments, which could lead to the risk for adverse drug events, for errors in a beneficiary's medication regimen, and for the need to readmit to the hospital due to deterioration of the patient's condition.³⁸ Additionally, we note that the goal of the admission source variable is not to identify or evaluate for increases in re-hospitalization in the home health beneficiary population but rather to align payment with the costs of providing home health care. Other CMS initiatives such as the HH QRP as well as the HH VBP demonstration take into account readmissions, among other measures of quality. However, because this population is at higher risk for possible readmission to an institutional setting, we believe that more intensive supports, partnered with differentiated payment weights, are appropriate in crafting a payment system that better reflects the costs incurred by HHAs while also promoting the delivery of quality care to the Medicare population. In summary, clinical research continues to indicate that the needs of the institutional population are intensive. Likewise, our analysis of home health data shows that costs sustained by home health agencies for those beneficiaries admitted from institutional settings are higher than community entrants. Therefore, we believe that accounting for these material differences in the care needs of the beneficiary population admitted from institutional settings and their resultant, differentiated resource use, will serve to better align payments with actual costs incurred by HHAs when caring for Medicare beneficiaries.

We expect that HHAs will continue to provide the most appropriate care to Medicare home health beneficiaries, regardless of admission source or any other category related to home health payment. As we noted in the CY 2018 HH PPS proposed rule, the primary goal of home health care is to provide restorative care when improvement is expected, maintain function and health status if improvement is not expected, slow the rate of functional decline to avoid institutionalization in an acute or

post-acute care setting, and/or facilitate transition to end-of-life care as appropriate (82 FR 35348). The primary goal of the HH PPS is to align payment with the costs of providing home health care. Furthermore, in our CY 2000 HH PPS final rule, commenters asserted that patients admitted to home health from the hospital were often more acutely ill and resource-intensive than other patients, particularly when compared with beneficiaries who had no institutional care prior to admission (64 FR 41147). We appreciate the concerns expressed in response to the CY 2018 HH PPS proposed rule regarding possible behavioral changes by providers given the perceived incentives created by the admission source categories within the alternative case-mix adjustment methodology. However, we continue to expect that HHAs will provide the appropriate care needed by all beneficiaries who are eligible for the home health benefit, including those beneficiaries with medically-complex conditions who are admitted from the community. We will carefully monitor the outcomes of the proposed change, including any impacts to community entrants, and make further refinements as necessary.

Regarding the incorporation of other clinical settings into the definition of the institutional category under the alternative case-mix adjustment methodology that some commenters raised in response to the CY 2018 HH PPS proposed rule, such as emergency department (ED) use and observational stays, we propose to only include those stays that are considered institutional stays in other Medicare settings. For example, observational stays do not count towards the 3-day window for an admission to a SNF because they are not categorized as inpatient. Additionally, in our analysis of 2017 HH claims data, we identified those HH stays that, within the 14 days prior to admission to HH, had been preceded by ED visits or outpatient observational stays and isolated these stays from stays that would otherwise be grouped into the community admission source category. As demonstrated in Table 36, 30-day periods of care for beneficiaries with a preceding ED visit (which would otherwise be grouped into the community admission source category) do not show higher resource use when compared to those beneficiaries entering from acute or PAC settings, with an average resource use at \$1,660.64 per home health period as compared to \$2,171.00 for institutional admits. When compared with those patients admitted from the community, admissions from

³⁵ O'Connor, M. (2012, February). Hospitalization Among Medicare-Reimbursed Skilled Home Health Recipients. Retrieved March 02, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4690459>.

³⁶ Rosati, R. J., Huang, L., Navaie-Waliser, M., & Feldman, P. H. (2003). Risk Factors for Repeated Hospitalizations Among Home Healthcare Recipients. *Journal For Healthcare Quality*, 25(2), 4–11. doi:10.1111/j.1945–1474.2003.tb01038.x.

³⁷ Forster, A. J. (2003). The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital. *Annals of Internal Medicine*, 138(3), 161. doi:10.7326/0003–4819–138–3–200302040–00007.

³⁸ Meyers, A. G., Salanitro, A., Wallston, K. A., Cawthon, C., Vasilevskis, E. E., Goggins, K. M., . . . Kripalani, S. (2014). Determinants of health after hospital discharge: Rationale and design of the Vanderbilt Inpatient Cohort Study (VICS). *BMC Health Services Research*, 14(1). doi:10.1186/1472–6963–14–10.

the ED show somewhat higher resource use at \$1,660.64 per home health period as compared to \$1,337.73 for

community admits. We note that the volume of patients with preceding ED

visits is relatively low, at about 5.8 percent of total home health periods.

TABLE 36—AVERAGE RESOURCE USE BY ADMISSION SOURCE (14 DAY LOOK-BACK, 30 DAY PERIODS) ADMISSION SOURCE: COMMUNITY, INSTITUTIONAL, AND EMERGENCY DEPARTMENT

	Average resource use	Number of 30-day periods	Percent of 30-day periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Community	\$1,337.73	5,905,217	68.5	\$1,108.57	\$558.54	\$1,035.34	\$1,779.73
Institutional	2,171.00	2,215,971	25.7	1,303.24	1,246.05	1,920.06	2,791.91
Emergency Department	1,660.64	503,588	5.8	1,197.60	782.63	1,396.50	2,225.38
Total	1,570.68	8,624,776	100.0	1,221.38	679.12	1,272.18	2,117.47

Similarly, 30-day periods for beneficiaries with preceding observational stays (which would otherwise be grouped into the

community admission source category) also do not show higher resource use when compared to those beneficiaries entering from acute or PAC settings, as

described in Table 37, with average resource use at \$1,820.06 per home health period as compared to \$2,171.00 for institutional admits.

TABLE 37—AVERAGE RESOURCE USE BY ADMISSION SOURCE (14 DAY LOOK-BACK; 30 DAY PERIODS) ADMISSION SOURCE: COMMUNITY, INSTITUTIONAL, AND OBSERVATIONAL STAYS

	Average resource use	Number of 30-day periods	Percent of 30-day periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Community	\$1,350.90	6,242,043	72.4%	\$1,114.94	\$564.31	\$1,048.86	\$1,799.27
Institutional	2,171.00	2,215,971	25.7%	1,303.24	1,246.05	1,920.06	2,791.91
Observational Stays	1,820.06	166,762	1.9%	1,180.96	960.15	1,589.08	2,399.68
Total	1,570.68	8,624,776	100.0%	1,221.38	679.12	1,272.18	2,117.47

When compared with those patients admitted from the community, admissions from observational stays show higher resource use at \$1,820.06 per home health period as compared to \$1,350.90 for community admits. However, the volume of patients with preceding observational stays is very low, at about 2 percent of total home health periods.

In summary, home health stays with preceding observational stays and ED visits show resource use that falls between that of the institutional and community categories. However, the resource use is not equivalent to that of the institutional settings; therefore, we do not believe it appropriate to include observational stays and ED visits in the institutional category for the purposes of the PDGM. Additionally, including these stays in the institutional category would lead to a small reduction in the overall average resource use and related case mix weights for groups admitted from acute and PAC settings. Moreover, including ED or observational stays with discharges from acute care hospitals, LTCHs, IRFs and SNFs would be inconsistent with section 1861(tt)(1) of the Act, which defines the term “post-institutional home health services” as discharges from hospitals (which include IRFs and LTCHs) and SNFs

within 14 days of when home health care is initiated.

We explored the option of creating a third admission source category specifically for observational stays/ED visits. In order to more fully understand the potential impact of a third category, we analyzed the overall impact of the creation of such a category. For the purposes of this analysis, in the event that a home health stay was preceded by both an institutional stay and an observation stay or ED visit, the case would be grouped into the institutional category. Our findings indicate for those HH stays with a preceding outpatient observational stay/ED visit, the overall payment weight for associated groups for “early” 30-day periods (as defined in section III.F.4 of this rule) would be approximately 6 percent higher than the community admission counterparts, whereas institutional stays would see weights that are approximately 19 percent higher than community admissions. When examining the overall payment weights for “late” 30-day periods (as defined in section III.F.4 of this rule), HH stays with a preceding outpatient admission would observe weights that are approximately 10 percent higher than the community admission counterparts, whereas institutional stays would see weights

that are approximately 43 percent higher than community admissions. However, we are concerned that a third admission source category for observational stays and ED visits could create an incentive for providers to encourage outpatient encounters both prior to a 30-day period of care or within a 30-day period of care within 14 days of the start of the next 30-day period, thereby potentially inappropriately increasing costs to the Medicare program overall. The clinical threshold for an observational stay or an ED visit is not as high as that required for an institutional admission, and we are concerned that home health agencies may encourage beneficiaries to engage with emergency departments before initiating a home health stay.

For example, in the FY 2014 IPPS/LTCH PPS final rule and also the Medicare Benefit Policy Manual Chapter 1—Inpatient Hospital Services Covered Under Part A, CMS clarified and specified in the regulations that an individual becomes an inpatient of a hospital, including a long term care hospital or a Critical Access Hospital, when formally admitted as such pursuant to an order for inpatient admission by a physician or other qualified practitioner described in the final regulations (78 FR 50495). The

order is required for payment of hospital inpatient services under Medicare Part A. CMS also specified that for those hospital stays in which the physician expects the beneficiary to require care that crosses two midnights and admits the beneficiary based upon that expectation, Medicare Part A payment is generally appropriate. Additionally, for the purposes of admissions to skilled nursing facilities, the Medicare Benefit Policy Manual Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance states that in order to qualify for post-hospital extended care services, the individual must have been an inpatient of a hospital for a medically necessary stay of at least three consecutive calendar days and that time spent in observation or in the emergency room prior to (or in lieu of) an inpatient admission to the hospital does not count toward the 3-day qualifying inpatient hospital stay, as a person who appears at a hospital's emergency room seeking examination or treatment or is placed on observation has not been admitted to the hospital as an inpatient; instead, the person receives outpatient services. Furthermore, admission to an inpatient rehabilitation facility (IRF) requires that for IRF care to be considered reasonable and necessary, the documentation in the patient's IRF medical record must demonstrate a reasonable expectation that the patient must require active and ongoing intervention of multiple therapy disciplines, at least one of which must be PT or OT; require an intensive rehabilitation therapy program, generally consisting of 3 hours of therapy per day at least 5 days per week; or in certain well-documented cases, at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period, beginning with the date of admission; reasonably be expected to actively participate in, and benefit significantly from the intensive rehabilitation therapy program; require physician supervision by a rehabilitation physician, with face-to-face visits at least 3 days per week to assess the patient both medically and functionally and to modify the course of treatment as needed; and require an intensive and coordinated interdisciplinary team approach to the delivery of rehabilitative care, as described in detail in Medicare Benefit Policy Manual, Chapter 1—Inpatient Hospital Services Covered Under Part A 110.2—Inpatient Rehabilitation Facility Medical Necessity Criteria.

Conversely, CMS specified that for hospital stays in which the physician expects the patient to require care less

than two midnights, payment under Medicare Part A is generally inappropriate. (However, we note that in the CY 2016 Outpatient Prospective Payment System final rule, CMS adopted a policy such that for stays for which the physician expects the patient to need less than two midnights of hospital care (and the procedure is not on the inpatient-only list or otherwise listed as a national exception), an inpatient admission may be payable under Medicare Part A on a case-by-case basis based on the judgment of the admitting physician (80 FR 70297).)

Regarding emergency department visits by Medicare beneficiaries, services are generally covered by Medicare Part B in instances where a beneficiary experiences an injury, a sudden illness, or an illness that quickly worsens. In the case of observational stays, as described in the Medicare Claims Processing Manual, Chapter 12, observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. As described in the Medicare Benefit Policy Manual, Chapter 6—Hospital Services Covered Under Part B 20.6—Outpatient Observation Services, observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. Moreover, the Medicare Claims Processing Manual in Chapter 4—Part B Hospital, 290—Outpatient Observation Services states that observation services are covered by Medicare only when provided by the order of a physician or another individual authorized by state licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient tests. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. In summary, the clinical thresholds for coverage and payment for an admission to institutional settings are higher when compared with ED visits and observational stays. Finally, we note that the proportion of home health

periods with admissions from ED visits and observational stays is low relative to community and institutional counterparts. Creating a third community admission source category for observational stays and ED visits would potentially introduce added complexity into the payment system for a small portion of home health stays, which could lead to the creation of payment groups that contain very few stays with very little difference in case-mix weights across the landscape of groups.

For all of these reasons, we believe that incorporating HH stays with preceding observational stays and ED visits into the community admission category is most appropriate at this time. However, we note that as we receive and evaluate new data related to the provision of Medicare home health care under the PDGM, we will continue to assess the appropriateness of the payment levels for admission source within a home health period and give consideration to any cost differentiation evidenced by the resources required by those home health patients with a preceding outpatient event.

Regarding the operational aspects of the admission source category, as described in the CY 2018 HH PPS proposed rule, we have developed automated claims processing procedures with the goal of reducing the amount of administrative burden associated with the admission source category of the alternative case-mix adjustment methodology (82 FR 35309). For example, Medicare systems will automatically determine whether a beneficiary has been discharged from an institutional setting for which Medicare paid the claim, using information used during claims processing to systematically identify admission source and address this issue. When the Medicare claims processing system receives a Medicare home health claim, the systems will check for the presence of a Medicare acute or PAC claim for an institutional stay. If such an institutional claim is found, and the institutional stay occurred within 14 days of the home health admission, our systems will trigger an automatic adjustment of the corresponding HH claim to the appropriate institutional category. Similarly, when the Medicare claims processing system receives a Medicare acute or PAC claim for an institutional stay, the systems will check for the presence of a subsequent HH claim with a community payment group. If such a HH claim is found, and the institutional stay occurred within 14 days of the home health admission, our systems will trigger an automatic

adjustment of the HH claim to the appropriate institutional category. This process may occur any time within the 12-month timely filing period for the acute or PAC claim. The OASIS assessment will not be utilized in evaluating for admission source information.

Moreover, as we also proposed in the CY 2018 HH PPS proposed rule, we propose in this rule that newly-created occurrence codes would also be established, allowing HHAs to manually indicate on Medicare home health claims that an institutional admission had occurred prior to the processing of an acute or PAC Medicare claim, if any, in order to receive the higher payment associated with the institutional admission source sooner (82 FR 35312). However, the usage of the occurrence codes is limited to situations in which the HHA has information about the acute or PAC stay. We also noted that the use of these occurrence codes would not be limited to home health beneficiaries for whom the acute or PAC claims were paid by Medicare. HHAs would also use the occurrence codes for beneficiaries with acute or PAC stays paid by other payers, such as the Veterans Administration (VA).

If a HHA does not include on the HH claim the occurrence code indicating that a home health patient had a previous institutional stay, processed either by Medicare or other institutions such as the VA, such an admission will be categorized as “community” and paid accordingly. However, if later a Medicare acute or PAC claim for an institutional stay occurring within 14 days of the home health admission is submitted within the timely filing deadline and processed by the Medicare systems, the HH claim would be automatically adjusted and re-categorized as an institutional admission and appropriate payment modifications would be made. If there was a non-Medicare institutional stay occurring within 14 days of the home health admission but the HHA was not aware of such a stay, upon learning of such a stay, the HHA would be able to resubmit the HH claim that included an occurrence code, subject to the timely filing deadline, and payment adjustments would be made accordingly.

We note that the Medicare claims processing system will check for the presence of an acute or PAC Medicare claim for an institutional stay occurring within 14 days of the home health admission on an ongoing basis and automatically assign the home health claim as “community” or “institutional” appropriately. As a

result, with respect to a HH claim with a Medicare institutional stay occurring within 14 days of home health admission, we will not require the submission of an occurrence code in order to appropriately categorize the HH claim to the applicable admission source. With respect to a HH claim with a non-Medicare institutional stay occurring with 14 days of home health admission, a HHA would need to submit an occurrence code on the HH claim in order to have the HH claim categorized as “institutional” and paid the associated higher amount. Additionally, we plan to provide education and training regarding all aspects of the admission source process and to develop materials for guidance on claims adjustments, for resolution of claims processing issues, for defining timely filing windows, and for appropriate usage of occurrence codes through such resources as the Medicare Learning Network. We will also update guidance in the Medicare Claims Processing Manual as well as the Medicare Benefit Policy Manual as appropriate with detailed procedures. We will also work with our Medicare Administrative Contractors (MACs) to address any concerns regarding the processing of home health claims as well as develop training materials to facilitate all aspects of the transition to the PDGM, including the unique aspects of the admission source categories.

With regards to the length of time for resubmission of home health claims that reflect a non-Medicare institutional claim, all appropriate Medicare rules regarding timely filing of claims will still apply. Procedures required for the resubmission of home health claims will apply uniformly for those claims that require editing due to the need to add or remove occurrence codes. Details regarding the timely filing guidelines for the Medicare program are available in the Medicare Claims Processing Manual, Chapter 1—General Billing Requirements, which is available at the following website: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c01.pdf>. Additionally, adjustments to any re-submitted home health claims will be processed in the same manner as other edited Medicare home health claims. Additionally, we plan to perform robust testing within the Medicare claims processing system to optimize and streamline the payment process.

Regarding the process by which HHAs should verify a non-Medicare institutional stay, as we noted in the CY 2018 HH PPS proposed rule, we expect home health agencies would

utilize discharge summaries from all varieties of institutional providers (that is, Medicare and non-Medicare) to inform the usage of these occurrence codes, and these discharge documents should already be part of the beneficiary’s home health medical record used to support the certification of patient eligibility as outlined in § 424.22(c) (82 FR 35309). Providers should utilize existing strategies and techniques for verification of such stays and incorporate relevant clinical information into the plan of care, as is already required by our Conditions of Participation.

Our evaluation process within the Medicare claims processing system will check for the presence of an acute or PAC Medicare claim for an institutional stay occurring within 14 days of the home health admission on an ongoing basis. Under this approach, the Medicare systems would only evaluate for whether an acute or PAC Medicare claim for an institutional stay occurring within 14 days of the home health admission was processed by Medicare, not whether it was paid. Therefore, we do not expect that a home health claim will be denied due to unpaid Medicare claims for preceding acute or PAC admissions. Moreover, as previously stated above, we note that providers would have the option to submit the occurrence code indicating a preceding institutional stay in order to categorize the home health admission as “institutional.” In the case of a HHA submitting an occurrence code because of a preceding Medicare institutional stay, if upon medical review after finding no Medicare acute or PAC claims in the National Claims History, and there is documentation of a Medicare acute or PAC stay within the 14 days prior to the home health admission, but the institutional setting did not submit its claim in a timely fashion, or at all, we would permit the institutional categorization for the payment of the home health claim through appropriate administrative action. Similarly, in the case of a HHA submitting an occurrence code because of a preceding non-Medicare institutional stay, if documentation of a non-Medicare acute or PAC stay within the 14 days prior to the home health admission, is found, we would permit the categorization of the home health claim as “institutional”.

However, if upon medical review after finding no acute or PAC Medicare claims in the National Claims History, and there is no documentation of an acute or PAC stay, either a Medicare or non-Medicare stay, within 14 days of the home health admission, we would

correct the overpayment. If upon medical review after finding no Medicare acute or PAC claims in the National Claims History and we find that an HHA is systematically including occurrence codes that indicate the patient's admission source was "institutional," but no documentation exists in the medical record of Medicare or non-Medicare stays, we would refer the HHA to the zone program integrity contractor (ZPIC) for further review. Moreover, we intend to consider targeted approaches for medical review after the implementation of the admission source element of the PDGM, including potentially identifying HHAs that have claims that are consistently associated with acute or PAC denials, whose utilization pattern of acute or PAC occurrence codes is aberrant when compared with their peers, or other such metrics that would facilitate any targeted reviews.

For all of the reasons described above, we are proposing to establish two admission source categories for grouping 30-day periods of care under the PDGM—institutional and community—as determined by the healthcare setting utilized in the 14 days prior to home health admission. We are proposing that 30-day periods for beneficiaries with any inpatient acute care hospitalizations, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long term care hospital (LTCH) stays within the 14 days prior to a home health admission would be designated as institutional admissions. We are proposing that the institutional admission source category would also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the admission date and from date for the subsequent 30-day period of care do not match) as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge. However, we are proposing that we would not categorize PAC stays (SNF, IRF, LTCH stays) that occur during a previous 30-day period and within 14 days of a subsequent, contiguous 30-day period of care (that is, the admission date and from date for the subsequent 30-day period of care do not match) as institutional, as we would expect the HHA to discharge the patient if the patient required PAC in a different setting and then readmitted the patient,

if necessary, after discharge from such setting. If the patient was discharged and then readmitted to home health, the admission date and "from" date on the 30-day claim would match and the claims processing system will look for an acute or a PAC stay within 14 days of the home health admission date. This admission source designation process would be applicable to institutional stays paid by Medicare or any other payer. All other 30-day periods would be designated as community admissions.

For the purposes of a RAP, we would only adjust the final home health claim submitted for source of admission. For example, if a RAP for a community admission was submitted and paid, and then an acute or PAC Medicare claim was submitted for that patient before the final home health claim was submitted, we would not adjust the RAP and would only adjust the final home health claim so that it reflected an institutional admission. Additionally, HHAs would only indicate admission source occurrence codes on the final claim and not on any RAPs submitted.

We invite public comments on the admission source component of the proposed PDGM payment system.

6. Clinical Groupings

In the CY 2018 HH PPS proposed rule (82 FR 35307), we discussed the findings of the Home Health Study Report to Congress, which indicates that the current payment system may encourage HHAs to select certain types of patients over others.³⁹ Patients with a higher severity of illness, including those receiving a greater level of skilled nursing care; for example, patients with wounds, with ostomies, or who are receiving total parenteral nutrition or mechanical ventilation were associated with higher resource use and lower margins. This may have produced a disincentive for providing care for patients with higher clinical acuity, and thereby may have limited access of home health services to these vulnerable patient populations.⁴⁰ We noted that payment should be predicated on resource use and proposed that adjusting payment based on identified

clinical characteristics and associated services would better align payment with resource use.

For these reasons, we propose grouping 30-day periods of care into six clinical groups: Musculoskeletal Rehabilitation, Neuro/Stroke Rehabilitation, Wounds—Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care, Behavioral Health Care (including Substance Use Disorder), Complex Nursing Interventions, Medication Management, Teaching and Assessment (MMTA). These clinical groups are designed to capture the most common types of care that HHAs provide. We propose placement of each 30-day period of care into a specific clinical group based on the primary reason the patient is receiving home health care as determined by the principal diagnosis reported on the claim. Although the principal diagnosis code is the basis for the clinical grouping, secondary diagnosis codes and patient characteristics would then be used to case-mix adjust the period further through the comorbidity adjustment and functional level. A complete list of ICD-10-CM codes and their assigned clinical groupings is posted on the CMS HHA Center web page (<https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>). More information on the analysis and development of the groupings can be found in the CY 2018 HH PPS proposed rule as well as the HHGM technical report from December 2016, also available on the HHA Center webpage.

In the CY 2018 HH PPS proposed rule, we solicited comments on the clinical groups and the assigned clinical groupings of the ICD-10-CM codes. Additionally, in February 2018, a Technical Expert Panel (TEP) was held in order to gain insight from industry leaders, clinicians, patient representatives, and researchers with experience in home health care and/or experience in home health agency management. Many commenters and TEP members supported the patient-centered approach to grouping patients by clinical characteristics, and several commenters felt that the clinical groupings did capture the majority of characteristics of the home health population. Specifically, commenters generally approved of the higher-weighted complex nursing and wound groups, and agreed with the "importance the HHGM places on these complex patients through its proposed payment rate." One commenter stated that "the most complex and costly beneficiaries for a HHA are those that require intensive nursing care, while

³⁹ Report to Congress. Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations. Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf>.

⁴⁰ Report to the Congress: Medicare Payment Policy. (2015) Home health care services: Assessing payment adequacy and updating payments. Ch.9 <http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report.pdf?sfvrsn=0>.

those that require intensive therapy produce a significant margin with less cost." Additional comments on the clinical groups generally included the following: Concern that some diagnosis codes are not used to group claims into the six clinical groups; concern about reduced therapy use in the clinical groups that aren't specifically for musculoskeletal or neurological rehabilitation; concern that the groups do not capture clinically complex patients that require multiple home health disciplines; suggestions that the clinical groups should be based on impairments rather than diagnoses; and concern that the MMTA clinical group encompasses too many diagnosis codes. Several commenters expressed concern that certain ICD 10-CM diagnosis codes were not used for payment (for example, codes that were not used to group claims into the six clinical groupings), which could possibly restrict access to the benefit or force beneficiaries to seek care in institutional settings. Others had concerns regarding specific diagnosis codes they felt should be reassigned to different clinical groups.

As outlined in the HHGM technical report from December 2016 and in the CY 2018 HH PPS proposed rule (82 FR 35314), there were several reasons why a diagnosis code was not assigned to one of the six clinical groups. These included if the diagnosis code was too vague, meaning the code does not provide adequate information to support the need for skilled home health services (for example H57.9, Unspecified disorder of eye and adnexa); the code, based on ICD 10-CM, American Hospital Association (AHA) Coding Clinic, or Medicare Code Edits (MCE) would indicate a non-home health service (for example, dental codes); the code is a manifestation code subject to a manifestation/etiology convention, meaning that the etiology code must be reported as the principal diagnosis, or the code is subject to a code first sequencing convention (for example, G99.2 myelopathy in diseases classified elsewhere); the code identifies a condition which would be unlikely to require home health services (for example, L81.2, Freckles); the code is restricted to the acute care setting per ICD 10-CM/AHA Coding Clinic, or the diagnosis indicates death as the outcome (for example S06.1X7A, Traumatic cerebral edema with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness). We did, however, review and re-group certain codes based on commenter feedback. For example, with regard to the

classification of N39.0, Urinary tract infection, site not specified as an invalid code to group the home health period of care, we do agree that absent definitive information provided by the referring physician, a home health clinician would not know the exact site of a urinary tract infection (UTI). As such, Urinary tract infection, site not specified (N39.0) will be grouped under MMTA, as the home health services required would most likely involve teaching about the treatment for the UTI, as well as evaluating the effectiveness of the medication regimen. We encourage HHAs to review the list of diagnosis codes in the PDGM Grouping Tool posted on the HHA Center web page at: <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>. Additionally, the ICD-10-CM code set exceeds the ICD-9-CM in the number of diagnoses and conditions and contains codes that are much more granular. Therefore, we disagree that excluding certain codes from payment will restrict access, considering the increase in diagnoses potentially requiring home health.

With regard to commenter concern that the HHGM clinical groups did not account for the need for therapy in home health periods that are not specifically grouped into musculoskeletal or neurological rehabilitation, we continue to expect the ordering physician, in conjunction with the therapist to develop and follow a plan of care for any home health patient, regardless of clinical group, as outlined in the skilled service requirements at § 409.44, when therapy is deemed reasonable and necessary. Although the principal diagnosis is a contributing factor in the PDGM and determines the clinical group, it is not the only consideration in determining what home health services are needed in a patient's plan of care. It is the responsibility of the patient's treating physician to determine if and what type of therapy the patient needs regardless of clinical grouping. In accordance with § 409.44(c)(1)(i), the therapy goals must be established by a qualified therapist in conjunction with the physician when determining the plan of care. As such, therapy may likely be included in the plan of care for a patient in any of the six clinical groupings. Any therapy indicated in the plan of care is expected to meet the requirements outlined in § 409.44, which states that all therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist). Additional requirements

dictate that the amount, frequency, and duration of the services must be reasonable and necessary, as determined by a qualified therapist and/or physician, using accepted standards of clinical practice. One goal in developing the PDGM is to provide an appropriate payment based on the identified resource use of different patient groups, not to encourage, discourage, value, or devalue one type of skilled care over another.

Likewise, for patients requiring two or three home health disciplines, the PDGM takes into account the functional level and comorbidities of the patient after the primary reason for the period is captured by the clinical grouping. Decreasing functional status, as indicated by a specific set of OASIS items, and the presence of certain comorbid conditions, is associated with increased resource use. Here is where, when combined with the clinical grouping, any multi-disciplinary therapy patients would be captured. For instance, a patient grouped into the Neuro-Rehabilitation clinical grouping with a high Functional Level (meaning high functional impairment) indicates increased therapy needs, potentially utilizing all skilled therapy disciplines. Additionally, the comorbidity adjustment further case mixes the period and increases payment to capture the additional resource use for a patient regardless of whether the services are skilled nursing or therapy based. Therefore, a patient with complex needs, including multiple therapy disciplines and medical management, is captured by the combination of the different levels of the PDGM. Furthermore, the current case-mix adjustment methodology does not differentiate between utilization of therapy disciplines and whether or not all three are utilized for the same patient. We have determined that the PDGM's functional level when combined with the clinical grouping and comorbidity adjustment actually provides a much clearer picture of the patient's needs, particularly in relation to therapy services.

Comments on the CY 2018 HH PPS proposed rule and at the 2018 TEP indicated that diagnosis does not always correlate with need and that impairments and functional limitations are better predictors of therapy services. Additionally, some commenters stated that clinicians are more likely to focus on impairments and functional limitations when conceptualizing overall patient care, and suggested using them as the basis for the clinical groups rather than diagnosis codes. We do agree that diagnosis alone does not

provide the entire clinical picture of the home health patient; however, in the same way the clinical group is one aspect of the PDGM, therapy services are only one aspect of home health. In fact, the multidisciplinary nature of the benefit is precisely the reason that diagnosis should be an important aspect of the clinical groupings model. The various home health disciplines have different but overlapping roles in treating the patient; however, a diagnosis is used across disciplines and has important implications for patient care. A patient’s diagnosis consists of a known set of signs and symptoms agreed upon by the medical community. Each different healthcare discipline uses these identifiable signs and symptoms to apply its own approach and skill set to treat the patient. However, it remains a patient centered approach.

Several commenters and TEP participants alike, stated that the MMTA clinical group is too broad and should be divided into more clinical groups or subgroups. One commenter questioned whether it made sense to assign patients to different clinical groupings if roughly 60 percent of 30-day periods will fall into the MMTA category. Others considered it an “other” category that was counter to the goal of clarifying the need for home health.

A significant goal of the PDGM is to clearly define what types of services are provided in home health and accurately ascribe payment to resource use. Our analysis showed that there are four very

broad categories of interventions frequently provided in the home that are not attributable to one specific intervention or diagnosis: Health teaching; guidance and counseling; case management; treatments and procedures; and surveillance. These categories cross the spectrum of diagnoses, medications, and interventions, which understandably is why this clinical grouping represents the majority of home health episodes. We believe that these four broad categories of interventions in MMTA cannot be underestimated in importance. We stated in the CY 2018 HH PPS proposed rule that many home health patients have multi-morbidity and polypharmacy, making education and surveillance crucial in the management of the home health patient in order to prevent medication errors and adverse effects. However, the principal diagnosis necessitating home care for these patients may not involve a complex nursing intervention, behavioral health, rehabilitation, or wound care. This group represents a broader, but no less important reason for home care. We believe MMTA is not so much an “other” category as much as it appears to represent the foundation of home health. Many commenters highlighted the complexity of home health patients; pointing to multi-morbidity, “quicker and sicker” discharges, and polypharmacy as important factors in maintaining home

health access. CMS agrees that these issues alone are important reasons for ordering home health services and necessitate their own clinical grouping.

When initially developing the model, we looked at breaking MMTA into subgroups in order to account for differences amongst diagnoses within the broader category of this group. We found that the variation in resource use was similar across those subgroups and determined separating diagnoses further would only serve to make the model more complex and without significant variations in case-mix. However, in response to public comments and the discussion at the 2018 TEP,²⁰ we performed further analysis on the division of MMTA into subgroups in order to estimate the payment regression if these groups were separated from MMTA. We conducted a thorough review of all the diagnosis codes grouped into MMTA. We then grouped the codes into subgroups based on feedback from public comments, which mainly focused on cardiac, oncology, infectious, and respiratory diagnoses. We created the additional subgroups (Surgical/Procedural Aftercare, Cardiac/Circulatory, Endocrine, GI/GU, Infectious Diseases/Neoplasms, Respiratory, and Other) based on data that showed above-average resource use for the codes in those groups, and then combined certain groups that had a minimal number of codes. Those results are shown in Table 38.

TABLE 38—DISTRIBUTION OF RESOURCE USE BY 30-DAY PERIODS
[MMTA subgroups]

Subgroup	N	Mean	Median
Aftercare	304,871	\$1,605.43	\$1,326.03
Cardiac/Circulatory	1,594,149	1,433.02	1,121.27
Endocrine	425,077	1,524.45	1,062.41
GI/GU	402,322	1,414.44	1,115.29
Infectious Diseases/Neoplasms/Blood-forming Diseases	347,755	1,400.65	1,077.58
Respiratory	724,722	1,411.61	1,122.23
Other	1,226,750	1,366.56	1,035.76
Total	5,025,646	1,428.17	1,105.20

Table 39 shows the impact each MMTA variable has on case-mix weight. The impact is calculated by taking the regression coefficient for each variable (unreported here) and dividing by the average resource use of the 30-day periods in the model. Model 1 shows the result when MMTA clinical group is not separated into subgroups. Model 1 shows that all else equal, being in

MMTA—Low Functional impairment causes no increase in case-mix weight (for example, a 30-day period’s case-mix weight would be calculated with the coefficients from the constant of the model plus the admission source/timing of the period plus the comorbidity adjustment). A 30-day period in MMTA—Medium Functional would increase the case-mix weight by 0.1560.

A 30-day period in MMTA—High Functional would increase the case-mix weight by 0.2731. Model 2 shows the same information but now includes the MMTA subgroups. In any given functional level, many of the MMTA subgroups have an impact on the case-mix weight that is similar to what is found in Model 1. For example, a period in MMTA (Other)—Medium Functional

²⁰ <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>.

has an increase in case-mix of 0.1568 (which is very similar to the 0.1560 value found in Model 1). There are some groups like Aftercare, Endocrine, and GI/GU which show different impacts than Model 1. Also, to a lesser extent

these differences also exist for the “Infectious Diseases/Neoplasms/Blood forming Diseases” and “Respiratory” subgroups. Some of these differences are driven by periods which are paid using an outlier adjustment. Model 3 removes

outliers and the corresponding results for the Endocrine subgroup are very similar to Model 1. Some differences (for example in Aftercare) persist; however, the change in case-mix weight remains similar to Model 1.

TABLE 39—CHANGE IN CASE-MIX WEIGHT ASSOCIATED WITH MMTA VARIABLES

Variable	Model 1	Model 2	Model 3 (outliers excluded)
	Change in case-mix weight	Change in case-mix weight	Change in case-mix weight
MMTA—Low Functional	0.000
MMTA—Medium Functional	0.1560
MMTA—High Functional	0.2731
MMTA (Other)—Low Functional	0.000	0.000
MMTA (Other)—Medium Functional	0.1568	0.1523
MMTA (Other)—High Functional	0.2896	0.2748
MMTA (Aftercare)—Low Functional	-0.1082	-0.1196
MMTA (Aftercare)—Medium Functional	0.0798	0.0701
MMTA (Aftercare)—High Functional	0.2588	0.2491
MMTA (Cardiac/Circulatory)—Low Functional	-0.0239	-0.0050
MMTA (Cardiac/Circulatory)—Medium Functional	0.1371	0.1652
MMTA (Cardiac/Circulatory)—High Functional	0.2737	0.2952
MMTA (Endocrine)—Low Functional	0.1105	0.0282
MMTA (Endocrine)—Medium Functional	0.2859	0.1833
MMTA (Endocrine)—High Functional	0.4071	0.3086
MMTA (GI/GU)—Low Functional	-0.0751	-0.0639
MMTA (GI/GU)—Medium Functional	0.0997	0.1256
MMTA (GI/GU)—High Functional	0.1992	0.2231
MMTA (Infectious Diseases/Neoplasms/Blood forming Diseases)—Low Functional	-0.0452	-0.0472
MMTA (Infectious Diseases/Neoplasms/Blood forming Diseases)—Medium Functional	0.1068	0.1128
MMTA (Infectious Diseases/Neoplasms/Blood forming Diseases)—High Functional	0.2281	0.2379
MMTA (Respiratory)—Low Functional	-0.0501	-0.0488
MMTA (Respiratory)—Medium Functional	0.1027	0.1163
MMTA (Respiratory)—High Functional	0.2241	0.2400

The results show that the change in case-mix weight was minimal for the 30-day periods assigned to these subgroups compared to the case-mix weights without the subgroups. Additionally, the impact of other variables in the model (admission source/timing, comorbidity adjustment) on the final case-mix weights were similar whether or not MMTA subgroups were used.

Overall, using the MMTA subgroup model would result in more payment groups but not dramatic differences in case-mix weights across those groups. For this reason, we are not proposing to divide the MMTA clinical group into subgroups and to leave them as is shown in Table 40. However, we are soliciting comments from the public on whether there may be other compelling reasons why MMTA should be broken

out into subgroups as shown in Table 38, even if the additional subgroups do not result in significant differences in case-mix weights across those subgroups. We note that we also plan continue to examine trends in reporting and resource utilization to determine if future changes to the clinical groupings are needed after implementation of the PDGM.

TABLE 40—PROPOSED CLINICAL GROUPS USED IN THE PDGM

Clinical groups	The primary reason for the home health encounter is to provide:
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition.
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke.
Wounds—Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care.	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions.
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric conditions, including substance use disorders.
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions including IV, TPN, enteral nutrition, ventilator, and ostomies.
Medication Management, Teaching and Assessment (MMTA).	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the above listed groups.

7. Functional Levels and Corresponding OASIS Items

As part of the overall payment adjustment under an alternative case-mix adjustment methodology, in the CY 2018 Home Health Prospective Payment System proposed rule (82 FR 35317), we proposed including a functional level adjustment to account for the resource costs associated with providing home health care to those patients with functional impairments. Research has shown a relationship exists between functional status, rates of hospital readmission, and the overall costs of health care services.⁴² Functional status is defined in a number of ways, but generally, functional status reflects an individual's ability to carry out activities of daily living (ADLs) and to participate in various life situations and in society.⁴³ CMS currently requires the collection of data on functional status in home health through a standardized assessment instrument: The Outcome and Assessment Information Set (OASIS). Under the current HH PPS, a functional status score is derived from the responses to those items and this score contributes to the overall case-mix adjustment for a home health episode payment.

Including functional status in the case-mix adjustment methodology allows for higher payment for those patients with higher service needs. As functional status is commonly used for risk adjustment in various payment systems, including in the current HH PPS, we proposed that the alternative case-mix adjustment methodology would also adjust payments based on responses to selected functional OASIS items that have demonstrated higher resource use. Therefore, we examined every OASIS item for potential inclusion in the alternative case-mix adjustment methodology including those items associated with functional status.

Generally, worsening functional status is associated with higher resource use, indicating that the responses to functional OASIS items may be useful as adjusters to construct case-mix weights for an alternative case-mix adjustment methodology. However, due

to the lack of variation in resource use across certain responses and because certain responses were infrequently chosen, we combined some responses into larger response categories to better capture the relationship between worsening functional status and resource use. The resulting combinations of responses for these OASIS items are found at Exhibit 7–2 in the HHGM technical report, “Overview of the Home Health Groupings Model,” on the HHA Center web page.⁴⁴

Each OASIS item included in the final model has a positive relationship with resource use, meaning as functional status declines (as measured by a higher response category), periods have more resource use, on average. As such, in the CY 2018 HH PPS proposed rule, we proposed that the following OASIS items would be included as part of the functional level adjustment under an alternative case-mix adjustment methodology:

- M1800: Grooming.
- M1810: Current Ability to Dress Upper Body.
- M1820: Current Ability to Dress Lower Body.
- M1830: Bathing.
- M1840: Toilet Transferring.
- M1850: Transferring.
- M1860: Ambulation/Locomotion.
- M1033 Risk of Hospitalization (at least four responses checked, excluding responses #8, #9, and #10).⁴⁵

In the CY 2018 HH PPS proposed rule, we discussed how under the HHGM a home health period of care receives points based on each of the responses associated with the proposed functional OASIS items which are then converted into a table of points corresponding to increased resource use. That is, the higher the points, the higher the functional impairment. The sum of all of these points' results in a functional impairment score which is used to group home health periods into a functional level with similar resource use. We proposed three functional impairment levels of low, medium, and high with approximately one third of home health periods from each of the clinical groups within each level. This means home health periods in the low impairment level have responses for the proposed functional OASIS items that are associated with the lowest resource use on average. Home health periods in the high impairment level have

responses for the proposed functional OASIS items that are associated with the highest resource use on average. We also proposed that the functional impairment level thresholds would vary between the clinical groups to account for the patient characteristics within each clinical group associated with increased resource costs affected by functional impairment. We provided a detailed analysis of the development of the functional points and the functional impairment level thresholds by clinical group in the HHGM technical report⁴⁶ and in Tables 36 and 37 in the CY 2018 HH PPS proposed rule (82 FR 35321).

In the CY 2018 HH PPS proposed rule, we solicited comments on the proposed functional OASIS items, the associated points, and the thresholds by clinical group used to group patients into three functional impairment levels under the HHGM, as outlined above. The majority of comments received were from physical therapists, physical therapy assistants, occupational therapists, and national physical, occupational, and speech-language pathology associations. Likewise, a Technical Expert Panel (TEP) was convened in February 2018 to collect perspectives, feedback, and identify and prioritize recommendations from a wide variety of industry experts and patient representatives regarding the public comments received on the proposed HHGM. Comments were very similar between those received on the CY 2018 HH PPS proposed rule and those made by the TEP participants.

Most commenters agreed that the level of functional impairment should be included as part of the overall case-mix adjustment in a revised case-mix model. Likewise, commenters were generally supportive of the OASIS items selected to be used in the functional level payment adjustment. Commenters noted that the role of patient characteristics and functional status as an indicator of resource use is a well-established principle in rehabilitation care. Some commenters stated that adopting a similar component in the home health payment system will help to remove the incentive to provide unnecessary therapy services to reach higher classifications for payment but will also move the HH PPS toward greater consistency with other post-acute care prospective payment systems. Other comments received on the functional impairment level adjustment

⁴² Burke, R. MD, MS, Whitfield, E. Ph.D., Hittle, D. Ph.D., Min, S. Ph.D., Levy, C. MD, Ph.D., Prochazka, A. MD, MS, Coleman, E. MD, MPH, Schwartz, R. MD, Ginde, A. (2016). “Hospital Readmission From Post-Acute Care Facilities: Risk Factors, Timing, and Outcomes”. *The Journal of Post-Acute Care and Long Term Care Medicine*. (17), 249–255.

⁴³ Clauser, S. Ph.D., and Arlene S. Bierman, M.D., M.S. (2003). “Significance of Functional Status Data for Payment and Quality”. *Health Care Financing Review*. 24(3), 1–12.

⁴⁴ <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

⁴⁵ Exclusions of the OASIS C–1 Item M1033 include, response #8: “currently reports exhaustion”; response #9: “other risk(s) not listed in 1–8; response #10: None of the above.

⁴⁶ “Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements Overview of the Home Health Groupings Model” located at <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

encompassed several common themes: The effect of the IMPACT Act provisions on the HHGM; adequacy of the functional impairment thresholds and corresponding payment adjustments; potential HHA behavioral changes to the provision of home health services; the impact of the removal of therapy thresholds on HHAs; and recommendations for the inclusion of other OASIS items into the functional impairment level adjustment.

We note that the analysis presented in the CY 2018 HH PPS proposed rule was based on CY 2016 home health episodes using version OASIS-C1/ICD-10 data set, which did not include the aforementioned IMPACT Act functional items. To accommodate new data being collected for the Home Health Quality Reporting Program in support of the IMPACT Act, CMS has proposed to add the functional items, Section GG, "Functional Abilities and Goals", to the OASIS data set effective January 1, 2019. Because these GG functional items are not required to be collected on the OASIS until January 1, 2019, we do not have the data to determine the effect, if any, of these newly added items on resource costs during a home health period of care. However, if the alternative case-mix adjustment methodology, is implemented in CY 2020, we would continue to examine the effects of all OASIS items, including the "GG" functional items, on resource use to determine if any refinements are warranted.

Addressing those comments regarding the use and adequacy of the functional impairment thresholds to adjust payment, we remind commenters that the structure of categorizing functional impairment into Low, Medium, and High levels has been part of the home health payment structure since the implementation of the HH PPS. The current HH PPS groups' scores are based on functional OASIS items with similar average resource use within the same functional level, with approximately a third of episodes classified as low functional score, a third of episodes are classified as medium functional score, and a third of episodes are classified as high functional score. Likewise, the PDGM groups' scores would be based on functional OASIS items with similar resource use and would have three levels of functional impairment severity: Low, medium and high. However, the three functional impairment thresholds vary between the clinical groups to account for the patient characteristics within that clinical group associated with increased resource costs affected by functional impairment. This is to further ensure that payment is more

accurately aligned with actual patient resource needs. As such, we believe the more granular structure of these functional levels provides the information needed on functional impairment and allows greater flexibility for clinicians to tailor a more patient-centered home health plan of care to meet the individualized needs of their patients. As HHA-reported OASIS information determines the functional impairment levels, accurate reporting on the OASIS will help to ensure that the case-mix adjustment is in alignment with the actual level of functional impairment.

Concerns regarding HHAs changing the way they provide services to eligible beneficiaries, specifically therapy services, should be mitigated by the more granular functional impairment level adjustment (for example, functional thresholds which vary between each of the clinical groups). The functional impairment level case-mix payment adjustment is reflective of the resource costs associated with these reported OASIS items and therefore ensures greater payment accuracy based on patient characteristics. We believe that this approach will help to maintain and could potentially increase access to needed therapy services. We remind HHAs that the provision of home health services should be based on patient characteristics and identified care needs. This could include those patients with complex and/or chronic care needs, or those patients requiring home health services over a longer period of time or for which there is no measureable or expected improvement.

While the majority of commenters agreed that the elimination of therapy thresholds is appropriate because of the financial incentive to overprovide therapy services, some commenters indicated that the reductions in payment for therapy visits could result in a decrease in HHA viability and could force some HHAs to go out of business, such as those HHAs that provide more therapy services than nursing. We note that section 51001(a)(3) of the BBA of 2018 amended section 1894(b)(4)(B) of the Act to prohibit the use of therapy thresholds as part of the overall case-mix adjustment for CY 2020 and subsequent years. Consequently, we have no regulatory discretion in this matter.

Several commenters provided recommendations for additional OASIS items for inclusion to account for functional impairment. Most notably, commenters suggested adding OASIS items associated with cognition, instrumental activities of daily living (IADLs), and caregiver support. The

current HH PPS does not use OASIS items associated with cognition, IADLs, or caregiver support to case-mix adjust for payment. Nonetheless, the relationship between cognition and functional status is important and well-documented in health care literature so we included them in our analysis because they generally have clinical significance based on research and standards of practice. As described in the CY 2018 HH PPS proposed rule and the technical report, we examined every single OASIS item and its effect on costs. These included those OASIS items associated with cognition, IADLs, and caregiver support. Only those OASIS items associated with higher resource costs were considered for inclusion in the functional level adjustment in the HHGM. Despite commenters' recommendations, the variables suggested were only minimally helpful in explaining or predicting resource use and most reduced the amount of actual payment. As such, we excluded variables associated with cognition, IADLs, and caregiver support because they would decrease payment for a home health period of care which is counter to the purpose of a case-mix adjustment under the HHGM. The complete analysis of all of the OASIS items can be found in the HHGM technical report on the HHA Center web page.⁴⁷

After careful consideration of all comments received on the functional level adjustment as part of an alternative case-mix adjustment methodology, we believe that the three PDGM functional impairment levels in each of the six clinical groups are designed to capture the level of functional impairment. We believe that the more granular nature of the levels of functional impairment by clinical group would encourage therapists to determine the appropriate services for their patients in accordance with identified needs rather than an arbitrary threshold of visits. While the functional level adjustment is not meant to be a direct proxy for the therapy thresholds, the PDGM has other case-mix variables to adjust payment for those patients requiring multiple therapy disciplines or those chronically ill patients with significant functional impairment. We believe that also accounting for timing, source of admission, clinical group (meaning the primary reason the patient requires home health services), and the presence of comorbidities will provide the necessary adjustments to payment to ensure that care needs are met based on

⁴⁷ <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

actual patient characteristics. Therefore, we continue to uphold that the functional impairment level adjustment is sufficient and along with the other case-mix adjustments, payment will better align with the costs of providing services.

In summary, we are proposing that the OASIS items identified in the CY 2018 HH PPS proposed rule would be included as part of the functional impairment level payment adjustment under the proposed PDGM. These items are:

- M1800: Grooming.

- M1810: Current Ability to Dress Upper Body.
- M1820: Current Ability to Dress Lower Body.
- M1830: Bathing.
- M1840: Toilet Transferring.
- M1850: Transferring.
- M1860: Ambulation/Locomotion.
- M1033: Risk of Hospitalization.⁴⁸

We are proposing that a home health period of care receives points based on each of the responses associated with the proposed functional OASIS items which are then converted into a table of points corresponding to increased resource use (See Table 41). The sum of all of these points results in a functional

score which is used to group home health periods into a functional level with similar resource use. We are proposing three functional levels of low impairment, medium impairment, and high impairment with approximately one third of home health periods from each of the clinical groups within each functional impairment level (See Table 42). The CY 2018 HH PPS Proposed rule (82 FR 35320) and the technical report posted on the HHA Center web page provide a more detailed explanation as to the construction of these functional impairment levels using the proposed OASIS items.

TABLE 41—OASIS POINTS TABLE FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS, CY 2017

	Response category	Points (2017)	Percent of periods in 2017 with this response category
M1800: Grooming	1	4	56.9
M1810: Current Ability to Dress Upper Body	1	6	60.0
M1820: Current Ability to Dress Lower Body	1	5	59.3
2	11	20.9	
M1830: Bathing	1	3	18.0
	2	13	53.1
	3	21	23.6
M1840: Toilet Transferring	1	4	32.1
M1850: Transferring	1	4	37.8
	2	8	59.2
M1860: Ambulation/Locomotion	1	11	25.2
	2	13	52.8
	3	25	14.8
M1033: Risk of Hospitalization	4 or more items checked	11	17.8

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017(as of March 2, 2018).

TABLE 42—THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, CY 2017

Clinical group	Level of impairment	Points (2017 data)
MMTA	Low	0–37
	Medium	38–53
	High	54+
Behavioral Health	Low	0–38
	Medium	39–53
	High	54+
Complex Nursing Interventions	Low	0–36
	Medium	37–57
	High	58+
Musculoskeletal Rehabilitation	Low	0–39
	Medium	40–53
	High	54+
Neuro Rehabilitation	Low	0–45
	Medium	46–61
	High	62+
Wound	Low	0–43
	Medium	44–63
	High	64+

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

⁴⁸ In Version OASIS C–2 (effective 1/1/2018), three responses are excluded: #8: “currently reports

exhaustion”, #9: “other risks not listed in 1–8”, and #10: “None of the above”.

Table 43 shows the average resource use by clinical group and functional level for CY 2017:

TABLE 43—AVERAGE RESOURCE USE BY CLINICAL GROUP AND FUNCTIONAL LEVEL, CY 2017

	Mean resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
MMTA—Low	\$1,236.05	1,650,146	19.1	\$1,076.20	\$511.06	\$907.38	\$1,632.74
MMTA—Medium	1,487.24	1,709,484	19.8	1,162.37	628.29	1,202.12	2,020.73
MMTA—High	1,667.38	1,402,299	16.3	1,274.53	719.29	1,371.99	2,265.39
Behavioral Health—Low	971.26	98,193	1.1	845.25	397.45	686.39	1,285.36
Behavioral Health—Medium	1,309.40	93,145	1.1	990.34	557.57	1,064.55	1,784.48
Behavioral Health—High	1,485.06	96,899	1.1	1,092.42	653.44	1,233.97	2,027.14
Complex—Low	1,313.78	104,504	1.2	1,194.16	553.50	953.84	1,669.45
Complex—Medium	1,668.06	104,717	1.2	1,415.99	694.35	1,275.32	2,202.65
Complex—High	1,771.05	97,779	1.1	1,527.71	704.28	1,336.79	2,361.61
MS Rehab—Low	1,545.07	587,873	6.8	1,048.07	779.96	1,323.12	2,055.60
MS Rehab—Medium	1,731.15	536,444	6.2	1,111.26	931.97	1,527.46	2,293.96
MS Rehab—High	1,900.89	469,117	5.4	1,243.84	1,009.66	1,672.76	2,520.57
Neuro—Low	1,591.74	308,011	3.6	1,163.69	744.21	1,323.86	2,127.18
Neuro—Medium	1,833.25	287,788	3.3	1,271.31	900.27	1,568.22	2,467.92
Neuro—High	1,945.49	303,787	3.5	1,420.56	899.47	1,618.16	2,629.54
Wound—Low	1,663.25	275,383	3.2	1,271.45	790.83	1,328.52	2,152.26
Wound—Medium	1,893.35	238,063	2.8	1,370.79	927.26	1,550.78	2,475.29
Wound—High	2,044.09	261,144	3.0	1,520.35	975.19	1,644.10	2,669.06
Total	1,570.68	8,624,776	100.0	1,221.38	679.12	1,272.18	2,117.47

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

Like the annual recalibration of the case-mix weights under the current HH PPS, we expect that annual recalibrations would also be made to the PDGM case-mix weights. If the PDGM is finalized for CY 2020, we will update the functional points and thresholds using the most current claims data available. Likewise, we would continue to analyze all of the components of the case-mix adjustment, including adjustment for functional status, and would make refinements as necessary to ensure that payment for home health periods are in alignment with the costs of providing care. We invite comments on the proposed OASIS items and the associated points and thresholds used to group patients into three functional impairment levels under the PDGM, as outlined above.

8. Comorbidity Adjustment

The alternative case-mix adjustment methodology proposed in the CY 2018 HH PPS proposed rule, groups home health periods based on the primary reason for home health care (principal diagnosis), functional level, admission source, and timing. To further account for differences in resource use based on patient characteristics, in the CY 2018 HH PPS proposed rule, we proposed to use the presence of comorbidities as part of the overall case-mix adjustment under the alternative case-mix adjustment methodology. Specifically,

we proposed a home health specific list of comorbidities further refined into broader, body system-based categories and more granular subcategories to capture those conditions that affect resource costs during a home health period of care. The proposed comorbidities included those conditions that represent more than 0.1 percent of periods and had at least as high as the median resource use as they indicate a direct relationship between the comorbidity and resource utilization.

Specifically, we proposed a list based on the principles of patient assessment by body systems and their associated diseases, conditions, and injuries to develop larger categories of conditions that identified clinically relevant relationships associated with increased resource use. The broad, body system-based categories we proposed to use to group comorbidities within the HHGM included the following:

- Heart Disease
- Respiratory Disease
- Circulatory Disease and Blood Disorders
- Cerebral Vascular Disease
- Gastrointestinal Disease
- Neurological Disease and Associated Conditions
- Endocrine Disease
- Neoplasms
- Genitourinary and Renal Disease
- Skin Disease
- Musculoskeletal Disease or Injury

- Behavioral Health (including Substance Use Disorders)
- Infectious Disease

These broad categories used to group comorbidities within the alternative case-mix adjustment methodology were further refined by grouping similar diagnoses within the broad categories into statistically and clinically significant subcategories which would receive the comorbidity adjustment in the alternative case-mix adjustment methodology (for example, Heart Disease 1; Cerebral Vascular Disease 4). All of the comorbidity diagnoses grouped into the aforementioned categories and subcategories are posted on the Home Health Agency web page and listed in the HHGM technical report at the following link: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

We originally proposed that if a 30-day period of care had at least one secondary diagnosis reported on the home health claim that fell into one of the subcategories, that 30-day period of care would receive a comorbidity adjustment to account for higher costs associated with the comorbidity. Therefore, the payment adjustment for comorbidities would be predicated on the presence of one of the identified diagnoses within the subcategories associated with increased resource use at or above the median. The comorbidity adjustment amount would be the same

across all of the subcategories. A 30-day period of care would receive only one comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the subcategories associated with higher resource use. If there is no reported diagnosis that meets the comorbidity adjustment criteria, the 30-day period of care would not qualify for the payment adjustment.

We solicited comments on the proposed comorbidity adjustment in the CY 2018 HH PPS proposed rule, including the proposed comorbidity diagnoses and their associated subcategories, as part of the overall alternative case-mix adjustment methodology. While all commenters supported the inclusion of a comorbidity adjustment, most commenters said that a single comorbidity payment amount as part of the overall case-mix adjustment is insufficient to fully capture the home health needs and resource costs associated with the presence of comorbidities. Meeting the requirement of section 51001 of the BBA of 2018, a Technical Expert Panel (TEP) was convened in February 2018 to collect perspectives, feedback, and identify and prioritize recommendations from a wide variety of industry experts and patient representatives regarding the public comments received on the proposed alternative case-mix adjustment methodology. Comments on the comorbidity adjustment and suggestions for refinement to this adjustment were very similar between those received on the CY 2018 HH PPS proposed rule and those made by the TEP participants. Specifically, the majority of commenters stated that the presence of multiple comorbidities has more of an effect on home health resource use than a single comorbidity and that any case-mix adjustment should account for multiple comorbidities. There was general agreement that most home health patients have multiple conditions which increase the complexity of their care and affects the ability to care for one's self at home. Several suggested that CMS should let the data help determine how many comorbidity adjustment levels there should be and what percentage of 30-day periods should be in each level. Some commenters stated they preferred specificity and complexity over simplicity if the complexity improved accuracy. Others suggested including interactions between comorbidities in the model, specifically interactions of comorbid conditions with the principal diagnosis and with other comorbidities.

Commenters and TEP members alike focused on those conditions they saw as most impactful on the provision of care to home health beneficiaries. These conditions included chronic respiratory and cardiac conditions, as well as psychological and diabetes-related conditions. Most encouraged CMS to continue to develop a system to allow for appropriate changes to be made over time to the list of comorbidity subcategories that would assign a comorbidity adjustment to a 30-day period of care.

We agree with commenters that the relationship between comorbidities and resource use can be complex and that a single adjustment, regardless of the type or number of comorbidities, may be insufficient to fully capture the resource use of a varied population of home health beneficiaries. However, we also recognize that adjusting payment based on the number of reported comorbidities may encourage HHAs to inappropriately report comorbid conditions in order to increase payment, regardless of any true impact on the home health plan of care. Currently, OASIS instructions state that clinicians must list each diagnosis for which the patient is receiving home care and to enter the level of highest specificity as required by ICD-10 CM coding guidelines. These instructions state that clinicians should list diagnoses in the order that best reflects the seriousness of each condition and supports the disciplines and services provided.⁴⁹ We also note that CMS currently uses interaction items as part of the HH PPS case-mix adjustments. In the CY 2008 HH PPS final rule (72 FR 49772), we added secondary diagnoses and their interactions with the principal diagnosis as part of the clinical dimension in the overall case-mix adjustment. However, analysis since then has shown that nominal case-mix growth became an ongoing issue resulting from the incentive in the current HH PPS to code only those conditions associated with clinical points even though the data did not show an associated increase in resource utilization. Likewise, when we looked at a multi-morbidity approach to the overall case-mix adjustment to a home health period of care, for the CY 2018 HH PPS proposed rule our analysis showed that the reporting of secondary diagnoses on home health claims was not robust enough to support a payment adjustment based on the presence of

multiple comorbidities. This means that the data did not show significant variations in resource use with an increase in reported comorbidities.

In spite of concerns of potential manipulation of coding patterns to increase payment due to the comorbidity adjustment, the results of our most recent analyses for this proposed rule show compelling evidence that patients with certain comorbidities and interactions of certain comorbid conditions (as described later in this section) have home health episodes with higher resource use than home health episodes without those comorbidities or interactions. The goal of our analyses was to identify those clinically and statistically significant comorbidities and interactions that could be used to further case-mix adjust a 30-day home health period of care. As a result of these analyses, we identified that there were certain individual comorbidity subgroups and interactions of the comorbidity subgroups (for example, having diagnoses associated with two of the comorbidity subgroups) which could be used as part of the comorbidity case-mix adjustment in the PDGM.

To identify these relationships with resource utilization, we looked at all diagnoses reported on the OASIS (M1021, M1023, and M1025) for each 30-day period of care. These fields represent 18 different diagnoses which could be reported on the OASIS. In the PDGM, the principal diagnosis assigns each 30-day period of care into a clinical group which identifies the primary reason the patient requires home health services. During our analysis, this usually was the reported principal diagnosis, but in cases where the diagnosis did not link to a clinical group (for example, the diagnosis could not be reported as a principal diagnosis in accordance with ICD-10 CM coding guidelines), we used a secondary diagnosis to assign the 30-day period of care into a clinical group. Any other diagnoses, except the one used to link the 30-day period of care into a clinical group, were considered comorbidities. However, if one of those comorbid diagnoses was in the same ICD-10 CM block of codes as the diagnosis used to place the 30-day period of care into a clinical group, then that comorbid diagnosis was excluded (for example, if the reported principal diagnosis was I63.432, Cerebral infarction due to embolism of left post cerebral artery, and the reported secondary diagnosis was I65.01, Occlusion and stenosis of right vertebral artery, I65.01 would be excluded as a comorbidity as both codes are in the same block of ICD-10

⁴⁹ "Outcome and Assessment I OASIS Information Set C2 Guidance Manual Effective January 1, 2018 accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-C2-Guidance-Manual-Effective_1_1_18.pdf.

diagnosis codes, Cerebrovascular Diseases, and both would group into the Neuro clinical group if reported as the principal diagnosis). Then, we checked those reported comorbid diagnoses against the home health-specific comorbidity subgroup list to see if any reported secondary diagnoses are listed in a subgroup (for example, if a reported secondary diagnosis was I50.9, Heart Failure, unspecified, this diagnosis is found in the Heart 11 subgroup).

We went through the following steps to determine which individual comorbidity subgroups would be used as part of the comorbidity adjustment:

- After dropping the comorbidity subgroups with a small number of 30-

day periods of care (for example, those that made up fewer than 0.1 percent of 30-day periods of care), this left 59 different comorbidity subgroups.

- Of those, there are 56 comorbidity subgroups with a p-value less than or equal to 0.05.
- Of those 56 subgroups, there are 22 comorbidity subgroups that have a positive coefficient when regressing resource use on the comorbidity subgroups (and the interactions as described below) and indicators for the clinical group, functional level, admission source, and timing. We determine the median coefficient of those 22 comorbidity subgroups to be \$60.67.

• There are 11 comorbidity subgroups with coefficients that are at or above the median (for example, \$60.67 or above). This is a decrease from the 15 subgroups presented in the CY 2018 HH PPS proposed rule. Potential reasons for this decrease include the use of CY 2017 data in this analysis, whereas the 2018 HH PPS proposed rule used CY 2016 data; the combination and/or addition of comorbidity groups; and the inclusion of the interactions between the comorbidities.

Those 11 individual comorbidity subgroups that are statistically and clinically significant for potential inclusion in the comorbidity case-mix adjustment are listed below in Table 44:

TABLE 44—INDIVIDUAL SUBGROUPS FOR COMORBIDITY ADJUSTMENT

Comorbidity subgroup	Description	Coefficient
Neuro 11	Includes diabetic retinopathy and other blindness	\$61.23
Neuro 10	Includes diabetic neuropathies	67.98
Circulatory 9	Includes acute and chronic embolisms and thrombosis	86.62
Heart 11	Includes heart failure	101.57
Cerebral 4	Includes sequelae of cerebrovascular diseases	128.78
Neuro 5	Includes Parkinson's Disease	144.99
Skin 1	Includes cutaneous abscess, cellulitis, and lymphangitis	174.93
Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia	204.42
Circulatory 10	Includes varicose veins with ulceration	215.67
Skin 3	Include diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	365.78
Skin 4	Includes stages Two-Four and unstageable pressure ulcers by site	484.83

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

Next, we examined the impact of interactions between the various comorbidity subgroups on resource use. The following steps show how we identified which interactions (for example, diagnoses from two different comorbidity subgroups) had a clinically and statistically significant relationship with increased resource utilization and could be used for the comorbidity adjustment:

- After dropping the combinations of comorbidity subgroups and interactions with a small number of 30-day periods of care (that is, those that made up fewer than 0.1 percent of 30-day periods of

care), there are 343 different comorbidity subgroup interactions (for example, comorbidity subgroup interaction Skin 1 plus Skin 3). As mentioned previously, we regressed resource use on the comorbidity subgroups, the interactions, and indicators for the clinical group, functional level, admission source, and timing.

- From that regression, we found 187 comorbidity subgroup interactions with a p-value less than or equal to 0.05.
- Of those 187 comorbidity subgroup interactions, there are 27 comorbidity subgroup interactions where the

coefficient on the comorbidity subgroup interaction term plus the coefficients on both single comorbidity variables equals a value that exceeds \$150. We used \$150 as the inclusion threshold as this amount is approximately three times that of the median value for the individual comorbidity subgroups and we believe is appropriate to reflect the increased resource use associated with comorbidity interactions. The 27 comorbidity subgroup interactions that are statistically and clinically significant for potential inclusion in the comorbidity adjustment are listed in Table 45.

TABLE 45—COMORBIDITY SUBGROUP INTERACTIONS FOR COMORBIDITY ADJUSTMENT

Comorbidity subgroup interaction	Comorbidity subgroup	Description	Comorbidity subgroup	Description	Sum of interaction term plus single comorbidity coefficients
1	Circulatory 4	Hypertensive Chronic Kidney Disease	Neuro 11	Includes diabetic retinopathy and other blindness	\$151.98
2	Endocrine 3	Diabetes with Complications	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia ...	162.35
3	Neuro 3	Dementia in diseases classified elsewhere	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	190.30
4	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 1	Cutaneous abscess, cellulitis, and lymphangitis	193.33
5	Cerebral 4	Sequelae of Cerebrovascular Diseases	Heart 11	Heart Failure	195.55
6	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia.	Renal 3	Nephrogenic Diabetes Insipidus	202.44
7	Circulatory 10 ..	Includes varicose veins with ulceration	Endocrine 3	Diabetes with Complications	205.52
8	Heart 11	Heart Failure	Neuro 5	Parkinson's Disease	212.88

TABLE 45—COMORBIDITY SUBGROUP INTERACTIONS FOR COMORBIDITY ADJUSTMENT—Continued

Comorbidity subgroup interaction	Comorbidity subgroup	Description	Comorbidity subgroup	Description	Sum of interaction term plus single comorbidity coefficients
9	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	260.83
10	Neuro 3	Dementia in diseases classified elsewhere	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	274.16
11	Behavioral 2	Mood Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	287.42
12	Circulatory 10 ..	Includes varicose veins with ulceration	Heart 11	Heart Failure	292.39
13	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	296.70
14	Renal 1	Chronic kidney disease and ESRD	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	300.31
15	Respiratory 5 ...	COPD and Asthma	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	306.63
16	Skin 1	Cutaneous abscess, cellulitis, and lymphangitis.	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	390.47
17	Renal 3	Nephrogenic Diabetes Insipidus	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	422.34
18	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	422.20
19	Heart 12	Other Heart Diseases	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	423.08
20	Respiratory 5 ...	COPD and Asthma	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	428.02
21	Circulatory 7 ...	Atherosclerosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	432.46
22	Renal 1	Chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	436.39
23	Endocrine 3	Diabetes with Complications	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	487.96
24	Endocrine 3	Diabetes with Complications	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	504.54
25	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	509.63
26	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	529.47
27	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers.	Skin 4	Stages Two-Four and unstageable pressure ulcers by site.	750.85

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

In order to be considered a comorbidity subgroup interaction, at least two reported diagnoses, must occur in the above corresponding combinations, as shown in Table 45. For example, one diagnosis from Heart 11 must be reported along with at least one diagnosis from Neuro 5 in order to qualify for comorbidity subgroup interaction 8. In other words, the comorbidity subgroups are not interchangeable between the interaction groups (for example, reported conditions from the Renal 1 and Respiratory 5 subgroups would not be considered an interaction for purposes of the comorbidity adjustment).

For illustrative purposes, this would mean that if a 30-day period of care had the following secondary diagnoses reported, I50.22, chronic systolic (congestive) heart failure and G20, Parkinson’s Disease (these diagnoses fall under comorbidity subgroups Heart 11 and Neuro 5 respectively and are in the same comorbidity subgroup interaction), this interaction of comorbid conditions results in a higher level of resource use

than just having a comorbid diagnosis classified in Heart 11 or in Neuro 5. There will be an updated PDGM Grouper Tool posted on the HHA Center web page that HHAs can access to simulate the HIPPS code and case-mix weight under the PDGM.⁵⁰ This Grouper Tool allows providers to fill in information, including the comorbidities, to determine whether a home health period of care would receive a comorbidity adjustment under the PDGM.

The comorbidity interactions identify subgroup combinations of comorbidities that are associated with higher levels of resource use. As such, we believe that the comorbidity adjustment payment should be dependent on whether the 30-day period of care has an individual comorbidity subgroup associated with higher resource use or there is a comorbidity subgroup interaction resulting in higher resource use. Therefore, we propose to have three

⁵⁰ <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

levels in the PDGM comorbidity case-mix adjustment: No Comorbidity Adjustment, Low Comorbidity Adjustment, and High Comorbidity Adjustment. This means that depending on if and which secondary diagnoses are reported, a 30-day period of care may receive no comorbidity adjustment (meaning, no secondary diagnoses exist or do not meet the criteria for a comorbidity adjustment), a “low” comorbidity adjustment, or a “high” comorbidity adjustment. We propose that home health 30-day periods of care can receive a comorbidity payment adjustment under the following circumstances:

- *Low comorbidity adjustment:* There is a reported secondary diagnosis that falls within one of the home-health specific individual comorbidity subgroups, as listed in Table 44, (for example, Heart Disease 11, Cerebral Vascular Disease 4, etc.) associated with higher resource use, or;
- *High comorbidity adjustment:* There are two or more secondary diagnoses reported that fall within the

same comorbidity subgroup interaction, as listed in Table 45, (for example, Heart 11 plus Neuro 5) that are associated with higher resource use.

Under the PDGM, a 30-day period of care can receive payment for a low comorbidity adjustment or a high comorbidity adjustment, but not both. A 30-day period of care can receive only one low comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the individual

comorbidity subgroups or one high comorbidity adjustment regardless of the number of comorbidity group interactions, as applicable. The low comorbidity adjustment amount would be the same across all 11 individual comorbidity subgroups. Similarly, the high comorbidity adjustment amount would be the same across all 27 comorbidity subgroup interactions. See Table 48 in section III.F.10 of this proposed rule for the coefficient amounts associated with both the low

and high comorbidity adjustment, as well as for all of the case-mix variables in the PDGM. If a 30-day home health period of care does not have any reported comorbidities that fall into one of the payment adjustments described above, there would be no comorbidity adjustment applied. Table 46 illustrates the average resource use for each of the comorbidity levels as described in this section.

TABLE 46—AVERAGE RESOURCE USE BY COMORBIDITY ADJUSTMENT, CY 2017

	Mean resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
No Comorbidity Adjustment	\$1,539.92	5,402,694	62.6	\$1,183.86	\$673.27	\$1,253.95	\$2,078.68
Comorbidity Adjustment—Has at least one comorbidity from comorbidity list, no interaction from interaction list	1,575.12	2,721,969	31.6	1,248.71	658.77	1,262.47	2,131.92
Comorbidity Adjustment—Has at least one interaction from interaction list	1,878.84	500,113	5.8	1,412.06	880.07	1,523.87	2,469.93
Total	1,570.68	8,624,776	100.0	1,221.38	679.12	1,272.18	2,117.47

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018).

Changing to three comorbidity levels results in 216 possible case-mix groups for the purposes of adjusting payment in the PDGM. While this is more case-mix groups than the 144 case-mix groups proposed in the CY 2018 HH PPS proposed rule, this change is responsive to the comments received regarding refinements to the comorbidity adjustment without being unduly complex. We believe that this method for adjusting payment for the presence of comorbidities is more robust, reflective of patient characteristics, better aligns payment with actual resource use, and addresses comments received from the CY 2018 HH PPS proposed rule and recommendations from TEP members. The comorbidity payment adjustment takes into account the presence of individual comorbid conditions, as well as the interactions between multiple comorbid conditions, and reflects the types of conditions most commonly seen in home health patients. Similar to monitoring of nominal case-mix growth under the current HH PPS, upon implementation of the PDGM, CMS will monitor the reporting of secondary diagnoses to determine whether adjustments to payment based on the number of reported comorbidities is resulting in HHAs inappropriately

reporting comorbid conditions solely for the purpose of increased payment and appropriate program integrity actions will be taken.

As mentioned previously in this section, there will be an updated PDGM Grouper Tool posted on the HHA Center web page which will be key to understanding whether a 30-day home health period of care would receive a no, low, or high comorbidity adjustment under the PDGM. If implemented, we would continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements to help ensure that payment is in alignment with the actual costs of providing care. We invite comments on the change to the comorbidity case-mix adjustment in the PDGM including the three comorbidity levels: No Comorbidity, Low Comorbidity, and High Comorbidity Adjustment. We also invite comments on the payment associated with the Low Comorbidity and High Comorbidity Adjustment to account for increased resource utilization resulting from the presence of certain comorbidities and comorbidity interactions.

9. Change in the Low-Utilization Payment Adjustment (LUPA) Threshold

Currently, a 60-day episode with four or fewer visits is paid the national per visit amount by discipline, adjusted by the appropriate wage index based on the site of service of the beneficiary, instead of the full 60-day episode payment amount. Such payment adjustments are called Low Utilization Payment Adjustments (LUPAs). While the alternative case-mix model proposed in the CY 2018 HH PPS proposed rule still included LUPAs, the approach to calculating the LUPA thresholds needed to change due to the proposed change in the unit of payment to 30-day periods of care from 60-day episodes. The 30-day periods of care have substantially more episodes with four or fewer visits than 60-day episodes. To create LUPA thresholds we proposed in the CY 2018 HH PPS proposed rule to set the LUPA threshold at the 10th percentile value of visits or 2, whichever is higher, for each payment group. (82 FR 35324).

We received comments in response to the CY 2018 HH PPS proposed rule on maintaining the use of a single LUPA threshold instead of varying the thresholds at the subgroup level. Other commenters expressed concern that the variable LUPA thresholds will add

additional administrative burden and create additional opportunity for error. After analyzing the data to evaluate the potential impact, we believe that the change to a 30-day period of care under the proposed PDGM from the current 60-day episode warrants variable LUPA thresholds depending on the payment group to which it is assigned. We believe that the proposed LUPA thresholds that vary based on the case-mix assignment for the 30-day period of care in the proposed PDGM is an improvement over the current 5 visit threshold that does not vary by case-mix assignment. This is the same approach proposed in the CY 2018 proposed rule where LUPA thresholds would vary by case-mix group. LUPA thresholds that vary by case-mix group take into account different resource use patterns based on beneficiaries' clinical

characteristics. Additionally, we do not believe that the case-mix-specific LUPA thresholds would result in additional administrative burden as LUPA visits are billed the same as non-LUPA periods. Likewise, the PDGM will not be implemented until January 1, 2020, giving HHAs and vendors sufficient time to make necessary changes to their systems and to ensure that appropriate quality checks are in place to minimize any claims errors. Therefore, we propose to vary the LUPA threshold for a 30-day period of care under the PDGM depending on the PDGM payment group to which it is assigned.

We note that in the current payment system, approximately 8 percent of episodes are LUPAs. Under the PDGM, consistent with the CY 2018 HH PPS proposed rule, we propose the 10th percentile value of visits or 2 visits,

whichever is higher, in order to target approximately the same percentage of LUPAs (approximately 7.1 percent of 30-day periods would be LUPAs (assuming no behavior change)). For example, for episodes in the payment group corresponding to “MMTA—Functional Level Medium—Early Timing—Institutional Admission—No Comorbidity” (HIPPS code 2AB1 in Table 47), the threshold is four visits. If a home health 30-day period of care is assigned to that particular payment group had three or fewer visits the HHA would be paid using the national per-visit rates in section III.C.4 of this proposed rule instead of the case-mix adjusted 30-day period of care payment amount. The LUPA thresholds for the PDGM payment group with the corresponding HIPPS code is listed in Table 47.

TABLE 47—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED PDGM PAYMENT GROUPS

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit threshold (10th percentile or 2—whichever is higher)
1AA11	MMTA—Low	Early—Community	0	4
1AA21	MMTA—Low	Early—Community	1	4
1AA31	MMTA—Low	Early—Community	2	4
1AB11	MMTA—Medium	Early—Community	0	4
1AB21	MMTA—Medium	Early—Community	1	4
1AB31	MMTA—Medium	Early—Community	2	5
1AC11	MMTA—High	Early—Community	0	4
1AC21	MMTA—High	Early—Community	1	4
1AC31	MMTA—High	Early—Community	2	4
1BA11	Neuro—Low	Early—Community	0	4
1BA21	Neuro—Low	Early—Community	1	5
1BA31	Neuro—Low	Early—Community	2	5
1BB11	Neuro—Medium	Early—Community	0	5
1BB21	Neuro—Medium	Early—Community	1	5
1BB31	Neuro—Medium	Early—Community	2	5
1BC11	Neuro—High	Early—Community	0	4
1BC21	Neuro—High	Early—Community	1	5
1BC31	Neuro—High	Early—Community	2	5
1CA11	Wound—Low	Early—Community	0	4
1CA21	Wound—Low	Early—Community	1	4
1CA31	Wound—Low	Early—Community	2	4
1CB11	Wound—Medium	Early—Community	0	5
1CB21	Wound—Medium	Early—Community	1	5
1CB31	Wound—Medium	Early—Community	2	5
1CC11	Wound—High	Early—Community	0	4
1CC21	Wound—High	Early—Community	1	5
1CC31	Wound—High	Early—Community	2	4
1DA11	Complex—Low	Early—Community	0	3
1DA21	Complex—Low	Early—Community	1	2
1DA31	Complex—Low	Early—Community	2	4
1DB11	Complex—Medium	Early—Community	0	3
1DB21	Complex—Medium	Early—Community	1	3
1DB31	Complex—Medium	Early—Community	2	4
1DC11	Complex—High	Early—Community	0	3
1DC21	Complex—High	Early—Community	1	3
1DC31	Complex—High	Early—Community	2	3
1EA11	MS Rehab—Low	Early—Community	0	5
1EA21	MS Rehab—Low	Early—Community	1	5
1EA31	MS Rehab—Low	Early—Community	2	5
1EB11	MS Rehab—Medium	Early—Community	0	5
1EB21	MS Rehab—Medium	Early—Community	1	5
1EB31	MS Rehab—Medium	Early—Community	2	5

TABLE 47—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED PDGM PAYMENT GROUPS—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit threshold (10th percentile or 2—whichever is higher)
1EC11	MS Rehab—High	Early—Community	0	5
1EC21	MS Rehab—High	Early—Community	1	5
1EC31	MS Rehab—High	Early—Community	2	5
1FA11	Behavioral Health—Low	Early—Community	0	3
1FA21	Behavioral Health—Low	Early—Community	1	3
1FA31	Behavioral Health—Low	Early—Community	2	3
1FB11	Behavioral Health—Medium	Early—Community	0	4
1FB21	Behavioral Health—Medium	Early—Community	1	4
1FB31	Behavioral Health—Medium	Early—Community	2	4
1FC11	Behavioral Health—High	Early—Community	0	4
1FC21	Behavioral Health—High	Early—Community	1	4
1FC31	Behavioral Health—High	Early—Community	2	4
2AA11	MMTA—Low	Early—Institutional	0	3
2AA21	MMTA—Low	Early—Institutional	1	4
2AA31	MMTA—Low	Early—Institutional	2	4
2AB11	MMTA—Medium	Early—Institutional	0	4
2AB21	MMTA—Medium	Early—Institutional	1	5
2AB31	MMTA—Medium	Early—Institutional	2	5
2AC11	MMTA—High	Early—Institutional	0	4
2AC21	MMTA—High	Early—Institutional	1	4
2AC31	MMTA—High	Early—Institutional	2	4
2BA11	Neuro—Low	Early—Institutional	0	5
2BA21	Neuro—Low	Early—Institutional	1	5
2BA31	Neuro—Low	Early—Institutional	2	5
2BB11	Neuro—Medium	Early—Institutional	0	6
2BB21	Neuro—Medium	Early—Institutional	1	6
2BB31	Neuro—Medium	Early—Institutional	2	6
2BC11	Neuro—High	Early—Institutional	0	5
2BC21	Neuro—High	Early—Institutional	1	5
2BC31	Neuro—High	Early—Institutional	2	5
2CA11	Wound—Low	Early—Institutional	0	4
2CA21	Wound—Low	Early—Institutional	1	4
2CA31	Wound—Low	Early—Institutional	2	4
2CB11	Wound—Medium	Early—Institutional	0	5
2CB21	Wound—Medium	Early—Institutional	1	5
2CB31	Wound—Medium	Early—Institutional	2	5
2CC11	Wound—High	Early—Institutional	0	4
2CC21	Wound—High	Early—Institutional	1	5
2CC31	Wound—High	Early—Institutional	2	4
2DA11	Complex—Low	Early—Institutional	0	3
2DA21	Complex—Low	Early—Institutional	1	3
2DA31	Complex—Low	Early—Institutional	2	4
2DB11	Complex—Medium	Early—Institutional	0	4
2DB21	Complex—Medium	Early—Institutional	1	4
2DB31	Complex—Medium	Early—Institutional	2	5
2DC11	Complex—High	Early—Institutional	0	4
2DC21	Complex—High	Early—Institutional	1	4
2DC31	Complex—High	Early—Institutional	2	4
2EA11	MS Rehab—Low	Early—Institutional	0	5
2EA21	MS Rehab—Low	Early—Institutional	1	5
2EA31	MS Rehab—Low	Early—Institutional	2	5
2EB11	MS Rehab—Medium	Early—Institutional	0	6
2EB21	MS Rehab—Medium	Early—Institutional	1	6
2EB31	MS Rehab—Medium	Early—Institutional	2	6
2EC11	MS Rehab—High	Early—Institutional	0	6
2EC21	MS Rehab—High	Early—Institutional	1	6
2EC31	MS Rehab—High	Early—Institutional	2	6
2FA11	Behavioral Health—Low	Early—Institutional	0	3
2FA21	Behavioral Health—Low	Early—Institutional	1	3
2FA31	Behavioral Health—Low	Early—Institutional	2	4
2FB11	Behavioral Health—Medium	Early—Institutional	0	4
2FB21	Behavioral Health—Medium	Early—Institutional	1	4
2FB31	Behavioral Health—Medium	Early—Institutional	2	5
2FC11	Behavioral Health—High	Early—Institutional	0	4
2FC21	Behavioral Health—High	Early—Institutional	1	4
2FC31	Behavioral Health—High	Early—Institutional	2	5
3AA11	MMTA—Low	Late—Community	0	2
3AA21	MMTA—Low	Late—Community	1	2

TABLE 47—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED PDGM PAYMENT GROUPS—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit threshold (10th percentile or 2—whichever is higher)
3AA31	MMTA—Low	Late—Community	2	3
3AB11	MMTA—Medium	Late—Community	0	2
3AB21	MMTA—Medium	Late—Community	1	2
3AB31	MMTA—Medium	Late—Community	2	3
3AC11	MMTA—High	Late—Community	0	2
3AC21	MMTA—High	Late—Community	1	2
3AC31	MMTA—High	Late—Community	2	3
3BA11	Neuro—Low	Late—Community	0	2
3BA21	Neuro—Low	Late—Community	1	2
3BA31	Neuro—Low	Late—Community	2	2
3BB11	Neuro—Medium	Late—Community	0	2
3BB21	Neuro—Medium	Late—Community	1	2
3BB31	Neuro—Medium	Late—Community	2	3
3BC11	Neuro—High	Late—Community	0	2
3BC21	Neuro—High	Late—Community	1	2
3BC31	Neuro—High	Late—Community	2	2
3CA11	Wound—Low	Late—Community	0	2
3CA21	Wound—Low	Late—Community	1	3
3CA31	Wound—Low	Late—Community	2	3
3CB11	Wound—Medium	Late—Community	0	3
3CB21	Wound—Medium	Late—Community	1	3
3CB31	Wound—Medium	Late—Community	2	3
3CC11	Wound—High	Late—Community	0	3
3CC21	Wound—High	Late—Community	1	3
3CC31	Wound—High	Late—Community	2	3
3DA11	Complex—Low	Late—Community	0	2
3DA21	Complex—Low	Late—Community	1	2
3DA31	Complex—Low	Late—Community	2	2
3DB11	Complex—Medium	Late—Community	0	2
3DB21	Complex—Medium	Late—Community	1	2
3DB31	Complex—Medium	Late—Community	2	2
3DC11	Complex—High	Late—Community	0	2
3DC21	Complex—High	Late—Community	1	2
3DC31	Complex—High	Late—Community	2	2
3EA11	MS Rehab—Low	Late—Community	0	2
3EA21	MS Rehab—Low	Late—Community	1	2
3EA31	MS Rehab—Low	Late—Community	2	2
3EB11	MS Rehab—Medium	Late—Community	0	2
3EB21	MS Rehab—Medium	Late—Community	1	2
3EB31	MS Rehab—Medium	Late—Community	2	3
3EC11	MS Rehab—High	Late—Community	0	2
3EC21	MS Rehab—High	Late—Community	1	2
3EC31	MS Rehab—High	Late—Community	2	3
3FA11	Behavioral Health—Low	Late—Community	0	2
3FA21	Behavioral Health—Low	Late—Community	1	2
3FA31	Behavioral Health—Low	Late—Community	2	2
3FB11	Behavioral Health—Medium	Late—Community	0	2
3FB21	Behavioral Health—Medium	Late—Community	1	2
3FB31	Behavioral Health—Medium	Late—Community	2	2
3FC11	Behavioral Health—High	Late—Community	0	2
3FC21	Behavioral Health—High	Late—Community	1	2
3FC31	Behavioral Health—High	Late—Community	2	2
4AA11	MMTA—Low	Late—Institutional	0	3
4AA21	MMTA—Low	Late—Institutional	1	3
4AA31	MMTA—Low	Late—Institutional	2	3
4AB11	MMTA—Medium	Late—Institutional	0	3
4AB21	MMTA—Medium	Late—Institutional	1	3
4AB31	MMTA—Medium	Late—Institutional	2	4
4AC11	MMTA—High	Late—Institutional	0	3
4AC21	MMTA—High	Late—Institutional	1	3
4AC31	MMTA—High	Late—Institutional	2	4
4BA11	Neuro—Low	Late—Institutional	0	3
4BA21	Neuro—Low	Late—Institutional	1	4
4BA31	Neuro—Low	Late—Institutional	2	3
4BB11	Neuro—Medium	Late—Institutional	0	4
4BB21	Neuro—Medium	Late—Institutional	1	4
4BB31	Neuro—Medium	Late—Institutional	2	5
4BC11	Neuro—High	Late—Institutional	0	4

TABLE 47—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED PDGM PAYMENT GROUPS—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit threshold (10th percentile or 2—whichever is higher)
4BC21	Neuro—High	Late—Institutional	1	4
4BC31	Neuro—High	Late—Institutional	2	4
4CA11	Wound—Low	Late—Institutional	0	3
4CA21	Wound—Low	Late—Institutional	1	3
4CA31	Wound—Low	Late—Institutional	2	3
4CB11	Wound—Medium	Late—Institutional	0	4
4CB21	Wound—Medium	Late—Institutional	1	4
4CB31	Wound—Medium	Late—Institutional	2	4
4CC11	Wound—High	Late—Institutional	0	3
4CC21	Wound—High	Late—Institutional	1	4
4CC31	Wound—High	Late—Institutional	2	4
4DA11	Complex—Low	Late—Institutional	0	2
4DA21	Complex—Low	Late—Institutional	1	3
4DA31	Complex—Low	Late—Institutional	2	3
4DB11	Complex—Medium	Late—Institutional	0	3
4DB21	Complex—Medium	Late—Institutional	1	3
4DB31	Complex—Medium	Late—Institutional	2	4
4DC11	Complex—High	Late—Institutional	0	3
4DC21	Complex—High	Late—Institutional	1	3
4DC31	Complex—High	Late—Institutional	2	3
4EA11	MS Rehab—Low	Late—Institutional	0	3
4EA21	MS Rehab—Low	Late—Institutional	1	3
4EA31	MS Rehab—Low	Late—Institutional	2	3
4EB11	MS Rehab—Medium	Late—Institutional	0	4
4EB21	MS Rehab—Medium	Late—Institutional	1	4
4EB31	MS Rehab—Medium	Late—Institutional	2	4
4EC11	MS Rehab—High	Late—Institutional	0	4
4EC21	MS Rehab—High	Late—Institutional	1	4
4EC31	MS Rehab—High	Late—Institutional	2	4
4FA11	Behavioral Health—Low	Late—Institutional	0	2
4FA21	Behavioral Health—Low	Late—Institutional	1	2
4FA31	Behavioral Health—Low	Late—Institutional	2	2
4FB11	Behavioral Health—Medium	Late—Institutional	0	3
4FB21	Behavioral Health—Medium	Late—Institutional	1	3
4FB31	Behavioral Health—Medium	Late—Institutional	2	3
4FC11	Behavioral Health—High	Late—Institutional	0	3
4FC21	Behavioral Health—High	Late—Institutional	1	3
4FC31	Behavioral Health—High	Late—Institutional	2	4

In summary, we propose to vary the LUPA threshold for a 30-day period of care under the PDGM depending on the PDGM payment group to which it is assigned. We also propose that the LUPA thresholds for each PDGM payment group would be re-evaluated every year based on the most current utilization data available. We invite public comments on the LUPA threshold methodology proposed for the PDGM and the associated regulations text changes in section III.F.13 of this proposed rule.

10. HH PPS Case-Mix Weights Under the PDGM

Section 1895(b)(4)(B) requires the Secretary to establish appropriate case mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services. In the CY 2018 HH PPS proposed rule (82

FR 35270), we proposed an alternative case-mix adjustment methodology to better align payment with patient care needs. The proposed alternative case-mix adjustment methodology places patients into meaningful payment categories based on patient characteristics (principal diagnosis, functional level, comorbid conditions, referral source and timing). We did not finalize the alternative case-mix adjustment methodology in the CY 2018 final rule in order to consider comments and feedback for any potential refinements to the model. Refinements were made to the comorbidity case-mix adjustment while all other variables remain as proposed in the CY 2018 HH PPS proposed rule (for example, clinical group, functional level, admission source, and episode timing). As outlined in previous sections of this proposed rule, we are again proposing an alternative case-mix adjustment

methodology, called the PDGM, but this methodology now results in 216 unique case-mix groups. These 216 unique case-mix payment groups are called Home Health Resource Groups (HHRGs). In accordance with the BBA of 2018, the proposed PDGM will be implemented in a budget neutral manner.

To generate PDGM case-mix weights, we utilized a data file based on home health episodes of care, as reported in Medicare home health claims. The claims data provide episode-level data as well as visit-level data. The claims also provide data on whether non-routine supplies (NRS) was provided during the episode and the total charges for NRS. We used CY 2017 home health claims data with linked OASIS assessment data to obtain patient characteristics. We determined the case-mix weight for each of the different PDGM payment groups by regressing

resource use on a series of indicator variables for each of the categories using a fixed effects model. The regression measures resource use with the Cost per Minute (CPM) + NRS approach outlined in section III.F.2 of this proposed rule. The model used in the PDGM payment regression generates outcomes that are statistically significant and consistent with findings.

We received comments in response to the proposed alternative case-mix adjustment methodology in the CY 2018 HH PPS proposed rule on the standards for subsequent case-mix weight recalibration (nature and timing). Similar to the annual recalibration of the case-mix weights under the current HH PPS, annual recalibration will be made to the PDGM case-mix weights. We will make refinements as necessary to ensure that payment for home health periods are in alignment with costs. We note that this includes a re-calculation of the proposed PDGM case-mix weights for CY 2020 in the CY 2020 HH PPS proposed rule using CY 2018 home health claims data linked with OASIS assessment data. In other words, the table below represents the PDGM case-mix weights if we were to implement the PDGM in CY 2019. However, since we are proposing to implement the PDGM on January 1, 2020, the actual PDGM case-mix weights for CY 2020 will be updated in the CY 2020 HH PPS

proposed rule. We also received a comment from MedPAC about the development of alternative case-mix adjustment methodology using the regression approach, which is a statistical estimate of the cost associated with a payment group instead of the actual cost. MedPAC stated that this approach results in estimated payments that may not equal the actual costs experienced by HHAs. As noted, CMS has used a regression approach since the inception of the HH PPS in 2000. The regression smoothens weights compared to a system where each payment group receives a weight that is based solely on the average resource use of all 30-day periods in a payment group compared to the overall average resource use across all 30 day periods. Smoothing the weights helps to see relationships between variables and foresee trends. In addition, using a regression approach to calculate case-mix weights allows CMS to use a fixed effects model, which will estimate the variation observed within individual HHAs and opposed to estimating the variation across HHAs. With the fixed effects, the coefficients should better estimate the relationship the regression variables have with resource use compared to not accounting for fixed effects. We continue to believe that using a regression approach for the calculation

of the HH PPS case-mix weights is most appropriate.

After best fitting the model on home health episodes from 2017 data, we used the estimated coefficients of the model to predict the expected average resource use of each episode based on the five PDGM categories. In order to normalize the results, we have divided the regression predicted resource use of each episode by the overall average resource use of all episodes used to estimate the model in order to calculate the case mix weight of all episodes within a particular payment group, where each payment group is defined as the unique combination of the subgroups within the five PDGM categories (admission source, timing of the 30-day period, clinical grouping, functional level, and comorbidity adjustment). The case-mix weight is then used to adjust the base payment rate to determine each period's payment. Table 48 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use. Information can be found in section III.F.6 of this rule for the clinical groups, section III.F.7 of this rule for the functional levels, section III.F.5 for admission source, section III.F.4 for timing, and section III.F.8 for the comorbidity adjustment.

TABLE 48—COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR PDGM PAYMENT GROUP

Variable	Coefficient	Coefficient divided by average resource use
Clinical Group and Functional Level (MMTA—Low is excluded)		
MMTA—Medium Functional	\$237.83	0.1514
MMTA—High Functional	416.75	0.2653
Behavioral Health—Low Functional	– 116.39	– 0.0741
Behavioral Health—Medium Functional	169.86	0.1081
Behavioral Health—High Functional	309.97	0.1974
Complex—Low Functional	– 27.39	– 0.0174
Complex—Medium Functional	331.88	0.2113
Complex—High Functional	476.69	0.3035
MS Rehab—Low Functional	141.37	0.0900
MS Rehab—Medium Functional	338.96	0.2158
MS Rehab—High Functional	558.95	0.3559
Neuro—Low Functional	329.19	0.2096
Neuro—Medium Functional	593.98	0.3782
Neuro—High Functional	711.48	0.4530
Wound—Low Functional	368.43	0.2346
Wound—Medium Functional	628.37	0.4001
Wound—High Functional	822.84	0.5239
Referral Source With Timing (Community Early excluded)		
Community—Late	– 646.84	– 0.4118
Institutional—Early	278.85	0.1775
Institutional—Late	45.71	0.0291

TABLE 48—COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR PDGM PAYMENT GROUP—Continued

Variable	Coefficient	Coefficient divided by average resource use
Comorbidity Adjustment (No Comorbidity Adjustment Group is excluded)		
Comorbidity Adjustment—Has at least one comorbidity from comorbidity list, no interaction from interaction list	92.44	0.0589
Comorbidity Adjustment—Has at least one interaction from interaction list	345.20	0.2198
Constant	\$1,560.37	0.9934
Average Resource Use	\$1,570.68
N	8,624,776
Adj. R-Squared	0.2925

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 (as of March 2, 2018) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Table 49 presents the case-mix weight for each HHRG in the regression model (Table 48). LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded. Please find LUPA information in section III.F.9 of this rule. Weights are determined by first calculating the predicted resource use for episodes with a particular combination of admission source, episode timing, clinical grouping, functional level, and comorbidity adjustment. This combination specific calculation is then divided by the average resource use of all the episodes that were used to estimate the standard

30-day payment rate, which is \$1,570.68. The resulting ratio represents the case-mix weight for that particular combination of a HHRG payment group. The adjusted R-squared value for this model is 0.2925 which is slightly higher than the adjusted R-squared value of 0.2704 that we proposed in CY 2018 by using the CY 2016 claims data. The adjusted R-squared value provides a measure of how well observed outcomes are replicated by the model, based on the proportion of total variation of outcomes explained by the model.

As noted above, there are 216 different HHRG payment groups under

the PDGM. There are 15 HHRG payment groups that represent roughly 50.2 percent of the total episodes. There are 61 HHRG payment groups that represent roughly 1.0 percent of total episodes. The HHRG payment group with the smallest weight has a weight of 0.5075 (community admitted, late, behavioral health, low functional impairment level, with no comorbidity adjustment). The HHRG payment group with the largest weight has a weight of 1.9146 (institutional admitted, early, wound, high functional impairment level, with interactive comorbidity adjustment).

TABLE 49—CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Proposed CY 2019 weight
1AA11	MMTA—Low	Early—Community	0	0.9934
1AA21	MMTA—Low	Early—Community	1	1.0523
1AA31	MMTA—Low	Early—Community	2	1.2132
1AB11	MMTA—Medium	Early—Community	0	1.1449
1AB21	MMTA—Medium	Early—Community	1	1.2037
1AB31	MMTA—Medium	Early—Community	2	1.3646
1AC11	MMTA—High	Early—Community	0	1.2588
1AC21	MMTA—High	Early—Community	1	1.3176
1AC31	MMTA—High	Early—Community	2	1.4785
1BA11	Neuro—Low	Early—Community	0	1.2030
1BA21	Neuro—Low	Early—Community	1	1.2619
1BA31	Neuro—Low	Early—Community	2	1.4228
1BB11	Neuro—Medium	Early—Community	0	1.3716
1BB21	Neuro—Medium	Early—Community	1	1.4305
1BB31	Neuro—Medium	Early—Community	2	1.5914
1BC11	Neuro—High	Early—Community	0	1.4464
1BC21	Neuro—High	Early—Community	1	1.5053
1BC31	Neuro—High	Early—Community	2	1.6662
1CA11	Wound—Low	Early—Community	0	1.2280
1CA21	Wound—Low	Early—Community	1	1.2869
1CA31	Wound—Low	Early—Community	2	1.4478
1CB11	Wound—Medium	Early—Community	0	1.3935
1CB21	Wound—Medium	Early—Community	1	1.4523
1CB31	Wound—Medium	Early—Community	2	1.6133
1CC11	Wound—High	Early—Community	0	1.5173
1CC21	Wound—High	Early—Community	1	1.5762
1CC31	Wound—High	Early—Community	2	1.7371
1DA11	Complex—Low	Early—Community	0	0.9760

TABLE 49—CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Proposed CY 2019 weight
1DA21	Complex—Low	Early—Community	1	1.0348
1DA31	Complex—Low	Early—Community	2	1.1958
1DB11	Complex—Medium	Early—Community	0	1.2047
1DB21	Complex—Medium	Early—Community	1	1.2636
1DB31	Complex—Medium	Early—Community	2	1.4245
1DC11	Complex—High	Early—Community	0	1.2969
1DC21	Complex—High	Early—Community	1	1.3558
1DC31	Complex—High	Early—Community	2	1.5167
1EA11	MS Rehab—Low	Early—Community	0	1.0834
1EA21	MS Rehab—Low	Early—Community	1	1.1423
1EA31	MS Rehab—Low	Early—Community	2	1.3032
1EB11	MS Rehab—Medium	Early—Community	0	1.2092
1EB21	MS Rehab—Medium	Early—Community	1	1.2681
1EB31	MS Rehab—Medium	Early—Community	2	1.4290
1EC11	MS Rehab—High	Early—Community	0	1.3493
1EC21	MS Rehab—High	Early—Community	1	1.4082
1EC31	MS Rehab—High	Early—Community	2	1.5691
1FA11	Behavioral Health—Low	Early—Community	0	0.9193
1FA21	Behavioral Health—Low	Early—Community	1	0.9782
1FA31	Behavioral Health—Low	Early—Community	2	1.1391
1FB11	Behavioral Health—Medium	Early—Community	0	1.1016
1FB21	Behavioral Health—Medium	Early—Community	1	1.1604
1FB31	Behavioral Health—Medium	Early—Community	2	1.3214
1FC11	Behavioral Health—High	Early—Community	0	1.1908
1FC21	Behavioral Health—High	Early—Community	1	1.2496
1FC31	Behavioral Health—High	Early—Community	2	1.4106
2AA11	MMTA—Low	Early—Institutional	0	1.1710
2AA21	MMTA—Low	Early—Institutional	1	1.2298
2AA31	MMTA—Low	Early—Institutional	2	1.3907
2AB11	MMTA—Medium	Early—Institutional	0	1.3224
2AB21	MMTA—Medium	Early—Institutional	1	1.3812
2AB31	MMTA—Medium	Early—Institutional	2	1.5422
2AC11	MMTA—High	Early—Institutional	0	1.4363
2AC21	MMTA—High	Early—Institutional	1	1.4951
2AC31	MMTA—High	Early—Institutional	2	1.6561
2BA11	Neuro—Low	Early—Institutional	0	1.3805
2BA21	Neuro—Low	Early—Institutional	1	1.4394
2BA31	Neuro—Low	Early—Institutional	2	1.6003
2BB11	Neuro—Medium	Early—Institutional	0	1.5491
2BB21	Neuro—Medium	Early—Institutional	1	1.6080
2BB31	Neuro—Medium	Early—Institutional	2	1.7689
2BC11	Neuro—High	Early—Institutional	0	1.6239
2BC21	Neuro—High	Early—Institutional	1	1.6828
2BC31	Neuro—High	Early—Institutional	2	1.8437
2CA11	Wound—Low	Early—Institutional	0	1.4055
2CA21	Wound—Low	Early—Institutional	1	1.4644
2CA31	Wound—Low	Early—Institutional	2	1.6253
2CB11	Wound—Medium	Early—Institutional	0	1.5710
2CB21	Wound—Medium	Early—Institutional	1	1.6299
2CB31	Wound—Medium	Early—Institutional	2	1.7908
2CC11	Wound—High	Early—Institutional	0	1.6948
2CC21	Wound—High	Early—Institutional	1	1.7537
2CC31	Wound—High	Early—Institutional	2	1.9146
2DA11	Complex—Low	Early—Institutional	0	1.1535
2DA21	Complex—Low	Early—Institutional	1	1.2124
2DA31	Complex—Low	Early—Institutional	2	1.3733
2DB11	Complex—Medium	Early—Institutional	0	1.3823
2DB21	Complex—Medium	Early—Institutional	1	1.4411
2DB31	Complex—Medium	Early—Institutional	2	1.6020
2DC11	Complex—High	Early—Institutional	0	1.4745
2DC21	Complex—High	Early—Institutional	1	1.5333
2DC31	Complex—High	Early—Institutional	2	1.6942
2EA11	MS Rehab—Low	Early—Institutional	0	1.2610
2EA21	MS Rehab—Low	Early—Institutional	1	1.3198
2EA31	MS Rehab—Low	Early—Institutional	2	1.4807
2EB11	MS Rehab—Medium	Early—Institutional	0	1.3868
2EB21	MS Rehab—Medium	Early—Institutional	1	1.4456
2EB31	MS Rehab—Medium	Early—Institutional	2	1.6065
2EC11	MS Rehab—High	Early—Institutional	0	1.5268
2EC21	MS Rehab—High	Early—Institutional	1	1.5857

TABLE 49—CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Proposed CY 2019 weight
2EC31	MS Rehab—High	Early—Institutional	2	1.7466
2FA11	Behavioral Health—Low	Early—Institutional	0	1.0969
2FA21	Behavioral Health—Low	Early—Institutional	1	1.1557
2FA31	Behavioral Health—Low	Early—Institutional	2	1.3166
2FB11	Behavioral Health—Medium	Early—Institutional	0	1.2791
2FB21	Behavioral Health—Medium	Early—Institutional	1	1.3380
2FB31	Behavioral Health—Medium	Early—Institutional	2	1.4989
2FC11	Behavioral Health—High	Early—Institutional	0	1.3683
2FC21	Behavioral Health—High	Early—Institutional	1	1.4272
2FC31	Behavioral Health—High	Early—Institutional	2	1.5881
3AA11	MMTA—Low	Late—Community	0	0.5816
3AA21	MMTA—Low	Late—Community	1	0.6405
3AA31	MMTA—Low	Late—Community	2	0.8014
3AB11	MMTA—Medium	Late—Community	0	0.7330
3AB21	MMTA—Medium	Late—Community	1	0.7919
3AB31	MMTA—Medium	Late—Community	2	0.9528
3AC11	MMTA—High	Late—Community	0	0.8469
3AC21	MMTA—High	Late—Community	1	0.9058
3AC31	MMTA—High	Late—Community	2	1.0667
3BA11	Neuro—Low	Late—Community	0	0.7912
3BA21	Neuro—Low	Late—Community	1	0.8500
3BA31	Neuro—Low	Late—Community	2	1.0110
3BB11	Neuro—Medium	Late—Community	0	0.9598
3BB21	Neuro—Medium	Late—Community	1	1.0186
3BB31	Neuro—Medium	Late—Community	2	1.1796
3BC11	Neuro—High	Late—Community	0	1.0346
3BC21	Neuro—High	Late—Community	1	1.0934
3BC31	Neuro—High	Late—Community	2	1.2544
3CA11	Wound—Low	Late—Community	0	0.8162
3CA21	Wound—Low	Late—Community	1	0.8750
3CA31	Wound—Low	Late—Community	2	1.0360
3CB11	Wound—Medium	Late—Community	0	0.9817
3CB21	Wound—Medium	Late—Community	1	1.0405
3CB31	Wound—Medium	Late—Community	2	1.2015
3CC11	Wound—High	Late—Community	0	1.1055
3CC21	Wound—High	Late—Community	1	1.1643
3CC31	Wound—High	Late—Community	2	1.3253
3DA11	Complex—Low	Late—Community	0	0.5642
3DA21	Complex—Low	Late—Community	1	0.6230
3DA31	Complex—Low	Late—Community	2	0.7840
3DB11	Complex—Medium	Late—Community	0	0.7929
3DB21	Complex—Medium	Late—Community	1	0.8518
3DB31	Complex—Medium	Late—Community	2	1.0127
3DC11	Complex—High	Late—Community	0	0.8851
3DC21	Complex—High	Late—Community	1	0.9440
3DC31	Complex—High	Late—Community	2	1.1049
3EA11	MS Rehab—Low	Late—Community	0	0.6716
3EA21	MS Rehab—Low	Late—Community	1	0.7305
3EA31	MS Rehab—Low	Late—Community	2	0.8914
3EB11	MS Rehab—Medium	Late—Community	0	0.7974
3EB21	MS Rehab—Medium	Late—Community	1	0.8563
3EB31	MS Rehab—Medium	Late—Community	2	1.0172
3EC11	MS Rehab—High	Late—Community	0	0.9375
3EC21	MS Rehab—High	Late—Community	1	0.9963
3EC31	MS Rehab—High	Late—Community	2	1.1573
3FA11	Behavioral Health—Low	Late—Community	0	0.5075
3FA21	Behavioral Health—Low	Late—Community	1	0.5664
3FA31	Behavioral Health—Low	Late—Community	2	0.7273
3FB11	Behavioral Health—Medium	Late—Community	0	0.6898
3FB21	Behavioral Health—Medium	Late—Community	1	0.7486
3FB31	Behavioral Health—Medium	Late—Community	2	0.9095
3FC11	Behavioral Health—High	Late—Community	0	0.7790
3FC21	Behavioral Health—High	Late—Community	1	0.8378
3FC31	Behavioral Health—High	Late—Community	2	0.9987
4AA11	MMTA—Low	Late—Institutional	0	1.0225
4AA21	MMTA—Low	Late—Institutional	1	1.0814
4AA31	MMTA—Low	Late—Institutional	2	1.2423
4AB11	MMTA—Medium	Late—Institutional	0	1.1740
4AB21	MMTA—Medium	Late—Institutional	1	1.2328
4AB31	MMTA—Medium	Late—Institutional	2	1.3937

TABLE 49—CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Proposed CY 2019 weight
4AC11	MMTA—High	Late—Institutional	0	1.2879
4AC21	MMTA—High	Late—Institutional	1	1.3467
4AC31	MMTA—High	Late—Institutional	2	1.5076
4BA11	Neuro—Low	Late—Institutional	0	1.2321
4BA21	Neuro—Low	Late—Institutional	1	1.2910
4BA31	Neuro—Low	Late—Institutional	2	1.4519
4BB11	Neuro—Medium	Late—Institutional	0	1.4007
4BB21	Neuro—Medium	Late—Institutional	1	1.4595
4BB31	Neuro—Medium	Late—Institutional	2	1.6205
4BC11	Neuro—High	Late—Institutional	0	1.4755
4BC21	Neuro—High	Late—Institutional	1	1.5344
4BC31	Neuro—High	Late—Institutional	2	1.6953
4CA11	Wound—Low	Late—Institutional	0	1.2571
4CA21	Wound—Low	Late—Institutional	1	1.3160
4CA31	Wound—Low	Late—Institutional	2	1.4769
4CB11	Wound—Medium	Late—Institutional	0	1.4226
4CB21	Wound—Medium	Late—Institutional	1	1.4814
4CB31	Wound—Medium	Late—Institutional	2	1.6424
4CC11	Wound—High	Late—Institutional	0	1.5464
4CC21	Wound—High	Late—Institutional	1	1.6053
4CC31	Wound—High	Late—Institutional	2	1.7662
4DA11	Complex—Low	Late—Institutional	0	1.0051
4DA21	Complex—Low	Late—Institutional	1	1.0639
4DA31	Complex—Low	Late—Institutional	2	1.2249
4DB11	Complex—Medium	Late—Institutional	0	1.2338
4DB21	Complex—Medium	Late—Institutional	1	1.2927
4DB31	Complex—Medium	Late—Institutional	2	1.4536
4DC11	Complex—High	Late—Institutional	0	1.3260
4DC21	Complex—High	Late—Institutional	1	1.3849
4DC31	Complex—High	Late—Institutional	2	1.5458
4EA11	MS Rehab—Low	Late—Institutional	0	1.1125
4EA21	MS Rehab—Low	Late—Institutional	1	1.1714
4EA31	MS Rehab—Low	Late—Institutional	2	1.3323
4EB11	MS Rehab—Medium	Late—Institutional	0	1.2383
4EB21	MS Rehab—Medium	Late—Institutional	1	1.2972
4EB31	MS Rehab—Medium	Late—Institutional	2	1.4581
4EC11	MS Rehab—High	Late—Institutional	0	1.3784
4EC21	MS Rehab—High	Late—Institutional	1	1.4373
4EC31	MS Rehab—High	Late—Institutional	2	1.5982
4FA11	Behavioral Health—Low	Late—Institutional	0	0.9484
4FA21	Behavioral Health—Low	Late—Institutional	1	1.0073
4FA31	Behavioral Health—Low	Late—Institutional	2	1.1682
4FB11	Behavioral Health—Medium	Late—Institutional	0	1.1307
4FB21	Behavioral Health—Medium	Late—Institutional	1	1.1895
4FB31	Behavioral Health—Medium	Late—Institutional	2	1.3505
4FC11	Behavioral Health—High	Late—Institutional	0	1.2199
4FC21	Behavioral Health—High	Late—Institutional	1	1.2787
4FC31	Behavioral Health—High	Late—Institutional	2	1.4397

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

In conjunction with the implementation of the PDGM, we are proposing to revise the frequency with which we update the HH PPS Grouper software used to assign the appropriate HIPPS code used for case-mix adjustment onto the claim. Since CY 2004 when the HH PPS moved from a fiscal year to a calendar year basis, we have updated the Grouper software twice a year. We provide an updated version of the Grouper software effective every October 1 in order to address ICD coding revisions, which are effective on October 1. We also provide an updated

version of the HH PPS Grouper software effective on January 1 in order to capture the new or revised HH PPS policies that become effective on January 1. In an effort to reduce provider burden associated with testing and installing two software releases, we propose to discontinue the October release of the HH PPS Grouper software and provide a single HH PPS Grouper software release effective January 1 of each calendar year. We propose that the January release of the HH PPS Grouper software would include the most recent revisions to the ICD coding system as

well as the payment policy updates contained in the HH PPS final rule. Therefore, under this proposal, during the last quarter of each calendar year, HHAs would continue to use the ICD–10–CM codes and reporting guidelines that they would have used for the first three calendar quarters. HHAs would begin using the most recent ICD–10–CM codes and reporting guidelines on home health claims beginning on January 1 of each calendar year. We are soliciting comments on this proposal.

We invite comments on the proposed PDGM case-mix weights, case-mix

weight methodology and proposed annual recalibration of the case-mix weights, updates to the HH PPS Grouper software, and the associated regulations text changes in section III.F.13 of this proposed rule.

11. Low-Utilization Payment Adjustment (LUPA) Add-On Payments and Partial Payment Adjustments Under PDGM

LUPA episodes qualify for an add-on payment in the case that the established episode is the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, LUPA add-on payments are made because the national per-visit payment rates do not adequately account for the front-loading of costs for the first episode of care as the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. Under the PDGM, we propose that the LUPA add-on factors will remain the same as the current payment system, described in section III.C.4 of this proposed rule. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount.

The current partial episode payment (PEP) adjustment is a proportion of the episode payment and is based on the span of days including the start-of-care date (for example, the date of the first billable service) through and including the last billable service date under the original plan of care before the intervening event in a home health beneficiary's care defined as:

- A beneficiary elected transfer, or
- A discharge and return to home health that would warrant, for purposes of payment, a new OASIS assessment, physician certification of eligibility, and a new plan of care.

We received comments on eliminating PEPs in response to the CY 2018 HH PPS proposed rule. We note that the change in the unit of payment from 60 days to 30 days will reduce the number of instances where a PEP adjustment occurs. However, we believe maintaining a PEP adjustment policy is appropriate to ensure that Medicare is not paying twice for the same period of

care, as the PEP is involved with patient transfers there is a risk of a duplicate payment error. For example, if a patient chooses to transfer to a different HHA during the course of a home health period of care, the payment is proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event and ensures that Medicare is not paying two HHAs for the same 30-day period of care.

In summary for 30-day periods of care, we propose that the process for partial payment adjustments would remain the same as the existing policies pertaining to partial episode payments. When a new 30-day period begins due to the intervening event of the beneficiary elected transfer or discharge and return to home health during the 30-day episode, the original 30-day period would be proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event. The proportional payment is the partial payment adjustment. The partial payment adjustment is calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of 30. The proportion is multiplied by the original case-mix and wage index 30-day payment.

12. Payments for High-Cost Outliers Under the PDGM

As described in section III.E of this proposed rule, section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount in the case of outliers because of unusual variations in the type or amount of medically necessary care. The history of and current methodology for payment of high-cost outliers under the HH PPS is described in detail in section III.E of this proposed rule. In the CY 2018 HH PPS proposed rule (82 FR 35270), we proposed that we would maintain the current methodology for payment of high-cost outliers upon implementation of a 30-day unit of payment and that we would calculate payment for high-cost outliers based upon 30-day periods of care.

Commenters expressed concerns regarding the outlier policy proposed in the CY 2018 HH PPS proposed rule and the potential for more providers to exceed the 10 percent outlier cap under a 30-day period of care. Commenters also suggested modification to the 8-hour cap on the amount of time per day that is permitted to be counted toward

the estimation of an episode's costs for outlier calculation purposes.

While we appreciate commenters' feedback regarding the proposed outlier payment policy described in the CY 2018 HH PPS proposed rule, we are proposing to maintain the existing outlier policy under the proposed PDGM, except that outlier payments would be determined on a 30-day basis to align with the 30-day unit of payment under the proposed PDGM. We believe that maintaining the existing outlier policy and applying such policy to 30-day periods of care would ensure a smooth transition within the framework of the proposed PDGM. We plan to closely evaluate and model projected outlier payments within the framework of the PDGM and consider modifications to the outlier policy as appropriate. The requirement that the total amount of outlier payments not exceed 2.5 percent of total home health payments as well as the 10 percent cap on outlier payments at the home health agency level are statutory requirements, as described in section 1895(b)(5) of the Act. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5 percent maximum outlier payment amount.

Regarding the 8-hour limit on the amount of time per day counted toward the estimation of an episode's costs, as noted in the CY2017 HH PPS final rule (81 FR 76729), where a patient is eligible for coverage of home health services, Medicare statute limits the amount of part-time or intermittent home health aide services and skilled nursing services covered during a home health episode. Section 1861(m)(7)(B) of the Act states that the term " 'part-time or intermittent services' means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week)." Therefore, the daily and weekly cap on the amount of skilled nursing and home health aide services combined is a limit defined within the statute. As we further noted in the CY 2018 HH PPS final rule (81 FR 76729), because outlier payments are predominately driven by the provision of skilled nursing services, the 8-hour daily cap on services aligns with the statute, which requires that skilled nursing and home health aide services combined be furnished less than 8 hours each day. Therefore, we believe that maintaining the 8-hour per day cap is appropriate under the proposed PDGM.

Simulating payments using preliminary CY 2017 claims data and the CY 2019 payment rates, we estimate that outlier payments under the proposed PDGM with 30-day periods of care would comprise approximately 4.77 percent of total HH PPS payments in CY 2019. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we currently estimate that the FDL ratio under the proposed PDGM would need to change from 0.55 to 0.71. However, given the proposed implementation of the PDGM for 30-day periods of care beginning on or after January 1, 2020, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete utilization data available at the time of CY 2020 rate-setting.

We invite public comments on maintaining the current outlier payment methodology outlined in section III.E of this proposed rule for the proposed PDGM and the associated changes in the regulations text as described in section III.F.13 of this proposed rule.

13. Conforming Regulations Text Revisions for the Implementation of the PDGM in CY 2020

We are proposing to make a number of revisions to the regulations to implement the PDGM for episodes beginning on or after January 1, 2020, as outlined in sections III.F.1 through III.F.12 of this proposed rule. We propose to make conforming changes in § 409.43 and part 484 Subpart E to revise the unit of service from a 60-day episode to a 30-day period. In addition, we are proposing to restructure § 484.205. These revisions would be effective on January 1, 2020. Specifically, we propose to:

- Revise § 409.43, which outlines plan of care requirements. We propose to revise several paragraphs to phase out the unit of service from a 60-day episode for claims beginning on or before December 31, 2019, and to implement a 30-day period as the new unit of service for claims beginning on or after January 1, 2020 under the PDGM. We propose to move and revise paragraph (c)(2) to § 484.205 as paragraph (c)(2) aligns more closely with the regulations addressing the basis of payment.
 - Revise the definitions of rural area and urban area in § 484.202 to remove “with respect to home health episodes ending on or after January 1, 2006” from each definition as this verbiage is no longer necessary.
 - Restructure § 484.205 to provide more logical organization and revise to

account for the change in the unit of payment under the HH PPS for CY 2020. The PDGM uses 30-day periods rather than the 60-day episode used in the current payment system. Therefore, we propose to revise § 484.205 to remove references to “60-day episode” and to refer more generally to the “national, standardized prospective payment”. We are also proposing revisions to § 484.205 as follows:

- ++ Add paragraphs to paragraph (b) to define the unit of payment.
- ++ Move language which addresses the requirement for OASIS submission from § 484.210 and insert it into § 484.205 as new paragraph (c).
- ++ Move paragraph (c)(2) from § 409.43 to § 484.205 as new paragraph (g) in order to better align with the regulations detailing the basis of payment.
- ++ Add paragraph (h) to discuss split percentage payments under the current model and the proposed PDGM.

We are not proposing to change the requirements or policies relating to durable medical equipment or furnishing negative pressure wound therapy using a disposable device.

- Remove § 484.210 which discusses data used for the calculation of the national prospective 60-day episode payment as we believe that this information is duplicative and already incorporated in other sections of part 484, subpart E.
 - Revise the section heading of § 484.215 from “Initial establishment of the calculation of the national 60-day episode payment” to “Initial establishment of the calculation of the national, standardized prospective 60-day episode payment and 30-day payment rates.” Also, we propose to add paragraph (f) to this section to describe how the national, standardized prospective 60-day episode payment rate is converted into a national, standardized prospective 30-day period payment and when it applies.
 - Revise the section heading of § 484.220 from “Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels” to “Calculation of the case-mix and wage area adjusted prospective payment rates.” We propose to remove the reference to “national 60-day episode payment rate” and replace it with “national, standardized prospective payment”.
 - Revise the section heading in § 484.225 from “Annual update of the unadjusted national prospective 60-day episode payment rate” to “Annual update of the unadjusted national, standardized prospective 60-day episode and 30-day payment rates”.

Also, we propose to revise § 484.225 to remove references to “60-day episode” and to refer more generally to the “national, standardized prospective payment”. In addition, we propose to add paragraph (d) to describe the annual update for CY 2020 and subsequent calendar years.

- Revise the section heading of § 484.230 from “Methodology used for the calculation of low-utilization payment adjustment” to “Low utilization payment adjustment”. Also, we propose to designate the current text to paragraph (a) and insert language such that proposed paragraph (a) applies to claims beginning on or before December 31, 2019, using the current payment system. We propose to add paragraph (b) to describe how low utilization payment adjustments are determined for claims beginning on or after January 1, 2020, using the proposed PDGM.
 - Revise the section heading of § 484.235 from “Methodology used for the calculation of partial episode payment adjustments” to “Partial payment adjustments”. We propose to remove paragraphs (a), (b), and (c). We propose to remove paragraphs (1), (2), and (3) which describe partial payment adjustments from paragraph (d) in § 484.205 and incorporate them into § 484.235. We propose to add paragraph (a) to describe partial payment adjustments under the current system, that is, for claims beginning on or before December 31, 2019, and paragraph (b) to describe partial payment adjustments under the proposed PDGM, that is, for claims beginning on or after January 1, 2020.

- Revise the section heading for § 484.240 from “Methodology used for the calculation of the outlier payment” to “Outlier payments.” In addition, we propose to remove language at paragraph (b) and append it to paragraph (a). We propose to add language to proposed revised paragraph (a) such that paragraph (a) will apply to payments under the current system, that is, for claims beginning on or before December 31, 2019. We propose to revise paragraph (b) to describe payments under the proposed PDGM, that is, for claims beginning on or after January 1, 2020. In paragraph (c), we propose to replace the “estimated” cost with “imputed” cost. Lastly, we propose to revise paragraph (d) to reflect the per-15 minute unit approach to imputing the cost for each claim.

We are soliciting comments on the proposed PDGM as outlined in sections III.F.1 through III.F.12 and the associated regulations text changes

described above and in section IX of this proposed rule.

G. Proposed Changes Regarding Certifying and Recertifying Patient Eligibility for Medicare Home Health Services

1. Background

Sections 1814(a) and 1835(a) of the Act require that a physician certify patient eligibility for home health services (and recertify, where such services are furnished over a period of time). The certifying physician is responsible for determining whether the patient meets the eligibility criteria (that is, homebound status and need for skilled services) and for understanding the current clinical needs of the patient such that the physician can establish an effective plan of care. In addition, as a condition for payment, section 6407 of the Affordable Care Act amended sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act requiring, as part of the certification for home health services, that prior to certifying a patient's eligibility for the Medicare home health benefit the certifying physician must document that the physician himself or herself or an allowed non-physician practitioner had a face-to-face encounter with the patient. The regulations at 42 CFR 424.22(a) and (b) set forth the requirements for certification and recertification of eligibility for home health services. The regulations at § 424.22(c) provide the supporting documentation requirements used as the basis for determining patient eligibility for Medicare home health services.

2. Current Supporting Documentation Requirements

In determining whether the patient is or was eligible to receive services under the Medicare home health benefit at the start of care, as of January 1, 2015, we require documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) to be used as the basis for certification of home health eligibility as described at § 424.22(c). Specifically, the certifying physician and/or the acute/post-acute care facility medical record (if the patient was directly admitted to home health) for the patient must contain information that justifies the referral for Medicare home health services. This includes documentation that substantiates the patient's:

- Need for the skilled services; and
- Homebound status;

Likewise, the certifying physician and/or the acute/post-acute care facility

medical record (if the patient was directly admitted to home health) for the patient must contain the actual clinical note for the face-to-face encounter visit that demonstrates that the encounter:

- Occurred within the required timeframe,
- Was related to the primary reason the patient requires home health services; and
- Was performed by an allowed provider type.

This information can be found most often in clinical and progress notes and discharge summaries. While the face-to-face encounter must be related to the primary reason for home health services, the patient's skilled need and homebound status can be substantiated through an examination of all submitted medical record documentation from the certifying physician, acute/post-acute care facility, and/or HHA (if certain requirements are met). The synthesis of progress notes, diagnostic findings, medications, and nursing notes, help to create a longitudinal clinical picture of the patient's health status to make the determination that the patient is eligible for home health services. HHAs must obtain as much documentation from the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) as they deem necessary to assure themselves that the Medicare home health patient eligibility criteria have been met. HHAs must be able to provide it to CMS and its review entities upon request. If the documentation used as the basis for the certification of eligibility (that is, the certifying physician's and/or the acute/post-acute care facility's medical record documentation) is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

3. Proposed Regulations Text Changes Regarding Information Used to Satisfy Documentation of Medicare Eligibility for Home Health Services

Section 51002 of the BBA of 2018 amended sections 1814(a) and 1835(a) of the Act to provide that, effective for physician certifications and recertifications made on or after January 1, 2019, in addition to using the documentation in the medical record of the certifying physician or of the acute or post-acute care facility (where home health services were furnished to an individual who was directly admitted to the HHA from such facility), the

Secretary may use documentation in the medical record of the HHA as supporting material, as appropriate to the case involved. We believe the BBA of 2018 provisions are consistent with our existing policy in this area, which is currently reflected in sub-regulatory guidance in the Medicare Benefit Policy Manual (Pub.100–02, chapter 7, section 30.5.1.2) and the Medicare Program Integrity Manual (Pub. 100–08, chapter 6, section 6.2.3).⁵¹ The sub-regulatory guidance describes the circumstances in which HHA documentation can be used along with the certifying physician and/or acute/post-acute care facility medical record to support the patient's homebound status and skilled need. Specifically, we state that information from the HHA, such as the plan of care required in accordance with 42 CFR 409.43 and the initial and/or comprehensive assessment of the patient required in accordance with 42 CFR 484.55, can be incorporated into the certifying physician's medical record for the patient and used to support the patient's homebound status and need for skilled care. However, this information must be corroborated by other medical record entries in the certifying physician's and/or the acute/post-acute care facility's medical record for the patient. This means that the appropriately incorporated HHA information, along with the certifying physician's and/or the acute/post-acute care facility's medical record, creates a clinically consistent picture that the patient is eligible for Medicare home health services. The certifying physician officially incorporates the HHA information into his/her medical record for the patient by signing and dating the material. Once incorporated, the documentation from the HHA, in conjunction with the certifying physician and/or acute/post-acute care facility documentation, must substantiate the patient's eligibility for home health services.

While we believe the provisions in section 51002 of the BBA of 2018 do not require a change to the current regulations because the provisions are consistent with existing CMS policy, we are discretionarily proposing to amend the regulations text at 42 CFR 424.22(c) to align the regulations text with current sub-regulatory guidance to allow medical record documentation from the HHA to be used to support the basis for certification and/or recertification of

⁵¹ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf> and <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c06.pdf>.

home health eligibility, if the following requirements are met:

- The documentation from the HHA can be corroborated by other medical record entries in the certifying physician's and/or the acute/post-acute care facility's medical record for the patient, thereby creating a clinically consistent picture that the patient is eligible for Medicare home health services as specified in § 424.22 (a)(1) and (b).

- The certifying physician signs and dates the HHA documentation demonstrating that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services. HHA documentation can include, but is not limited to, the patient's plan of care required in accordance with 42 CFR 409.43 and the initial and/or comprehensive assessment of the patient required in accordance with 42 CFR 484.55.

We believe that this proposal incorporates existing sub-regulatory flexibilities into the regulations text that allow HHA medical record documentation to support the basis of home health eligibility. By incorporating the existing sub-regulatory guidance into regulation, HHAs are assured that HHA-generated documentation can be used as supporting material for the basis of home health eligibility, as long as all conditions are met, as described previously. HHAs have the discretion to determine the type and format of any documentation used to support home health eligibility. The expectation is that the HHA-generated supporting medical record documentation would be used to support the existing medical record of the certifying physician or the acute/post-acute care facility to create a clinically consistent picture that the individual is confined to the home and requires skilled services. Anecdotally, we have received reports from HHAs that they typically include this supporting information on the plan of care. Generally, the certifying physician is also the physician who establishes the plan of care and the plan of care must be signed by the physician. Consequently, no additional burden is incurred by either the HHA or the certifying physician. As existing sub-regulatory guidance allows HHA-generated documentation to be used as supporting material for the physician's determination of eligibility for home health services, we expect that most HHAs already have a process in place to provide this information to the certifying physician or the acute/post-

acute care facility. We welcome comments on this assumption.

We invite comments on this proposal to amend the regulations text at § 424.22(c), which would codify subregulatory guidance allowing HHA-generated medical record documentation to be used as supporting material to the certifying physician's or the acute and/or post-acute care facility's medical record documentation as part of the certification and/or recertification of eligibility for home health services, under certain circumstances. The corresponding proposed regulations text changes can be found in section VIII. of this proposed rule.

4. Proposed Elimination of Recertification Requirement To Estimate How Much Longer Home Health Services Will Be Required

In the CY 2018 HH PPS proposed rule (82 FR 35378), we invited public comments about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. Specifically, we asked the public to submit their ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. We specifically stated that CMS would not respond to the comment submissions in the final rule. Instead, we would review the comments submitted in response to the requests for information and actively consider them as we develop future regulatory proposals or future sub-regulatory policy guidance.

Several commenters requested that CMS consider eliminating the requirement that the certifying physician include an estimate of how much longer skilled services will be required at each home health recertification, as set forth at § 424.22(b)(2) and in sub-regulatory guidance in the Medicare Benefit Policy Manual (Chapter 7, Section 30.5.2). Commenters stated that this estimate is duplicative of the Home Health Conditions of Participation (CoP) requirements for the content of the home health plan of care, set out at 42 CFR 484.60(a)(2).

The Home Health CoP at § 484.60(a)(2) sets forth the requirements for the content of the home health plan of care, which includes the types of services, supplies, and equipment required, as well as, the

frequency and duration of visits to be made. Commenters stated that the plan of care requirement already includes the frequency and duration of visits to be made and is an estimate of how much longer home health services are expected to be required by the patient. They observed that including this information as part of the recertification statement is duplicative and unnecessary. Commenters went on to say that because the certifying physician must review, sign and date the plan of care at least every 60-days, he/she is attesting to how much longer he/she thinks the patient will require home health services. Commenters also stated that this estimate appears to have no value to the patient, the physician, the HHA, or to CMS, but failure to include the physician's estimate of how much longer skilled care will be required can result in claim denials.

We have determined that the estimate of how much longer skilled care will be required at each recertification is not currently used for quality, payment, or program integrity purposes. Given this consideration and the Home Health CoP requirements for the content of the home health plan of care, and to mitigate any potential denials of home health claims that otherwise would meet all other Medicare requirements, we are proposing to eliminate the regulatory requirement as set forth at 42 CFR 424.22(b)(2), that the certifying physician, as part of the recertification process, provide an estimate of how much longer skilled services will be required. All other recertification content requirements under § 424.22(b)(2) would remain unchanged. We believe the elimination of this recertification requirement would result in a reduction of burden for certifying physicians by reducing the amount of time physicians spend on the recertification process and would result in an overall cost savings of \$14.2 million. We provided a more detailed description of this burden reduction in section VIII.C.1.c. of this proposed rule.

We invite comments regarding the proposed elimination of the requirement that the certifying physician include an estimate of how much longer skilled services will be required at each home health recertification, as well as the corresponding regulations text changes at § 424.22(b)(2).

While we are not proposing any additional changes to the home health payment regulations in this proposed rule as suggested by commenters in the RFI, we will continue to consider whether future regulatory or sub-regulatory changes are warranted to reduce unnecessary burden. We thank

the commenters for taking the time to convey their thoughts and suggestions on this initiative.

H. Proposed Change Regarding Remote Patient Monitoring Under the Medicare Home Health Benefit

Section 4012 of the 21st Century Cures Act directed the Centers for Medicare & Medicaid Services (CMS) to provide information on the current use of and/or barriers to telehealth services. This directive, along with advancements in technology, prompted us to examine ways in which HHAs can integrate telehealth and/or remote patient monitoring into the care planning process. Telehealth services, under section 1834(m)(4) of the Act, include services such as professional consultations, office visits, pharmacologic management, and office psychiatry services furnished via a telecommunications system by a distant site physician or practitioner to a patient located at a designated “originating site.” Originating sites, as defined under section 1834(m)(4)(C) of the Act, generally must be certain kinds of healthcare settings located in certain geographic areas. This definition generally does not include the beneficiary’s home. As a Medicare condition for payment, an *interactive* telecommunications system generally is required when furnishing telehealth services. Medicare defines “interactive telecommunication systems” as audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner (42 CFR 410.78). Telehealth services are used to substitute for professional in-person visits when certain eligibility criteria are met. For patients receiving care under the Medicare home health benefit, section 1895(e)(1)(A) of the Act prohibits payment for services furnished via a telecommunications system if such services substitute for in-person home health services ordered as part of a plan of care certified by a physician. However, the statute does not define the term “telecommunications system” as it relates to the provision of home health care and explicitly notes that an HHA is not prevented from providing services via a telecommunications system, assuming the service is not considered a home health visit for purposes of eligibility or payment.

Remote patient monitoring, while a service using a form of telecommunications, is not considered a Medicare telehealth service as defined under section 1834(m) of the Act, but rather uses “digital technologies to collect medical and other forms of

health data from individuals in one location and electronically transmit that information securely to health care providers in a different location for assessment and recommendations.”⁵² For example, remote patient monitoring allows the patient to collect and transmit his or her own clinical data, such as weight, blood pressure, and heart rate for monitoring and analysis. The clinical data is monitored without a direct interaction between the practitioner and beneficiary, and then reviewed by the HHA for potential consultation with the certifying physician for changes in the plan of care. Additionally, because remote patient monitoring is not statutorily considered a telehealth service, it would not be subject to the restrictions on originating site and interactive telecommunications systems technology.

We believe remote patient monitoring could be beneficial in augmenting the home health services outlined in the patient’s plan of care, without replicating or replacing home health visits. The plan of care, in accordance with the home health conditions of participation (CoPs), must identify patient-specific measurable outcomes and goals, and be established, periodically reviewed, and signed by a physician (42 CFR 484.60(a)). The HHA must also promptly alert the relevant physician(s) to any changes in the patient’s condition or needs that suggest that outcomes are not being achieved, or that the plan of care must be altered (42 CFR 484.60(c)). Remote patient monitoring could enable the HHA to more quickly identify any changes in the patient’s clinical condition, as well as monitor patient compliance, prompting physician review of, and potential changes to, the plan of care, as required per the CoPs. Particularly in cases where the home health patient is admitted for skilled observation and assessment of the patient’s condition due to a reasonable potential for complications or an acute episode, remote patient monitoring could augment home health visits until the patient’s clinical condition stabilized. Fluctuating or abnormal vital signs could be monitored between visits, potentially leading to quicker interventions and updates to the treatment plan.

A review of the literature shows that utilizing remote patient monitoring in chronic disease management has the potential to “significantly improve an individual’s quality of life, allowing

⁵² <http://www.cchpca.org/remote-patient-monitoring>.

patients to maintain independence, prevent complications, and minimize costs.”⁵³ Specifically for patients with chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF), research indicates that remote patient monitoring has been successful in reducing readmissions and long-term acute care utilization.⁵⁴ Likewise, a systematic review of evidence collected by the Agency for Healthcare Research and Quality (AHRQ) revealed that remote patient monitoring of chronic cardiac and respiratory conditions resulted in lower mortality, improved quality of life, and reductions in hospital admissions.⁵⁵ If changes in condition are identified early through careful monitoring, serious complications may be avoided, potentially preventing emergency department visits and hospital admissions. Surveillance and case management are frequently occurring interventions in home health, and remote patient monitoring leverages technology to encourage patient involvement and accountability in order to improve care coordination.

Anecdotally, we have heard from various home health agencies regarding integration of remote patient monitoring into the care planning process. For example, on a recent site visit to a home health agency, CMS participated in a care coordination meeting, which included a discussion of the agency’s experience implementing remote patient monitoring in home health episodes. Certain patients with chronic conditions received tablets pre-loaded with software enabling patients to take and transmit their vital signs on a daily basis. The transmitted health data was then monitored and analyzed by an outside service, which contacted the HHA with any changes or abnormalities. This example highlights how remote patient monitoring could be integrated into the home health episode of care.

Additionally, we believe that the growth of technology and new software development could be used in the

⁵³ Rojhan, K., Laplante, S., Sloand, J., Main, C., Ibrahim, A., Wild, J., Sturt, N. Remote Monitoring of Chronic Diseases: A Landscape Assessment of Policies in Four European Countries (2016) PLOS One. V11 (5) <https://dx.doi.org/10.1371/journal.pone.0155738>.

⁵⁴ Broad, J., Davis, C., Bender, M., Smith, T. (2014) Feasibility and Acute Care Utilization Outcomes of a Post-Acute Transitional Telemonitoring Program for Underserved Chronic Disease Patients. Journal of Cardiac Failure. Vol 20 (8S) S116. <http://dx.doi.org/10.1016/j.cardfail.2014.06.328>.

⁵⁵ Department of Health and Human Services, Agency for Healthcare Research and Quality, Telehealth: Mapping the Evidence for Patient Outcomes from Systematic Reviews, Technical Brief Number 26 (Washington, DC: June 2016).

provision of care and care coordination in the home, as well as empower patients to be active participants in their disease management. Other than the statutory requirement that services furnished via a telecommunications system may not substitute for in-person home health services ordered as part of a plan of care certified by a physician, we do not have specific policies surrounding the use of remote patient monitoring by HHAs. We anticipate that HHAs would follow clinical and manufacturer guidelines when implementing the technology into clinical practice, while still meeting all statutory requirements, conditions for payment, and the home health conditions of participation.

Medicare began making separate payment in CY 2018 for CPT code 99091 that allows physicians and other healthcare professionals to bill for the collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional (82 CFR 53013). CPT code 99091 is paid under the Medicare physician fee schedule, and thus cannot be billed by HHAs. Additionally, it includes the *interpretation* of the physiologic data, whereas the HHA would only be responsible for the collection of the data. However, with this distinction, we feel the code's description accurately describes remote monitoring services. Therefore, we propose to define remote patient monitoring under the Medicare home health benefit as "the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA."

Although the cost of remote patient monitoring is not separately billable under the HH PPS and may not be used as a substitute for in-person home health services, there is nothing to preclude HHAs from using remote patient monitoring to augment the care planning process as appropriate. As such, we believe the expenses of remote patient monitoring, if used by the HHA to augment the care planning process, must be reported on the cost report as allowable administrative costs (that is, operating expenses) that are factored into the costs per visit. Currently, costs associated with remote patient monitoring are reported on line 23.20 on Worksheet A, as direct costs associated with telemedicine. For 2016, approximately 3 percent of HHAs reported telemedicine costs that accounted for roughly 1 percent of their total agency costs on the HHA cost

report. However, these costs are not allocated to the costs per visit. We propose to amend the regulations at 42 CFR 409.46 to include the costs of remote patient monitoring as an allowable administrative cost (that is, operating expense), if remote patient monitoring is used by the HHA to augment the care planning process. This would allow HHAs to report the costs of remote patient monitoring on the HHA cost report as part of their operating expenses. These costs would then be factored into the costs per visit. Factoring the costs associated with remote patient monitoring into the costs per visit has important implications for assessing home health costs relevant to payment, including HHA Medicare margin calculations. We are soliciting comments on the proposed definition of remote patient monitoring under the HH PPS to describe telecommunication services used to augment the plan of care during a home health episode. Additionally, we welcome comments regarding additional utilization of telecommunications technologies for consideration in future rulemaking. We are also soliciting comments on the proposed changes to the regulations at 42 CFR 409.46, to include the costs of remote patient monitoring as allowable administrative costs (that is, operating expenses), as detailed in section IX. of this proposed rule.

IV. Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), we began testing the HHVBP Model on January 1, 2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, we selected nine states for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified Home Health Agencies (HHAs) providing services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington (competing HHAs) are required to compete in the Model. Requiring all Medicare-certified HHAs

providing services in the selected states to participate in the Model ensures that: (1) There is no selection bias; (2) participating HHAs are representative of HHAs nationally; and, (3) there is sufficient participation to generate meaningful results.

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act beginning in CY 2018 based on the competing HHAs' performance on applicable measures. Payment adjustments will be increased incrementally over the course of the HHVBP Model in the following manner: (1) A maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year (PY) comprised of: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS) and completed Home Health Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys for all patients serviced by the HHA and select claims data elements; and (2) three New Measures for which points are achieved for reporting data.

For CY 2019, we are proposing to remove five measures and add two new proposed composite measures to the applicable measure set for the HHVBP model, revise our weighting methodology for the measures, and rescore the maximum number of improvement points.

B. Quality Measures

1. Proposal To Remove Two OASIS-Based Measures Beginning With Performance Year 4 (CY 2019)

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 New Measures (80 FR 68671 through 68673) for the HHVBP Model used in PY1, referred to as the starter set. We also stated that this set of measures will be subject to change or retirement during subsequent model years and revised through the rulemaking process (80 FR 68669).

The measures were selected for the Model using the following guiding principles: (1) Use a broad measure set that captures the complexity of the services HHAs provide; (2) incorporate flexibility for future inclusion of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) measures that cut across post-acute care settings; (3) develop 'second generation' (of the HHVBP Model) measures of patient outcomes, health and functional status, shared decision making, and patient activation; (4) include a balance of process, outcome and patient experience measures; (5) advance the ability to measure cost and value; (6) add measures for appropriateness or overuse; and (7) promote infrastructure investments. This set of quality measures encompasses the multiple National Quality Strategy (NQS) domains⁵⁶ (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care; (2) Care coordination; (3) Population & community health; (4) Person- and Caregiver-centered experience and outcomes; (5) Safety; and (6) Efficiency and cost reduction. Figures 4a and 4b of the CY 2016 HH PPS final rule identified 15 outcome measures (five from the HHCAHPS, eight from OASIS, and two claims-based measures), and nine process measures (six from OASIS, and three New Measures, which were not previously reported in the home health setting) for use in the Model.

In the CY 2017 HH PPS final rule, we removed four measures from the measure set for PY1 and subsequent performance years: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received, for the reasons discussed in that final rule (81 FR 76743 through 76747).

In the CY 2018 HH PPS final rule, we removed the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care from the set of applicable measures beginning with PY3 for the reasons discussed in that final rule (82 FR 51703 through 51704).

For PY4 and subsequent performance years, we propose to remove two OASIS-based process measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures. We adopted the Influenza Immunization Received for Current Flu Season measure beginning PY1 of the model. Since that time, we have received input from both stakeholders and a Technical Expert Panel (TEP) convened by our contractor in 2017 that because the measure does not exclude HHA patients who were offered the vaccine but declined it and patients who were ineligible to receive it due to contraindications, the measure may not fully capture HHA performance in the administration of the influenza vaccine. In response to these concerns, we are proposing to remove the measure from the applicable measure set beginning PY4.

We also adopted the Pneumococcal Polysaccharide Vaccine Ever Received measure beginning PY1 of the model. This process measure reports the percentage of HH episodes during which patients were determined to have ever received the Pneumococcal Polysaccharide Vaccine. The measure is based on guidelines previously issued by the Advisory Committee on Immunization Practices (ACIP),⁵⁷ which recommended use of a single dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) among all adults aged 65 years and older and those adults aged 19–64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection.⁵⁸ In 2014, the ACIP updated its guidelines to recommend that both PCV13 and PPSV23 be given to all immunocompetent adults aged ≥65 years.⁵⁹ The recommended intervals for

⁵⁷ The Advisory Committee on Immunization Practices was established under Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs. (Charter of the Advisory Committee on Immunization Practices, filed April 1, 2018. <https://www.cdc.gov/vaccines/acip/committee/ACIP-Charter-2018.pdf>).

⁵⁸ Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1997;46:1–24.

⁵⁹ Tomczyk S, Bennett NM, Stoecker C, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: Recommendations of

sequential administration of PCV13 and PPSV23 depend on several patient factors including: The current age of the adult, whether the adult had previously received PPSV23, and the age of the adult at the time of prior PPSV23 vaccination (if applicable). Because the Pneumococcal Polysaccharide Vaccine Ever Received measure does not fully reflect the current ACIP guidelines, we are proposing to remove this measure from the model beginning PY4.

2. Proposal To Replace Three OASIS-Based Measures With Two Composite Measures Beginning With Performance Year 4

As previously noted, one of the goals of the HHVBP Model is to study new potential quality and efficiency measures for appropriateness in the home health setting. In the CY 2018 HH PPS Final Rule, we solicited comment on additional quality measures for future consideration in the HHVBP model, specifically a Total Change in ADL/IADL Performance by HHA Patients Measure, a Composite Functional Decline Measure, and behavioral health measures (82 FR 51706 through 51711). For the reasons discussed, we are proposing to replace three individual OASIS measures (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion) with two composite measures: Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility. These proposed measures use several of the same ADLs as the composite measures discussed in the CY 2018 HH PPS Final Rule (82 FR 51707). Our contractor convened a TEP in November 2017, which supported the use of two proposed composite measures in place of the three individual measures because HHA performance on the three individual measures would be combined with HHA performance on six additional ADL measures to create a more comprehensive assessment of HHA performance across a broader range of patient ADL outcomes. The TEP also noted that HHA performance is currently measured based on any change in improvement in patient status, while the composite measures would report the magnitude of patient change (either improvement or decline) across six self-care and three mobility patient outcomes.

There are currently three ADL improvement measures in the HHVBP Model (Improvement in Bathing,

the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63: 822–5.

⁵⁶ 2015 Annual Report to Congress, <http://www.aHRQ.gov/workingforquality/reports/annual-reports/nqs2015annrpt.htm>.

Improvement in Bed Transferring, and Improvement in Ambulation- Locomotion). The maximum cumulative score across all three measures is 30. Because we are proposing to replace these three measures with the two composite measures, we are also proposing that each of the two composite measures would have a maximum score of 15 points, to ensure that the relative weighting of ADL-based measures would stay the same if the proposal to replace the three ADL improvement measures with the two composite measures is adopted. That is, there would still be a maximum of 30 points available for ADL related measures.

The proposed Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures would represent a new direction in how quality of patient care is measured in home health. Both of these proposed composite measures combine several existing and endorsed Home Health Quality Reporting Program (HH QRP) outcome measures into focused composite measures to enhance quality reporting. These proposed composite measures fit within the *Patient and Family Engagement*⁶⁰ domain as functional status and functional decline are important to assess for residents in home health settings. Patients who receive care from an HHA may have functional limitations and may be at risk for further decline in function because of limited mobility and ambulation.

The proposed Total Normalized Composite Change in Self-Care measure computes the magnitude of change, either positive or negative, based on a normalized amount of possible change on each of six OASIS-based quality outcomes. These six outcomes are as follows:

- Improvement in Grooming (M1800)
- Improvement in Upper Body Dressing (M1810)
- Improvement in Lower Body Dressing (M1820)
- Improvement in Bathing (M1830)

- Improvement in Toileting Hygiene (M1845)
- Improvement in Eating (M1870)

The proposed Total Normalized Composite Change in Mobility measure computes the magnitude of change, either positive or negative, based on the normalized amount of possible change on each of three OASIS-based quality outcomes. These three outcomes are as follows:

- Improvement in Toilet Transferring (M1840)
- Improvement in Bed Transferring (M1850)
- Improvement in Ambulation/ Locomotion (M1860)

The magnitude of possible change for these OASIS items varies based on the number of response options. For example, M1800 (grooming) has four behaviorally-benchmarked response options (0 = most independent; 3 = least independent) while M1830 (bathing) has seven behaviorally-benchmarked response options (0 = most independent; 6 = least independent). The maximum possible change for a patient on item M1800 is 3, while the maximum possible change for a patient on item M1830 is 6. Both proposed composite measures would be computed and normalized at the episode level, then aggregated to the HHA level using the following steps:

- Step 1: Calculate absolute change score for each OASIS item (based on change between Start of Care(SOC)/ Resumption of Care (ROC) and discharge) used to compute the Total Normalized Composite Change in Self-Care (6 items) or Total Normalized Composite Change in Mobility (3 items) measures.
- Step 2: Normalize scores based on maximum change possible for each OASIS item (which varies across different items). The normalized scores result in a maximum possible change for any single item equal to "1"; this score is provided when a patient achieves the maximum possible change for the OASIS item.
- Step 3: Total score for Total Normalized Composite Change in Self-

Care or Total Normalized Composite Change in Mobility is calculated by summing the normalized scores for the items in the measure. Hence, the maximum possible range of normalized scores at the patient level for Total Normalized Composite Change in Self-Care is -6 to +6, and for Total Normalized Composite Change in Mobility is -3 to +3.

We created two prediction models for the proposed Total Normalized Composite Change in Self-Care (TNC_SC) and Total Normalized Composite Change in Mobility (TNC_MOB) measures using information from OASIS items and patient clinical condition categories (see Table 50 for details on the number of OASIS items and OASIS clinical categories used in the prediction models). We computed multiple ordinary least squares (OLS) analyses beginning with risk factors that were available from OASIS D items and patient condition groupings. Any single OASIS D item might have more than one risk factor because we create dichotomous risk factors for each response option on scaled (from dependence to independence) OASIS items. Those risk factors that were statistically significant at p <0.0001 level were kept in the prediction model. These two versions (CY 2014 and CY 2015) of the prediction models were done as "proof of concept." We are proposing that the actual prediction models that would be used if the proposed composite measures are finalized would use episodes of care that ended in CY 2017, which would be the baseline year for the quality outcome measures used to compute the two proposed composite measures, as listed previously. The baseline year for these two composite measures would be calendar year 2017.

The following Table 50 provides an overview of results from the CY 2014 and CY 2015 prediction models for each proposed measure with estimated R-squared values comparing observed vs. predicted episode-level performance.

TABLE 50—OBSERVED VERSUS PREDICTED EPISODE-LEVEL PERFORMANCE FOR THE PROPOSED TOTAL NORMALIZED COMPOSITE CHANGE MEASURES

Prediction model for	Number of OASIS items used	Number of clinical categories	R-squared value
2014 TNC_SC	42	14	0.299
2015 TNC_SC	41	13	0.311
2014 TNC_MOB	42	16	0.289

⁶⁰ 2017 Measures under Consideration List. <https://www.cms.gov/Medicare/Quality-Initiatives->

Patient-Assessment-Instruments/QualityMeasures/

Downloads/2017-CMS-Measurement-Priorities-and-Needs.pdf.

TABLE 50—OBSERVED VERSUS PREDICTED EPISODE-LEVEL PERFORMANCE FOR THE PROPOSED TOTAL NORMALIZED COMPOSITE CHANGE MEASURES—Continued

Prediction model for	Number of OASIS items used	Number of clinical categories	R-squared value
2015 TNC_MOB	41	18	0.288

Table 50 presents the following summary information for the prediction models for the two proposed composite measures.

- Prediction Model for: This column identifies the measure and year of data used for the two “proof of concept” prediction models created for each of the two proposed composite measures, Total Normalized Composite Change in Self-Care (TNC_SC) and Total Normalized Composite Change in Mobility (TNC_MOB). The development of the prediction models was identical in terms of the list of potential risk factors and clinical categories. The only difference was one set of prediction models used episodes of care that ended in CY 2014, while the other set of prediction models used episodes of care that ended in CY 2015.

- Number of OASIS Items Used: This column indicates the number of OASIS items used as risk factors in the prediction model. For each prediction model, the number of OASIS items used is based on the number of risk factors that were statistically significant at p <0.0001 level in the prediction model.

- Number of Clinical Categories: This column indicates the number of patient clinical categories (for example, diagnoses related to infections or neoplasms or endocrine disorders) that are used as risk factors in the prediction model.

- R-squared Value: The R-squared values are a measure of the proportion of the variation in outcomes that is accounted for by the prediction model. The results show that the methodology that was used to create the prediction

models produced very consistent models that predict at least 29 percent of the variability in the proposed composite measures.

The prediction models are applied at the episode level to create a specific predicted value for the composite measure for each episode of care. These episode level predicted values are averaged to compute a national predicted value and an HHA predicted value. The episode level observed values are averaged to compute the HHA observed value. The HHA TNC_SC and TNC_MOB observed scores are risk adjusted based on the following formula:

$$HHA\ Risk\ Adjusted = HHA\ Observed + National\ Predicted - HHA\ Predicted$$

HHAs are not allowed to skip any of the OASIS items that are used to compute these proposed composite measures or the risk factors that comprise the prediction models for the two proposed composite measures. The OASIS items typically do not include “not available (NA)” or “unknown (UK)” response options, and per HHQR requirements,⁶¹ HHAs must provide responses to all OASIS items for the OASIS assessment to be accepted into the CMS data repository. Therefore, while we believe the likelihood that a value for one of these items would be missing is extremely small, we are proposing to impute a value of “0” if a value is “missing.” Specifically, if for some reason the information on one or more OASIS items that are used to compute TNC_SC or TNC_MOB is missing, we impute the value of “0” (no

change) for the missing value. Similarly, if for some reason the information on one or more OASIS items that are used as a risk factor is missing, we impute the value of “0” (no effect) for missing values that comprise the prediction models for the two proposed composite measures. Table 51 contains summary information for these two proposed composite measures. Because the proposed TNC_SC and TNC_MOB are composite measures rather than simple outcome measures, the terms “Numerator” and “Denominator” do not apply to how these measures are calculated. Therefore, for these proposed composite measures, the “Numerator” and “Denominator” columns in Table 51 are replaced with columns describing “Measure Computation” and “Risk Adjustment”.

Table 51 contains the set of applicable measures under the HHVBP model, if we finalize our proposals to remove the OASIS-based measures, Influenza Immunization Received for Current Flu Season, Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in Ambulation-Locomotion, Improvement in Bed Transferring, and Improvement in Bathing, and add the two proposed OASIS-based outcome composite measures, Total Change in Self-Care and Total Change in Mobility. This measure set, if our proposals are finalized, would be applicable to PY4 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking.

TABLE 51—MEASURE SET FOR THE HHVBP MODEL BEGINNING PY 4*

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care.	Improvement in Dyspnea.	Outcome	NA	OASIS (M1400).	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Communication & Care Coordination.	Discharged to Community.	Outcome	NA	OASIS (M2420).	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.

⁶¹ Data Specifications—<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/DataSpecifications.html>.

TABLE 51—MEASURE SET FOR THE HHVBP MODEL BEGINNING PY 4 *—Continued

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Efficiency & Cost Reduction.	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health.	Outcome	NQF0171	CCW (Claims).	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Efficiency & Cost Reduction.	Emergency Department Use without Hospitalization.	Outcome	NQF0173	CCW (Claims).	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Patient Safety	Improvement in Pain Interfering with Activity.	Outcome	NQF0177	OASIS (M1242).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient Safety	Improvement in Management of Oral Medications.	Outcome	NQF0176	OASIS (M2020).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient & Caregiver-Centered Experience.	Care of Patients ...	Outcome	CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Communications between Providers and Patients.	Outcome	CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Specific Care Issues.	Outcome	CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Overall rating of home health care.	Outcome	CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Willingness to recommend the agency.	Outcome	CAHPS	NA	NA.
Population/Community Health.	Influenza Vaccination Coverage for Home Health Care Personnel.	Process	NQF0431 (Used in other care settings, not Home Health).	Reported by HHAs through Web Portal.	Healthcare personnel in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) Received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere; Or (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other components of the vaccine or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; or (c) declined influenza vaccination; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the previously mentioned numerator categories.	Number of healthcare personnel who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.
Population/Community Health.	Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?	Process	NA	Reported by HHAs through Web Portal.	Total number of Medicare beneficiaries aged 60 years and over who report having ever received zoster vaccine (shingles vaccine).	Total number of Medicare beneficiaries aged 60 years and over receiving services from the HHA.

TABLE 51—MEASURE SET FOR THE HHVBP MODEL BEGINNING PY 4 *—Continued

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Communication & Care Coordination.	Advance Care Plan.	Process	NQF0326	Reported by HHAs through Web Portal.	Patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	All patients aged 65 years and older.
NQS domains	Measure title	Measure type	Identifier	Data source	Measure computation**	Risk adjustment**
Patient and Family Engagement.	Total Normalized Composite Change in Self-Care.	Composite Outcome.	NA	OASIS (M1800) (M1810) (M1820) (M1830) (M1845) (M1870).	The total normalized change in self-care functioning across six OASIS items (grooming, bathing, upper & lower body dressing, toilet hygiene, and eating).	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted - HHA Predicted.
Patient and Family Engagement.	Total Normalized Composite Change in Mobility.	Composite Outcome.	NA	OASIS (M1840) (M1850) (M1860).	The total normalized change in mobility functioning across three OASIS items (toilet transferring, bed transferring, and ambulation/locomotion).	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted - HHA Predicted.

*Notes: For more detailed information on the measures using OASIS refer to the OASIS-C2 Guidance Manual effective January 1, 2017 available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-C2-Guidance-Manual-6-29-16.pdf>. For NQF endorsed measures see The NQF Quality Positioning System available at <http://www.qualityforum.org/QPS>. For non-NQF measures using OASIS see links for data tables related to OASIS measures at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html>. For information on HHCAHPS measures see <https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx>. ** Because the proposed Total Normalized Composite Change in Self-Care and Mobility measures are composite measures rather than simply outcome measures, the terms "Numerator" and "Denominator" do not apply.

We invite public comment on the proposals to remove two OASIS-based measures, Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received, from the set of applicable measures for PY4 and subsequent performance years. We also invite public comment on the proposals to replace three OASIS-based measures, Improvement in Ambulation-Loocomotion, Improvement in Bed Transferring, and Improvement in Bathing, with two proposed composite measures, Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility, for PY4 and subsequent performance years.

3. Proposal To Reweight the OASIS-Based, Claims-Based, and HHCAHPS Measures

In the CY 2016 HH PPS final rule, we finalized weighting measures within each of the HHVBP Model's four classifications (Clinical Quality of Care, Care Coordination and Efficiency, Person and Caregiver-Centered Experience, and New Measures) the

same for the purposes of payment adjustment. We finalized weighting each individual measure equally because we did not want any one measure within a classification to be more important than another measure, to encourage HHAs to approach quality improvement initiatives more broadly, and to address concerns where HHAs may be providing services to beneficiaries with different needs. Under this approach, a measure's weight remains the same even if some of the measures within a classification group have no available data. We stated that in subsequent years of the Model, we would monitor the impact of equally weighting the individual measures and may consider changes to the weighting methodology after analysis and in rulemaking (80 FR 68679).

For PY4 and subsequent performance years, we are proposing to revise how we weight the individual measures and to amend § 484.320(c) accordingly. Specifically, we are proposing to change our methodology for calculating the Total Performance Score (TPS) by weighting the measure categories so that

the OASIS-based measure category and the claims-based measure category would each count for 35 percent and the HHCAHPS measure category would count for 30 percent of the 90 percent of the TPS that is based on performance of the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. Note that these measures and their proposed revised weights would continue to account for the 90 percent of the TPS that is based on the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. Data reporting for each New Measure would continue to have equal weight and account for the 10 percent of the TPS that is based on the New Measures collected as part of the Model. As discussed further below, we believe that this proposed reweighting, to allow for more weight for the claims-based measures, would better support improvement in those measures.

Weights would also be adjusted under this proposal for HHAs that are missing entire measure categories. For example,

if an HHA is missing all HHCAHPS measures, the OASIS and claims-based measure categories would both have the same weight (50 percent each). We believe that this approach would also increase the weight given to the claims-based measures, and as a result give HHAs more incentive to focus on improving them. Additionally, if measures within a category are missing, the weights of the remaining measures within that measure category would be adjusted proportionally, while the weight of the category as a whole would remain consistent. We are also proposing that the weight of the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure would be increased so that it has three times the weight of the Emergency Department Use without Hospitalization claims-based measure, based on our understanding that HHAs may have more control over the Acute Care

Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure. In addition, because inpatient hospitalizations generally cost more than ED visits, we believe improvement in the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health claims-based measure may have a greater impact on Medicare expenditures.

We are proposing to reweight the measures based on our ongoing monitoring and analysis of claims and OASIS-based measures, which shows that there has been a steady improvement in OASIS-based measures, while improvement in claims-based measures has been relatively flat. For example, Figures 5 and 6 show the change in average performance for the claims-based and OASIS-based performance measures used in the Model. For both figures, we report the trends observed in Model and non-

Model states. In both Model and non-Model states, there has been a slight increase (indicating worse performance) in the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health measure. For all OASIS-based measures, except the Improvement in Management of Oral Medications measure and the Discharge to Community measure, there has been substantial improvement in both Model and non-Model states. Given these results, we believe that increasing the weight given to the claims-based measures, and the Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health measure in particular, may give HHAs greater incentive to focus on quality improvement in the claims-based measures. Increasing the weight of the claims-based measures was also supported by the contractor's TEP.

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Figure 5

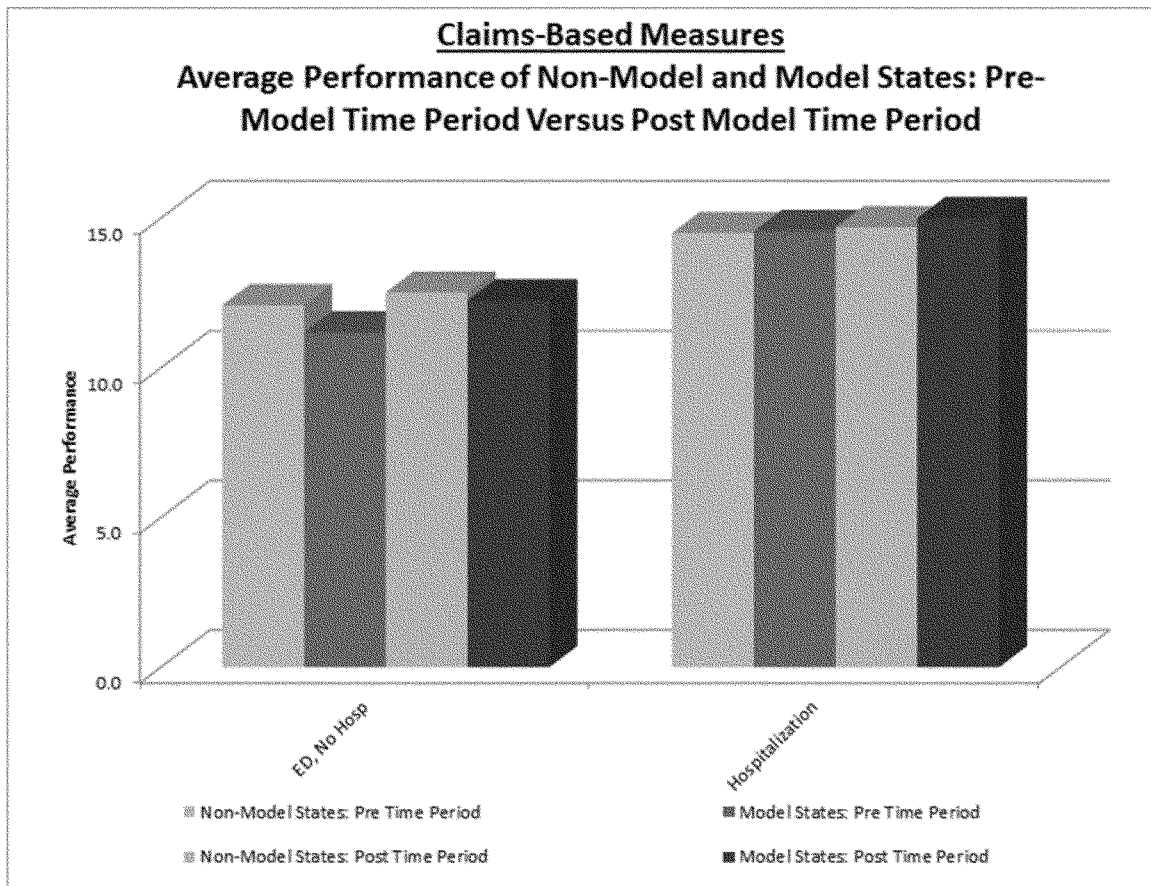


Figure 6

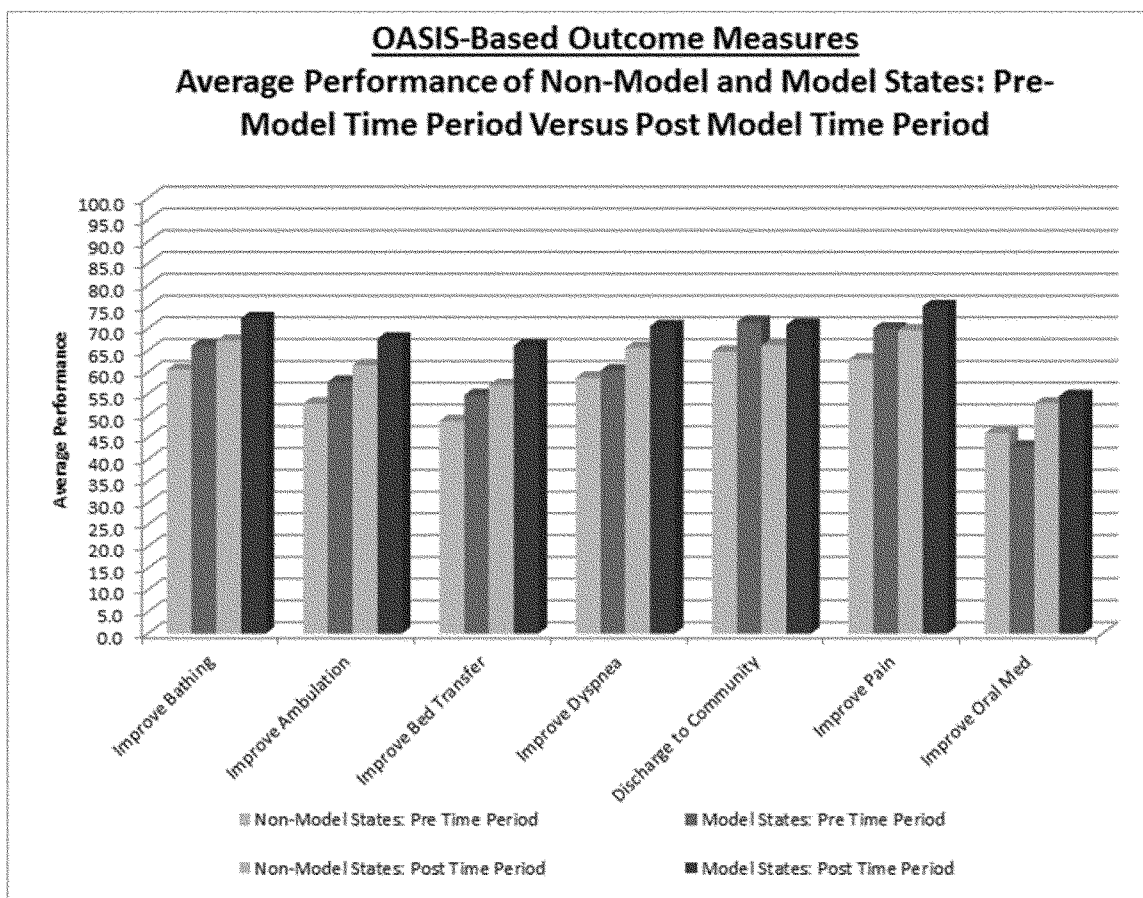


Table 52 shows the current and proposed weights for each measure based on this proposal to change the weighting methodology from weighting each individual measure equally to weighting the OASIS, claims-based, and HHCAHPS measure categories at 35-percent, 35-percent and 30-percent, respectively. Table 52 also shows the proposed weighting methodology based on various scoring scenarios. For example, for HHAs that are exempt from their beneficiaries completing HHCAHPS surveys, the total weight given to OASIS-based measures scores would be 50 percent, with all OASIS-based measures (other than the two

proposed composite measures) accounting for an equal proportion of that 50 percent, and the total weight given to the claims-based measures scores would be 50 percent, with the Acute Care Hospitalization: Unplanned Hospitalizations measure accounting for 37.50 percent and the ED Use without Hospitalization measure accounting for 12.50 percent. Finally, Table 52 shows the change in the number of HHAs, by size, that would qualify for a TPS and payment adjustment under the current and proposed weighting methodologies, using CY 2016 data. We note that Table 52 reflects only the proposed changes to the weighting methodology and not the

other proposed changes to the HHVBP model for CY 2019 which, if finalized, would change the proposed weights as set forth in Table 52. We refer readers to Table 65 in section X. of this proposed rule, which reflects the weighting that would apply if all of our proposed changes, including the proposed changes to the applicable measure set, are adopted for CY 2019. As reflected in that table, the two proposed composite measures, if finalized, would have weights of 7.5 percent when all three measure categories are reported.

TABLE 52: CURRENT AND PROPOSED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES

	Current Weights (equal weighting)				Proposed Weights (OASIS 35%; Claims 35%; HHCAPHS 30%)			
	All Measures (n=1,026)	No HHCAPHS (n=465)	No claims (n=20)	No claims or HHCAPHS (n=99)	All Measures (n=1,026)	No HHCAPHS (n=460)	No claims (n=20)	No claims or HHCAPHS (n=73)
<i>Large HHAs</i>	1023	382	20	49	1023	380	20	39
<i>Small HHAs</i>	3	83	0	50	3	80	0	34
OASIS								
Flu vaccine ever received*	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Pneumococcal vaccine*	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Bathing**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Bed Transfer**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Ambulation**	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Oral Meds	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Dyspnea	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Improve Pain	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
Discharge to Community	6.25%	9.09%	7.14%	11.11%	3.89%	5.56%	5.98%	11.11%
<i>Total weight for OASIS measures</i>	<i>56.25%</i>	<i>81.82%</i>	<i>64.26%</i>	<i>100.00%</i>	<i>35.00%</i>	<i>50.00%</i>	<i>53.85%</i>	<i>100.00%</i>
Claims								
Hospitalizations	6.25%	9.09%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%
Outpatient ED	6.25%	9.09%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%
<i>Total weight for claims measures</i>	<i>12.50%</i>	<i>18.18%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>35.00%</i>	<i>50.00%</i>	<i>0.00%</i>	<i>0.00%</i>
HHCAPHS								
Care of patients	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Communication between provider and patient	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Discussion of specific care issues	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Overall rating of care	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
Willingness to recommend HHA to family or friends	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%
<i>Total weight for HHCAPHS measures</i>	<i>31.25%</i>	<i>0.00%</i>	<i>35.70%</i>	<i>0.00%</i>	<i>30.00%</i>	<i>0.00%</i>	<i>46.15%</i>	<i>0.00%</i>

Notes: *Measures are proposed to be removed from the applicable measure set beginning CY 2019/PY 4.

**Measures are proposed to be removed if proposed composite measures are added to the applicable measure set beginning CY 2019/PY 4.

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 We invite public comment on the proposal to reweight the measures within the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience and Caregiver-Centered Experience classifications so that the OASIS-based measures account for 35-percent, the claims-based measures account for 35-percent, and the HHCAPHS account for 30-percent of the 90 percent of the TPS that is based on performance on these

measures, for PY4 and subsequent performance years. We are also proposing to amend § 484.320 to reflect these proposed changes. Specifically, we are proposing to amend § 484.320 to state that for performance years 4 and 5, CMS will sum all points awarded for each applicable measure within each

category of measures (OASIS-based, claims-based, and HHCAHPS) excluding the New Measures, weighted at 35-percent for the OASIS-based measure category, 35-percent for the claims-based measure category, and 30-percent for the HHCAHPS measure category, to calculate a value worth 90-percent of

the Total Performance Score. Table 53 is a sample calculation to show how this proposal, in connection with the proposed changes to the measure set, would affect scoring under the model as set forth in prior rulemaking (80 FR 68679 through 68686) when all three measure categories are reported.

TABLE 53—SAMPLE HHVBP TOTAL PERFORMANCE SCORE CALCULATION UNDER CURRENT AND PROPOSED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES

	Points for current measures	Current weight (%)	Points for proposed measures	Proposed weight (%)	Weighted points
OASIS:					
Composite self-care	N/A	0.00	7.661	7.50	9.19
Composite mobility	N/A	0.00	5.299	7.50	6.36
Flu vaccine ever received	7.662	6.25	N/A	0.00	N/A
Pneumococcal vaccine	8.162	6.25	N/A	0.00	N/A
Improvement in bathing	5.064	6.25	N/A	0.00	N/A
Improvement in bed transfer	4.171	6.25	N/A	0.00	N/A
Improvement in ambulation	3.725	6.25	N/A	0.00	N/A
Improve oral meds	3.302	6.25	3.302	5.00	2.64
Improve Dyspnea	4.633	6.25	4.633	5.00	3.71
Improve Pain	4.279	6.25	4.279	5.00	3.42
Discharge to community	0.618	6.25	0.618	5.00	0.49
Claims:					
Outpatient ED	0	6.25	0	8.75	0.00
Hospitalizations	1.18	6.25	1.18	26.25	4.96
HHCAHPS:					
Care of patients	10	6.25	10	6.00	9.60
Communication between provider and patient	10	6.25	10	6.00	9.60
Discussion of special care issues	10	6.25	10	6.00	9.60
Overall rating of care	5.921	6.25	5.921	6.00	5.68
Willingness to recommend HHA to family and friends	8.406	6.25	8.406	6.00	8.07
Total	87.123	100.00	100.00	57.776
Total performance score calculation				Current	Proposed
Raw score				87.123	57.776
Scaled score (adjusted for # of measures present)				58.082	57.776
Weighted score (90% of scaled score)				52.274	51.998
New measure score				100.000	100.000
Weighted new measure score (10% of new measure score)				10	10
TPS (sum of weighted score and weighted new measure score)				62.274	61.998

C. Performance Scoring Methodology

1. Proposal To Rescore the Maximum Amount of Improvement Points

In the CY 2016 HH PPS final rule, we finalized that an HHA could earn 0–10 points based on how much its performance in the performance period improved from its performance on each measure in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications during the baseline period. We noted, in response to public comment about our scoring methodology for improvement points, that we would monitor and evaluate the impact of awarding an equal amount of points for both achievement and improvement and may consider changes to the weight of the improvement score relative to the achievement score in

future years through rulemaking (80 FR 68682).

We are proposing to reduce the maximum amount of improvement points, from 10 points to 9 points, for PY4 and subsequent performance years for all measures except for, if finalized, the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which the maximum improvement points would be 13.5. The maximum score of 13.5 represents 90-percent of the maximum 15 points that could be earned for each of the two proposed composite measures. The HHVBP Model focuses on having all HHAs provide high quality care and we believe that awarding more points for achievement than for improvement beginning with PY4 of the model would support this goal. We expect that at this

point several years into participation in the Model, participating HHAs have had enough time to make the necessary investments in quality improvement efforts to support a higher level of care, warranting a slightly stronger focus on achievement over improvement on measure performance.

We believe that reducing the maximum improvement points to 9 would encourage HHAs to focus on achieving higher performance levels and incentivizing in this manner would encourage HHAs to rely less on their improvement and more on their achievement.

This proposal would also be consistent with public comments, and suggestions provided by our contractor’s TEP. As summarized in the CY 2016 HH PPS final rule, we received comments encouraging us to focus on rewarding

the achievement of specified quality scores, and reduce the emphasis on improvement scores after the initial 3 years of the HHVBP Model. Some commenters suggested measuring performance primarily based on achievement of specified quality scores with a declining emphasis over time on improvement versus achievement (80 FR 68682).

The TEP also agreed with reducing the maximum number of improvement points, which they believed would better encourage HHAs to pursue improved health outcomes for beneficiaries. We note that for the Hospital Value-Based Purchasing (HVBP) Program, CMS finalized a scoring methodology where hospitals could earn a maximum of 9 improvement points if their improvement score falls between the improvement threshold and the benchmark (76 FR 26515). Similarly,

HHVBP is now proposing a scoring methodology where HHAs could earn a maximum of 9 improvement points.

We propose that an HHA would earn 0–9 points based on how much its performance during the performance period improved from its performance on each measure in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver-Centered Experience classifications during the baseline period. A unique improvement range for each measure would be established for each HHA that defines the difference between the HHA's baseline period score and the same state level benchmark for the measure used in the achievement scoring calculation, according to the proposed improvement formula. If an HHA's performance on the measure during the performance period was—

- Equal to or higher than the benchmark score, the HHA could

receive an improvement score of 9 points (an HHA with performance equal to or higher than the benchmark score could still receive the maximum of 10 points for achievement);

- Greater than its baseline period score but below the benchmark (within the improvement range), the HHA could receive an improvement score of 0–9 (except for, if finalized, the Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility measures, for which the maximum improvement score would be 15) for each of the two proposed composite measures) based on the formula and as illustrated in the examples below; or,

- Equal to or lower than its baseline period score on the measure, the HHA could receive zero points for improvement.

$$9 \times \left(\frac{\text{HHA Performance Period Score} - \text{HHA Baseline Period Score}}{\text{Benchmark} - \text{HHA Baseline Period Score}} \right) - 0.5$$

2. Examples of Calculating Achievement and Improvement Scores

For illustrative purposes we present the following examples of how the proposed changes to the performance scoring methodology would be applied in the context of the measures in the Clinical Quality of Care, Care Coordination and Efficiency, and Person and Caregiver Centered Experience classifications. These HHA examples are based on data from 2015 (for the baseline period) and 2016 (for the performance year). Figure 7 shows the scoring for HHA 'A' as an example. The benchmark calculated for the improvement in pain measure is 97.676 for HHA A (note that the benchmark is calculated as the mean of the top decile in the baseline period for the state). The achievement threshold was 75.358 (this is defined as the performance of the median or the 50th percentile among HHAs in the baseline period for the state). HHA A's Year 1 performance rate for the measure was 98.348, which

exceeds the benchmark so the HHA earned the maximum 10 points based on its achievement score. Its improvement score is irrelevant in the calculation because measure performance exceeded the benchmark.

Figure 7 also shows the scoring for HHA 'B.' As referenced below, HHA B's performance on this measure went from 52.168 (which was below the achievement threshold) in the baseline period to 76.765 (which is above the achievement threshold) in the performance period. Applying the achievement scale, HHA B' would earn 1.067 points for achievement, calculated as follows: $9 * (76.765 - 75.358) / (97.676 - 75.358) + 0.5 = 1.067$.⁶² Calculating HHA B's improvement score yields the following result: based on HHA B's period-to-period improvement, from 52.168 in the baseline year to

⁶² Achievement points are calculated as $9 * (\text{HHA Performance Year Score} - \text{Achievement Threshold}) / (\text{Benchmark} - \text{Achievement threshold}) + 0.5$.

76.765 in the performance year, HHA B would earn 4.364 points, calculated as follows: $9 * (76.765 - 52.168) / (97.676 - 75.358) - 0.5 = 4.364$.⁶³ Because the higher of the achievement and improvement scores is used, HHA B would receive 4.364 points for this measure.

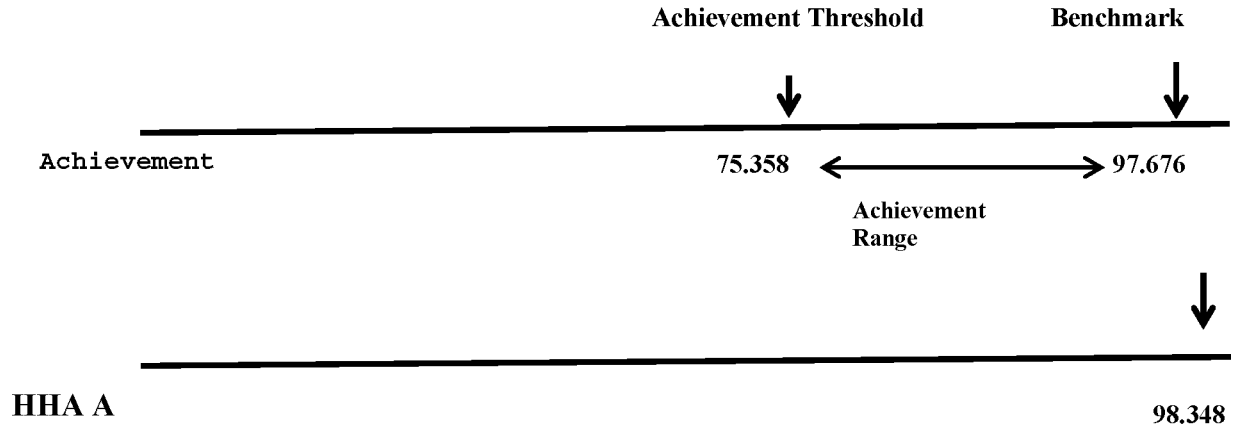
In Figure 8, HHA 'C' yielded a decline in performance on the improvement in pain measure, falling from 70.266 to 58.487. HHA C's performance during the performance period was lower than the achievement threshold of 75.358 and, as a result, the HHA would receive 0 points based on achievement. It would also receive 0 points for improvement, because its performance during the performance period was lower than its performance during the baseline period.

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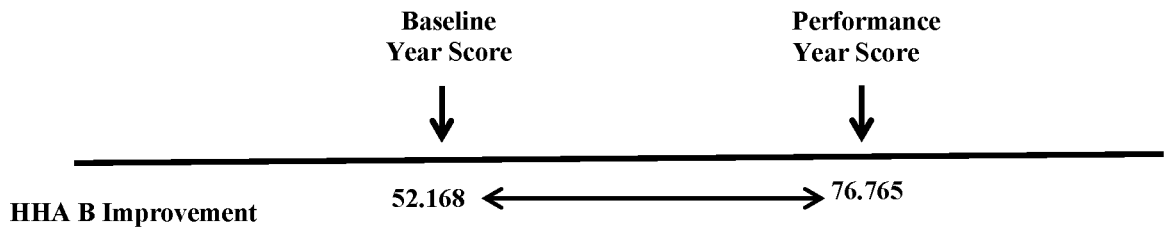
⁶³ The formula for calculating improvement points is $9 * (\text{HHA Performance Year Score} - \text{HHA Baseline Period Score}) / (\text{HHA Benchmark} - \text{HHA Baseline Period Score}) - 0.5$.

FIGURE 7: EXAMPLE OF AN HHA EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

Measure: Improvement in Pain



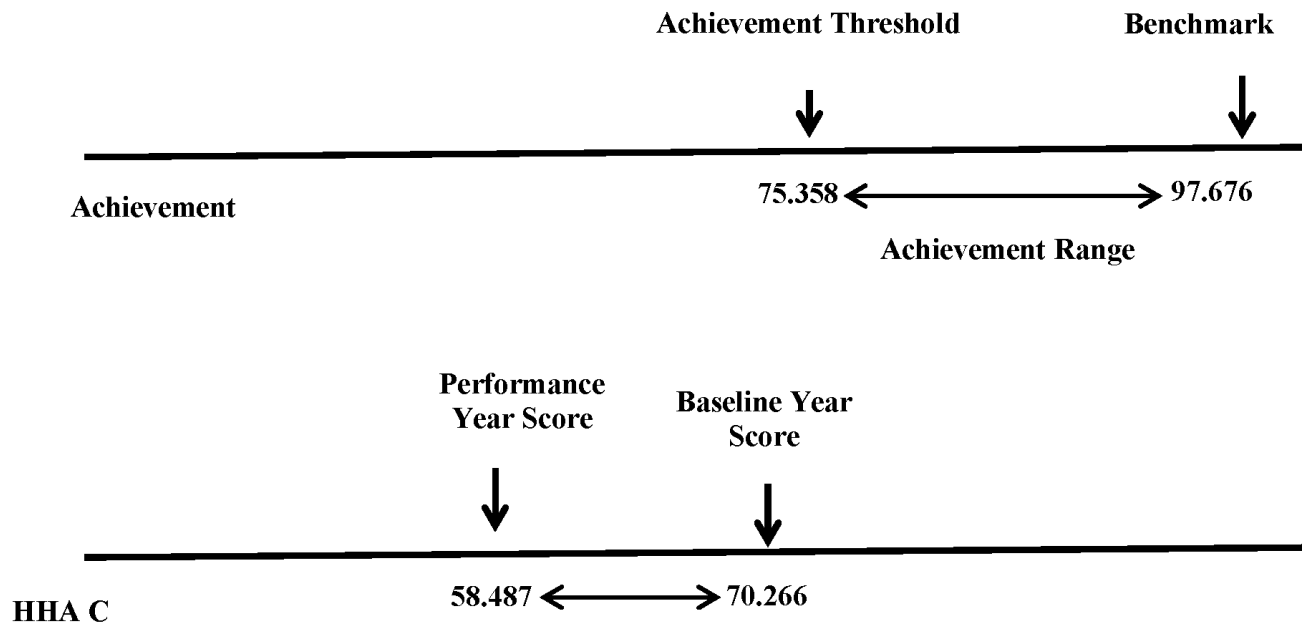
HHA A Score: 10 maximum points for achievement



HHA B Score: The greater of 1.067 points for achievement and 4.364 points for improvement.

FIGURE 8: EXAMPLE OF AN HHA NOT EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

Measure: Improvement in Pain



**HHA C Score: 0 points for improvement
and 0 points for achievement**

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We would monitor and evaluate the impact of reducing the maximum improvement points to 9 and would consider whether to propose more changes to the weight of the improvement score relative to the achievement score in future years through rulemaking.

We invite public comment on the proposal to reduce the maximum amount of improvement points, from 10 points to 9 points for PY 4 and subsequent performance years.

D. Update on the Public Display of Total Performance Scores

In the CY 2016 HH PPS final rule (80 FR 68658), we stated that one of the three goals of the HHVBP Model is to enhance the current public reporting processes. We reiterated this goal and continued discussing the public display of HHAs' Total Performance Scores (TPS) in the CY 2017 HH PPS final rule (81 FR 76751 through 76752). We believe that publicly reporting a participating HHA's TPS will encourage

providers and patients to use this information when selecting an HHA to provide quality care. We are encouraged by the previous stakeholder comments and support for public reporting that could assist patients, physicians, discharge planners, and other referral sources to choose higher-performing HHAs.

In the CY 2017 HH PPS final rule, we noted that one commenter suggested that we not consider public display until after the Model was evaluated. Another commenter favored the public display of the TPS, but recommended that CMS use a transparent process and involve stakeholders in deciding what will be reported, and provide a review period with a process for review and appeal before reporting.

As discussed in the CY 2017 HH PPS final rule, we are considering public reporting for the HHVBP Model after allowing analysis of at least eight quarters of performance data for the Model and the opportunity to compare how these results align with other publicly reported quality data (81 FR

76751). While we are not making a specific proposal at this time, we are soliciting further public comment on what information, specifically from the CY 2017 Annual Total Performance Score and Payment Adjustment Reports and subsequent annual reports, should be made publicly available. We note that HHAs have the opportunity to review and appeal their Annual Total Performance Score and Payment Adjustment Reports as outlined in the appeals process finalized in the CY 2017 HH PPS final rule (81 FR 76747 through 76750). Examples of the information included in the Annual Total Performance Score and Payment Adjustment Report include the agency: Name, address, TPS, payment adjustment percentage, performance information for each measure used in the Model (for example, quality measure scores, achievement, and improvement points), state and cohort information, and percentile ranking. Based on the public comments received, we will consider what information, specifically from the annual reports, we may

consider proposing for public reporting in future rulemaking.

V. Proposed Updates to the Home Health Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the Social Security Act (the Act) requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data with respect to a year in accordance with this clause, the Secretary is directed to reduce the HH market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, for 2015 and each subsequent year (except 2018), the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and further reduction of the increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

For more information on the policies we have adopted for the HH QRP, we refer readers to the CY 2007 HH PPS final rule (71 FR 65888 through 65891), the CY 2008 HH PPS final rule (72 FR 49861 through 49864), the CY 2009 HH PPS update notice (73 FR 65356), the CY 2010 HH PPS final rule (74 FR 58096 through 58098), the CY 2011 HH PPS final rule (75 FR 70400 through 70407), the CY 2012 HH PPS final rule (76 FR 68574), the CY 2013 HH PPS final rule (77 FR 67092), the CY 2014 HH PPS final rule (78 FR 72297), the CY 2015 HH PPS final rule (79 FR 66073 through 66074), the CY 2016 HH PPS final rule (80 FR 68690 through 68695), the CY 2017 HH PPS final rule (81 FR 76752), and the CY 2018 HH PPS final rule (82 FR 51711 through 51712).

Although we have historically used the preamble to the HH PPS proposed and final rules each year to remind stakeholders of all previously finalized program requirements, we have concluded that repeating the same discussion each year is not necessary for every requirement, especially if we have codified it in our regulations.

Accordingly, the following discussion is limited as much as possible to a discussion of our proposals for future years of the HH QRP, and represents the approach we intend to use in our rulemakings for this program going forward.

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

1. Background

For a detailed discussion of the considerations we historically used for measure selection for the HH QRP quality, resource use, and others measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696).

2. Accounting for Social Risk Factors in the HH QRP Program

In the CY 2018 HH PPS final rule (82 FR 51713 through 51714) we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.⁶⁴ Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.⁶⁵ As we noted in the CY 2018 HH PPS final rule (82 FR 51713 through 51714),

⁶⁴ See, for example United States Department of Health and Human Services. "Healthy People 2020: Disparities. 2014." Available at: <http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

⁶⁵ Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), "Report to Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs." December 2016. Available at: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

ASPE's report to Congress, which was required by the IMPACT Act, found that, in the context of value based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. ASPE is continuing to examine this issue in its second report required by the IMPACT Act, which is due to Congress in the fall of 2019. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.⁶⁶ The trial period ended in April 2017 and a final report is available at: http://www.qualityforum.org/SES_Trial_Period.aspx. The trial concluded that "measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship" between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,⁶⁷ allowing further examination of social risk factors in outcome measures.

In the CY 2018/FY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors could be used to stratify or risk adjust the measures (beyond dual eligibility), to consider the full range of differences in patient backgrounds that might affect outcomes, to explore risk adjustment approaches, and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In

⁶⁶ Available at http://www.qualityforum.org/SES_Trial_Period.aspx.

⁶⁷ Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=86357>.

general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, we are considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

C. Proposed Removal Factors for Previously Adopted HH QRP Measures

As a part of our Meaningful Measures Initiative, discussed in section I.D.1 of this proposed rule, we strive to put patients first, ensuring that they, along with their clinicians, are empowered to make decisions about their own healthcare using data-driven information that is increasingly aligned with a parsimonious set of meaningful quality measures. We began reviewing the HH QRP measure set in accordance with the Meaningful Measures Initiative discussed in section I.D.1 of this proposed rule, and we are working to identify how to move the HH QRP forward in the least burdensome manner possible, while continuing to prioritize and incentivize improvement in the quality of care provided to patients.

Specifically, we believe the goals of the HH QRP and the measures used in the program overlap with the Meaningful Measures Initiative priorities, including making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable.

We also evaluated the appropriateness and completeness of the HH QRP's current measure removal factors. In the CY 2017 HH PPS final rule (81 FR 76754 through 76755), we adopted a process for retaining, removing, and replacing previously adopted HH QRP measures. To be consistent with other established quality reporting programs, we are proposing to replace the six criteria used when considering a quality measure for removal, finalized in the CY 2017 HH PPS final rule (81 FR 76754 through 76755), with the following seven measure removal factors, finalized for the LTCH QRP in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), for the SNF QRP in the FY 2016 SNF PPS final rule (80 FR 46431 through 46432), and for the IRF QRP in the CY 2013 OPPTS/ASC final rule (77 FR 68502 through 68503), for use in the HH QRP:

- Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.
- Factor 5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available.
- Factor 6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

We believe these measure removal factors are substantively consistent with the criteria we previously adopted (only we are changing the terminology to call them "factors") and appropriate for use in the HH QRP. However, even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. Examples of such instances

could include when a particular measure addresses a gap in quality that is so significant that removing the measure could result in poor quality, or in the event that a given measure is statutorily required. Furthermore, we note that consistent with other quality reporting programs, we apply these factors on a case-by-case basis.

We finalized in the CY 2017 HH PPS final rule (81 FR 76755) that removal of a HH QRP measure would take place through notice and comment rulemaking, unless we determined that a measure was causing concern for patient safety. Specifically, in the case of a HH QRP measure for which there was a reason to believe that the continued collection raised possible safety concerns, we would promptly remove the measure and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle. In addition, we would immediately notify HHAs and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings. If we removed a measure from the HH QRP under these circumstances but also collected data on that measure under different statutory authority for a different purpose, we would notify stakeholders that we would also cease collecting the data under that alternative statutory authority.

In this proposed rule, we are proposing to adopt an additional factor to consider when evaluating potential measures for removal from the HH QRP measure set:

- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discussed in section I.D.1 of this proposed rule, with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the HH QRP measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to the following:

- Provider and clinician information collection burden and burden associated with the submitting/reporting of quality measures to CMS.
- The provider and clinician cost associated with complying with other HH programmatic requirements.

- The provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs.

- The cost to CMS associated with the program oversight of the measure, including measure maintenance and public display.

- The provider and clinician cost associated with compliance with other federal and state regulations (if applicable).

For example, it may be of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice). It may also be costly for HHAs to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. We may also have to expend resources to maintain the specifications for the measure, including the tools needed to collect, validate, analyze, and publicly report the measure data.

When these costs outweigh the evidence supporting the continued use of a measure in the HH QRP, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the HH QRP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data is of limited use because it cannot be easily interpreted by beneficiaries and used to influence their choice of providers. In these cases, removing the measure from the HH QRP may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on proposed Factor 8 on a case-by-case basis. For example, we may decide to retain a measure that is burdensome for HHAs to report if we conclude that the benefit to

beneficiaries is so high that it justifies the reporting burden. Our goal is to move the HH QRP program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposals to replace the six criteria used when considering a quality measure for removal with the seven measure removal factors currently adopted in the LTCH QRP, IRF QRP, and SNF QRP. We are also inviting public comment on our proposal to adopt new measure removal Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

D. Quality Measures Currently Adopted for the HH QRP

The HH QRP currently has 31 measures for the CY 2020 program year, as outlined in Table 54.

TABLE 54—MEASURES CURRENTLY ADOPTED FOR THE CY 2020 HH QRP

Short name	Measure name & data source
OASIS-Based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Bathing	Improvement in Bathing (NQF #0174).
Bed Transferring	Improvement in Bed Transferring (NQF #0175).
Depression Assessment	Depression Assessment Conducted.
Diabetic Foot Care	Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care (#0519).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) HH QRP.
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Dyspnea	Improvement in Dyspnea.
Falls Risk	Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537).
Influenza	Influenza Immunization Received for Current Flu Season (NQF #0522).
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
PPV	Pneumococcal Polysaccharide Vaccine Ever Received.
Pressure Ulcer/Injury	Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), removed as of January 1, 2019.
	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, effective January 1, 2019.
Surgical Wounds	Improvement in Status of Surgical Wounds (NQF #0178).
Timely Care	Timely Initiation Of Care (NQF #0526).
Claims-Based	
ACH	Acute Care Hospitalization During the First 60 Days of HH (NQF #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173).
ED Use without Readmission	Emergency Department Use without Hospital Readmission During the First 30 Days of HH (NQF #2505).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.

TABLE 54—MEASURES CURRENTLY ADOPTED FOR THE CY 2020 HH QRP—Continued

Short name	Measure name & data source
Rehospitalization	Rehospitalization During the First 30 Days of HH (NQF #2380).
HHCAHPS-Based	
Communication	How well did the home health team communicate with patients.
Overall Rating	How do patients rate the overall care from the home health agency.
Professional Care	How often the home health team gave care in a professional way.
Team Discussion	Did the home health team discuss medicines, pain, and home safety with patients.
Willing to Recommend	Will patients recommend the home health agency to friends and family.

E. Proposed Removal of HH QRP Measures Beginning With the CY 2021 HH QRP

To address the Meaningful Measures Initiative described in section I.D.1 of this proposed rule, we are proposing to remove seven measures from the HH QRP beginning with the CY 2021 HH QRP.

1. Proposed Removal of the Depression Assessment Conducted Measure

We are proposing to remove the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Depression Assessment Conducted Measure beginning with the CY 2010 HH QRP. Depression in the elderly is associated with disability, impaired well-being, service utilization,⁶⁸ and mortality.⁶⁹ This process measure reports the percentage of HH episodes in which patients were screened for depression (using a standardized depression screening tool) at start of care/resumption of care (SOC/ROC). The measure is calculated solely using the OASIS Item M1730, Depression Screening.⁷⁰ Item M1730 is additionally used at SOC/ROC as a risk adjuster in the calculation of several other OASIS-

based outcome measures currently adopted for the HH QRP.⁷¹

In our evaluation of the Depression Assessment Conducted Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (96.8 percent and 99.2 percent, respectively) when compared to the mean and median agency performance scores for this measure in 2010 (88.0 percent and 96.6 percent, respectively) indicate that an overwhelming majority of patients are screened for depression in the HH setting. Further, these performance scores demonstrate the improvement in measure performance since its adoption in the HH QRP. In addition, in 2017 the 75th percentile measure score (100 percent) and the 90th percentile measure score (100 percent) are statistically indistinguishable from each other, meaning that the measure scores do not meaningfully distinguish scores between HHAs. Further, the Truncated Coefficient of Variation (TCV)⁷² for this measure is 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we are proposing to remove the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure

performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M1730, Depression Screening at SOC/ROC for the purposes of this measure beginning January 1, 2020. HHAs would however continue to submit data on M1730 at the time point of SOC/ROC as a risk adjuster for several other OASIS-based outcome measures currently adopted for the HH QRP.⁷³ If finalized as proposed, data for this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

2. Proposed Removal of the Diabetic Foot Care and Patient/Caregiver Education Implemented During All Episodes of Care Measure

We are proposing to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure beginning with the CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes in which diabetic foot care and patient/caregiver education were included in the physician-ordered plan of care and

⁶⁸ Beekman A.T., Deeg D.J., Braam A.W., et al.: Consequences of major and minor depression in later life: A study of disability, well-being and service utilization. *Psychological Medicine* 27:1397–1409, 1997.

⁶⁹ Schulz, R., Beach, S.R., Ives, D.G., Martire, L.M., Ariyo, A.A., & Kop, W.J. (2000). Association between depression and mortality in older adults—The Cardiovascular Health Study. *Archives of Internal Medicine*, 160(12), 1761–1768.

⁷⁰ Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

⁷¹ The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), Improvement in Management of Oral Medications (NQF #0176), and Improvement in Status of Surgical Wounds (NQF #0178).

⁷² The truncated coefficient of variation (TCV) is the ratio of the standard deviation to the mean of the distribution of all scores, excluding the 5 percent most extreme scores. A small TCV (≤ 0.1) indicates that the distribution of individual scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual performance scores.

⁷³ The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), Improvement in Management of Oral Medications (NQF #0176), and Improvement in Status of Surgical Wounds (NQF #0178).

implemented (at the time of or at any time since the most recent SOC/ROC assessment). The measure numerator is calculated using OASIS Item M2401 row a, Intervention Synopsis: Diabetic foot care.⁷⁴

In our evaluation of the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (97.0 percent and 99.2 percent, respectively) when compared to the mean and median agency performance score for this measure in 2010 (86.2 percent and 91.7 percent, respectively), indicate that an overwhelming majority of HH episodes for patients with diabetes included education on foot care. Further, these scores demonstrate the improvement in measure performance since the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure's adoption in the HH QRP. In addition, in 2017 the 75th percentile measure score (100 percent) and the 90th percentile score (100 percent) are statistically indistinguishable from each other, meaning that the measure scores do not meaningfully distinguish between HHAs. Further, the TCV for this measure is 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we are proposing to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M2401 row a, Intervention Synopsis: Diabetic foot care at the time point of Transfer to an Inpatient Facility (TOC) and Discharge from Agency—Not to an Inpatient Facility (Discharge) for the purposes of the HH QRP beginning January 1, 2020. HHAs may enter an equal sign (=) for M2401, row a, at the

⁷⁴ Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

time point of TOC and Discharge on or after January 1, 2020. If finalized as proposed, data for this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

3. Proposed Removal of the Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537) Measure

We are proposing to remove the Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537) Measure⁷⁵ beginning with the CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes in which patients had a multifactor fall risk assessment at SOC/ROC. The measure is calculated using OASIS Item M1910, Falls Risk Assessment.⁷⁶

In our evaluation of the Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537) Measure, we found that HHA performance is very high and that meaningful distinctions in improvements in performance cannot be made. The mean and median agency performance scores for this measure in 2017 (99.3 percent and 100.0 percent, respectively) when compared to the mean and median agency performance score for this measure in 2010 (94.8 percent and 98.9 percent, respectively), indicate that an overwhelming majority of patients in an HHA have had a multifactor fall risk assessment at SOC/ROC and demonstrates the improvement in measure performance since its adoption. In addition, in 2017 the 75th percentile measure score (100 percent) and the 90th percentile measure score (100 percent) are statistically indistinguishable from each other,

⁷⁵ At the time, this measure was adopted as "Falls risk assessment for patients 65 and older." The name of this measure was updated in the CY 2018 HH PPS final rule (82 FR 51717).

⁷⁶ Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

meaning that the measure scores do not meaningfully distinguish between HHAs. Further, the TCV for this measure is 0.01, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.

For these reasons, we are proposing to remove the Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M1910, Falls Risk Assessment at SOC/ROC beginning January 1, 2020. HHAs may enter an equal sign (=) for M1910 at the time point of SOC and ROC beginning January 1, 2020. If finalized as proposed, data for this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

4. Proposed Removal of the Pneumococcal Polysaccharide Vaccine Ever Received Measure

We are proposing to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 3. A measure does not align with current clinical guidelines or practice.

In the CY 2010 HH PPS final rule (74 FR 58096 through 58098), we adopted the Pneumococcal Polysaccharide Vaccine Ever Received Measure beginning with CY 2010 HH QRP. This process measure reports the percentage of HH quality episodes during which patients were determined to have ever received the Pneumococcal Polysaccharide Vaccine. The measure is calculated using OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received.⁷⁷

At the time that this measure was adopted in the HH QRP, the Advisory Committee on Immunization Practices (ACIP),⁷⁸ which sets current clinical

⁷⁷ Measure specifications can be found in the Home Health Process Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Process-Measures-Table_OASIS-C2_4-11-18.pdf).

⁷⁸ The Advisory Committee on Immunization Practices was established under section 222 of the Public Health Service Act (42 U.S.C. 217a), as

guidelines, recommended use of a single dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) among all adults aged 65 years and older and those adults aged 19 to 64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection.⁷⁹

Since this measure was added to the HH QRP, the ACIP has updated its pneumococcal vaccination recommendations.⁸⁰ Two pneumococcal vaccines are currently licensed for use in the United States: the 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal vaccine (PPSV23). The ACIP currently recommends that both PCV13 and PPSV23 be given to all immunocompetent adults aged \geq 65 years. The recommended intervals for sequential administration of PCV13 and PPSV23 depend on several patient factors including: The current age of the adult, whether the adult had previously received PPSV23, and the age of the adult at the time of prior PPSV23 vaccination (if applicable).

The specifications for the Pneumococcal Polysaccharide Vaccine Ever Received Measure do not fully reflect the current ACIP guidelines. Therefore, we believe that the Pneumococcal Polysaccharide Vaccine Ever Received Measure no longer aligns with the current clinical guidelines or practice. For this reason, we are proposing to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 3. A measure does not align with current clinical guidelines or practice.

If finalized as proposed, HHAs would no longer be required to submit OASIS Items M1051, Pneumococcal Vaccine and M1056, Reason Pneumococcal Vaccine not received at the time point

amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs. (Charter of the Advisory Committee on Immunization Practices, filed April 1, 2018. <https://www.cdc.gov/vaccines/acip/committee/ACIP-Charter-2018.pdf>.)

⁷⁹ Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1997;46:1–24.

⁸⁰ Tomczyk S., Bennett N.M., Stoecker C., et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged \geq 65 years: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014;63: 822–5.

of TOC and Discharge for the purposes of the HH QRP beginning January 1, 2020. HHAs may enter an equal sign (=) for Items M1051 and M1056 at the time point of TOC and Discharge on or after January 1, 2020. If finalized as proposed, data for this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

5. Proposed Removal of the Improvement in the Status of Surgical Wounds Measure

We are proposing to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

In the CY 2008 HH PPS final rule (72 FR 49861 through 49863), we adopted the Improvement in the Status of Surgical Wounds Measure for the HH QRP beginning with the CY 2008 program year. This risk-adjusted outcome measure reports the percentage of HH episodes of care during which the patient demonstrates an improvement in the condition of skin integrity related to the surgical wounds. This measure is solely calculated using OASIS Items M1340, Does this patient have a Surgical Wound? and M1342, Status of Most Problematic Surgical Wound that is Observable.⁸¹ Items M1340 and M1342 are also used at the time points of SOC/ROC as risk adjusters in the calculation of several other OASIS-based outcome measures currently adopted for the HH QRP.⁸² Additionally, Items M1340 and M1342 are used at the time point of Discharge for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance that is used by HH surveyors during the survey process.⁸³

⁸¹ Measure specifications can be found in the Home Health Outcomes Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-C2_4-11-18.pdf).

⁸² The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), and Improvement in Management of Oral Medications (NQF #0176).

⁸³ Measure specifications can be found in the Home Health Potentially Avoidable Events Measures Table on the Home Health Quality

The Improvement in the Status of Surgical Wounds Measure is limited in scope to surgical wounds incurred by surgical patients and excludes HH episodes of care where the patient, at SOC/ROC, did not have any surgical wounds or had only a surgical wound that was unobservable or fully epithelialized. As a result, the majority of HHAs are not able to report data on the measure and the measure is limited in its ability to compare how well HHAs address skin integrity. For example, in 2016, only 13 percent of HH patients had a surgical wound at the beginning of their HH episode and only 36.6 percent of HHAs were able to report data on the measure with respect to that year.

In contrast, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) Measure (NQF #0678)⁸⁴ and its replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury Measure more broadly assess the quality of care furnished by HHAs with respect to skin integrity. These measures encourage clinicians to assess skin integrity in the prevention of pressure ulcers, as well as to monitor and promote healing in all HH patients, not just those with surgical wounds.

Therefore, we are proposing to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

If finalized as proposed, HHAs would no longer be required to submit OASIS Items M1340, Does this patient have a Surgical Wound? and M1342, Status of Most Problematic Surgical Wound that is Observable at the time points of SOC/ROC and Discharge for the purposes of this measure beginning with January 1, 2020 episodes of care. However, HHAs would still be required to submit data on Items M1340 and M1342 at the time point of SOC/ROC as risk adjusters for several other OASIS-based outcome measures currently adopted for the HH QRP,⁸⁵ and also at the time point of

Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

⁸⁴ To be replaced with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP.

⁸⁵ The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175),

Discharge for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance⁸⁶ that is used by HH surveyors during the survey process. If finalized as proposed, data on this measure would be publicly reported on HH Compare until January 2021.

We are inviting public comment on this proposal.

6. Proposed Removal of the Emergency Department Use Without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure

We are proposing to remove the Emergency Department (ED) Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available).

In the CY 2014 HH PPS final rule (78 FR 72298 through 72301), we adopted the claims-based ED Use without Hospital Readmission during the first 30 days of HH (NQF #2505) Measure beginning with CY 2014 HH QRP. The particular topic for this measure is ED utilization, as it estimates the risk-standardized rate of ED use without acute care hospital admission during the 30 days following the start of the HH stay for patients with an acute inpatient hospitalization in the 5 days before the start of their HH stay. The ED Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure is limited to Medicare FFS patients with a prior, proximal inpatient stay. Recent analyses from 2016 and 2017 show that this measure annually captured approximately 2.5 million (25.1 percent in 2016 and 25.1 percent in 2017) of Medicare FFS HH stays and was reportable for less than two-thirds of the HHAs (62.1 percent in 2016 and 62.6 percent in 2017).

The ED Use without Hospitalization During the First 60 Days of HH (NQF #0173) Measure also addresses the topic of ED utilization during a HH stay. This measure reports the percentage of Medicare FFS HH stays in which patients used the ED but were not

admitted to the hospital during the 60 days following the start of the HH stay. The ED Use without Hospitalization during the First 60 days of HH (NQF #0173) Measure includes Medicare FFS patients irrespective of whether or not they had an acute inpatient hospitalization in the five days prior to the start of the HH stay and spans the first 60 days of a HH episode. Recent analyses using 2016 and 2017 data show this measure annually captures approximately 8.3 million stays (81.9 percent in 2016 and 81.8 percent in 2017) and is reportable by a greater number of HHAs (88.8 percent in 2016 and 88.1 percent in 2017) than the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure.

The ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure addresses outcomes of Medicare FFS patients for a 30-day interval after the start of their HH care, regardless of the length of their HH stay. The more broadly applicable ED Use without Hospitalization during the First 60 days of HH (NQF #0173) Measure addresses these same outcomes for a greater number of Medicare FFS patients during the first 60 days of a HH stay and includes the 30-day interval of the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure. The measure specifications for both measures are otherwise harmonized along several measure dimensions, including data source, population, denominator exclusions, numerator, and risk adjustment methodology. As a result, removing the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure in favor of the ED Use without Hospitalization during the First 60 days of HH (NQF #173) Measure will not result in a loss of the ability to measure the topic of ED utilization for HH patients.

For these reasons, we are proposing to remove the ED Use without Hospital Readmission During the First 30 Days of HH (NQF #2505) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. If finalized as proposed, data for this measure would be reported on HH Compare until January 2020.

We are inviting public comment on this proposal.

7. Proposed Removal of the Rehospitalization During the First 30 Days of HH (NQF #2380) Measure

We are proposing to remove the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

In the CY 2014 HH PPS final rule (78 FR 72297 through 72301), we adopted the claims-based Rehospitalization during the first 30 Days of HH Measure beginning with the CY 2014 HH QRP. The measure was NQF-endorsed (NQF #2380) in December 2014. The Rehospitalization during the first 30 Days of HH (NQF #2380) Measure addresses the particular topic of acute care hospital utilization during a HH stay. This measure estimates the risk-standardized rate of unplanned, all-cause hospital readmissions for patients who had an acute inpatient hospitalization in the 5 days before the start of their HH stay and were admitted to an acute care hospital during the 30 days following the start of the HH stay (78 FR 72297 through 72301). The Rehospitalization During the First 30 Days of HH (NQF #2380) Measure only includes Medicare FFS patients. Recent analyses from 2016 and 2017 show that this measure annually captured approximately 2.5 million (25.1 percent in 2016 and 25.1 percent in 2017) of Medicare FFS HH stays and was reportable for less than two-thirds of the HHAs (62.1 percent in 2016 and 62.6 percent in 2017).

In the CY 2013 HH PPS final rule (77 FR 67093 through 67094), we finalized the claims-based Acute Care Hospitalization Measure. The measure's title was later updated to Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) to improve clarity.⁸⁷ The Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) Measure also addresses the topic of acute care hospital utilization during a HH stay. This measure reports the percentage of HH stays in which Medicare FFS patients were admitted to an acute care hospital during the 60 days following the start of the HH stay. The Acute Care Hospitalization during the First 60 Days of HH (NQF #0171) Measure includes Medicare FFS patients irrespective of whether or not

Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), and Improvement in Management of Oral Medications (NQF #0176).

⁸⁶ Measure specifications can be found in the Home Health Potentially Avoidable Events Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

⁸⁷ All-Cause Admissions and Readmissions 2015–2017 Technical Report, National Quality Forum, Washington DC, 2017. (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85033>) page 20.

they had an acute inpatient hospitalization in the five days prior to the start of the HH stay and spans the first 60 days of a HH episode. Recent analyses using 2016 and 2017 data show this measure annually captures approximately 8.3 million stays (81.9 percent in 2016 and 81.8 percent in 2017) and is reportable by a greater number of HHAs (88.8 percent in 2016 and 88.1 percent in 2017) than the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure.

The Rehospitalization during the First 30 Days of HH (NQF #2380) Measure addresses outcomes of Medicare FFS patients for a 30-day interval after the start of their HH care, regardless of the length of their HH stay. In contrast, the Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) Measure is broader because it addresses these same outcomes for a greater number of Medicare FFS patients during the first 60 Days of a HH stay, which includes the 30-day interval of the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure. The measure specifications for both measures are otherwise harmonized along several measure dimensions, including data source, population, denominator exclusions, numerator, and risk adjustment methodology. As a result, removing the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure in favor of the Acute Care Hospitalization during the First 60 Days of HH (NQF #0171) Measure will not result in a loss of the ability to measure the topic of acute care hospital utilization across the HH setting.

For these reasons, we are proposing to remove the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for particular topic is available. If finalized as proposed, data for this measure would be publicly reported on HH Compare January 2020.

We are inviting public comment on this proposal.

F. IMPACT Act Implementation Update

In the CY 2018 HH PPS final rule (82 FR 51731), we stated that we intended to specify two measures that would satisfy the domain of accurately communicating the existence and provision of the transfer of health information and care preferences under section 1899B(c)(1)(E) of the Act no later than January 1, 2019 and intend to propose to adopt them for the CY 2021

HH QRP, with data collection beginning on or about January 1, 2020.

As a result of the input provided during a public comment period between November 10, 2016 and December 11, 2016, input provided by a technical expert panel (TEP) convened by our contractor, and pilot measure testing conducted in 2017, we are engaging in continued development work on these two measures, including supplementary measure testing and providing the public with an opportunity for comment in 2018. Further, we reconvened a TEP for these measures in April 2018. We now intend to specify the measures under section 1899B(c)(1)(E) of the Act no later than January 1, 2020, and intend to propose to adopt the measures beginning with the CY 2022 HH QRP, with data collection at the time point of SOC, ROC and Discharge beginning with January 1, 2021. For more information on the pilot testing, we refer readers to: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

G. Form, Manner, and Timing of OASIS Data Submission

Our home health regulations, codified at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HHCAPHS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. We are proposing to revise § 484.250(a) to clarify that not all OASIS data described in § 484.55(b) and (d) are needed for purposes of complying with the requirements of the HH QRP. OASIS data items may be submitted for other established purposes unrelated to the HH QRP, including payment, survey, the HH VBP Model, or care planning. Any OASIS data that are not submitted for the purposes of the HH QRP are not used for purposes of HH QRP compliance.

We are inviting public comment on our proposal to revise our regulations at § 484.250(a) to clarify that not all OASIS data described in § 484.55(b) and (d) are needed for purposes of complying with the requirements of the HH QRP.

H. Proposed Policies Regarding Public Display for the HH QRP

Section 1899B(g) of the Act requires that data and information of PAC provider performance on quality measures and resource use and other measures be made publicly available

beginning not later than 2 years after the applicable specified 'application date'. In the CY 2018 HH PPS final rule (82 FR 51740 through 51741), we finalized that we would publicly display the Medicare Spending Per Beneficiary (MSPB)-PAC HH QRP beginning in CY 2019 based on one year of claims data on discharges from CY 2017.

In this proposed rule, we are proposing to increase the number of years of data used to calculate the MSPB-PAC HH QRP for purposes of display from 1 year to 2 years. Under this proposal, data on this measure would be publicly reported in CY 2019, or as soon thereafter as operationally feasible, based on discharges from CY 2016 and CY 2017. Increasing the measure calculation and public display periods from 1 to 2 years of data increases the number of HHAs with enough data adequate for public reporting for the MSPB-PAC HH QRP measure from 90.7 percent (based on August 1st, 2014—July 31st, 2015 Medicare FFS claims data) to 94.9 percent (based on August 1st, 2014—July 31st, 2016 Medicare FFS claims data). Increasing measure public display periods to 2 years also aligns with the public display periods of these measures in the IRF QRP, LTCH QRP and SNF QRP.

We invite public comment on our proposal to increase the number of years of data used to calculate the MSPB-PAC HH QRP for purposes of display from 1 year to 2 years.

I. Home Health Care Consumer Assessment of Healthcare Providers and Systems® (HHCAPHS)

We are not proposing changes to the Home Health Care Consumer Assessment of Healthcare Providers and Systems® (HHCAPHS) Survey requirements for CY 2019. Therefore, HHCAPHS Survey requirements are as codified in § 484.250 and the HHCAPHS survey vendors' data submission deadlines are as posted on HHCAPHS website at <https://homehealthcahps.org>.

VI. Medicare Coverage of Home Infusion Therapy Services

In this section of the rule, we discuss the new home infusion therapy benefit that was established in section 5012 of the 21st Century Cures Act. This benefit covers the nursing, patient training and education, and monitoring services associated with administering infusion drugs in a patient's home. This proposed rule would establish health and safety standards for home infusion therapy and consistency in coverage for home infusion therapy services. Section 1861(iii)(3)(D)(III) of the Act, as added

by section 5012(b) of the 21st Cures Act, requires that a qualified home infusion therapy supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and modifying the list of designated AOs. Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021. In addition, this proposed rule establishes regulations for the approval and oversight of accrediting organizations that provide accreditation to home infusion therapy suppliers. This rule also provides information on temporary transitional payments for home infusion therapy services for CYs 2019 and 2020, as mandated by section 50401 of the BBA of 2018, proposes a regulatory definition of “Infusion Drug Administration Calendar Day”, and solicits comments regarding payment for home infusion therapy services for CY 2021 and subsequent years as required by section 5012(d) of the 21st Century Cures Act.

A. General Background

1. Overview

Infusion drugs and administration services can be provided in multiple health care settings, including inpatient hospitals, skilled nursing facilities (SNFs), hospital outpatient departments (HOPDs), physician offices, and in the home. Traditional Fee-for-Service (FFS) Medicare provides coverage for infusion drugs, equipment, supplies, and administration services. However, Medicare coverage requirements and payment vary for each of these settings. Infusion drugs, equipment, supplies, and administration are all covered by Medicare in the inpatient hospital, SNFs, HOPDs, and physician’s offices. Generally, Medicare payment under Part A for the drugs, equipment, supplies, and services are bundled, meaning a single payment is made on the basis of expected costs for clinically-defined episodes of care. For example, if a beneficiary is receiving an infusion drug during an inpatient hospital stay, the Part A payment for the drug, supplies, equipment, and drug administration is included in the diagnosis-related group (DRG) payment to the hospital under the Medicare inpatient prospective payment system. Beneficiaries are liable for the Medicare inpatient hospital deductible. Similarly, if a beneficiary is receiving an infusion drug while in a SNF under a Part A stay, the payment for the drug,

supplies, equipment, and drug administration are included in the SNF prospective payment system payment. After 20 days of SNF care, there is a daily beneficiary cost-sharing amount through day 100 when the beneficiary becomes responsible for all costs for each day after day 100 of the benefit period. Under Medicare Part B, certain items and services are paid separately while other items and services may be packaged into a single payment together. For example, in an HOPD and in a physician’s office, the drug is paid separately, generally at the average sales price (ASP) plus 6 percent. There is also a separate payment for drug administration in which the payment for infusion supplies and equipment is packaged in the payment for administration. The separate payment for infusion drug administration in an HOPD and in a physician’s office generally includes a base payment amount for the first hour and a payment add-on that is a different amount for each additional hour of administration. The beneficiary is responsible for the 20 percent coinsurance under Medicare Part B. Medicare FFS covers outpatient infusion drugs under Part B, “incident to” a physician’s services, provided the drugs are not usually self-administered by the patient. Drugs that are “not usually self-administered,” are defined in our manual according to how the Medicare population as a whole uses the drug, not how an individual patient or physician may choose to use a particular drug. For the purpose of this exclusion, the term “usually” means more than 50 percent of the time for all Medicare beneficiaries who use the drug. The term “by the patient” means Medicare beneficiaries as a collective whole. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from Part B coverage. This determination is made on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.⁸⁸ The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.⁸⁹

Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home. Certain drugs can be infused in the home, but the nature of the home setting presents different challenges than the settings previously described. The components needed to perform home infusion

include the drug (for example, antibiotics, immune globulin), equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are necessary to train and educate the patient and caregivers on the safe administration of infusion drugs in the home. Visiting nurses often play a large role in home infusion. Nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to provide catheter and site care. Depending on patient acuity or the complexity of the drug administration, certain infusions may require more nursing time, especially those that require special handling or pre- or post-infusion protocols. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies. With regard to payment for home infusion therapy under traditional Medicare, drugs are generally covered under Part B or Part D. Certain infusion pumps, supplies (including home infusion drugs), and nursing are covered in some circumstances through the Part B durable medical equipment (DME) benefit, the Medicare home health benefit, or some combination of these benefits.

Medicare Part B covers a limited number of home infusion drugs through the DME benefit if: (1) The drug is necessary for the effective use of an external or implantable infusion pump classified as DME and determined to be reasonable and necessary for administration of the drug; and (2) the drug being used with the pump is itself reasonable and necessary for the treatment of an illness or injury. Only certain types of infusion pumps are covered under the DME benefit. The Medicare *National Coverage Determinations Manual*, chapter 1, part 4, § 280.1 describes the types of infusion pumps that are covered under the DME benefit.⁹⁰ For DME infusion pumps, Medicare Part B covers the infusion drugs and other supplies and services necessary for the effective use of the pump, but does not explicitly require or pay separately for any associated home infusion nursing services beyond what is necessary for teaching the patient and/or caregiver on how to operate the equipment in order to administer the

⁸⁸ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.

⁸⁹ www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D.

⁹⁰ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMS-Items/CMS014961.html>.

infusion safely and effectively.⁹¹ Through local coverage policies, the DME Medicare administrative contractors (MACs) specify the details of which infusion drugs are covered with these pumps. Examples of covered Part B DME infusion drugs include, among others, certain IV drugs for heart failure and pulmonary arterial hypertension, immune globulin for primary immune deficiency (PID), insulin, antifungals, antivirals, and chemotherapy, in limited circumstances.

2. Home Infusion Therapy Legislation

Section 5012 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) creates a separate Medicare Part B benefit category under 1861(s)(2)(GG) of the Act for coverage of home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously, or subcutaneously through a pump that is an item of DME, effective January 1, 2021. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the DME benefit. Section 1861(iii)(2) of the Act defines home infusion therapy to include the following items and services: the professional services (including nursing services), furnished in accordance with the plan, training and education (not otherwise included in the payment for the DME), remote monitoring, and other monitoring services for the provision of home infusion therapy furnished by a qualified home infusion therapy supplier in the patient's home. Section 1861(iii)(3)(B) of the Act defines the patient's home to mean a place of residence used as the home of an individual as defined for purposes of section 1861(n) of the Act. As outlined in section 1861(iii)(1) of the Act, i to be eligible to receive home infusion therapy services under the home infusion therapy benefit, the patient must be under the care of an applicable provider, defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant, and the patient must be under a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. The plan of care must be periodically reviewed by the physician in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C) of the

Act). Section 1861(iii)(3)(C) of the Act defines a "home infusion drug" under the home infusion therapy benefit as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the patient's home, through a pump that is an item of DME as defined under section 1861(n) of the Act. This definition does not include insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list.

Section 1861(iii)(3)(D)(i) of the Act defines a qualified home infusion therapy supplier as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are provided. The provision specifies qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an organization designated by the Secretary; and meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector. The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of medical services, in order to meet these requirements.

Section 1834(u) of the Act requires the Secretary to implement a payment system under which a single payment is made to a home infusion therapy supplier for the items and services (professional services, including nursing services; training and education; remote monitoring, and other monitoring services), beginning January 1, 2021. The single payment must take into account, as appropriate, types of infusion therapy, including variations in utilization of services by therapy type. In addition, the single payment amount is required to be adjusted to reflect geographic wage index and other costs that may vary by region, patient acuity, and complexity of drug administration. The single payment may be adjusted to reflect outlier situations, and other factors as deemed appropriate by the Secretary, which are required to be done in a budget neutral manner. Section 1834(u)(3) of the Act specifies that annual updates to the single payment are required to be made beginning January 1, 2022, by increasing the single payment amount by the percent increase in the Consumer Price Index (CPI) for all

urban consumers for the 12-month period ending with June of the preceding year, reduced by the multi-factor productivity adjustment. The unit of single payment for each infusion drug administration calendar day, including the required adjustments and the annual update, cannot exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services if furnished in a physician's office, and the single payment amount cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Section 1834(u)(4) of the Act also allows the Secretary discretion, as appropriate, to consider prior authorization requirements for home infusion therapy services. Finally, section 5012(c)(3) of the Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the HH PPS beginning on January 1, 2021.

B. Proposed Health and Safety Standards for Home Infusion Therapy

1. Introduction

Section 5012 of the Cures Act requires that, to receive payment under the Medicare home infusion therapy benefit, home infusion therapy suppliers must select a CMS-approved accreditation organization (AO) and undergo an accreditation review process to demonstrate that the home infusion therapy supplier meets the AO's standards. Section 1861(iii) of the Act, as added by section 5012 of the Cures Act, sets forth four elements for home infusion therapy in the following areas: (1) Requiring that the patient be under the care of a physician, nurse practitioner, or physician assistant; (2) requiring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient specific needs; (3) providing patients with education and training on the effective use of medications and equipment in the home (not otherwise paid for as durable medical equipment); and (4) providing monitoring and remote monitoring services associated with administering infusion drugs in a patient's home.

The Journal of Infusion Nursing standards of practice specifically address patient education, and state that it is the clinician's role to educate the patient, caregiver, and/or surrogate about the prescribed infusion therapy and plan of care including, but not limited to, purpose and expected outcome(s) and/or goals of treatment, infusion therapy administration; infusion device-related care; potential

⁹¹ See 42 CFR 424.57(c)(12), which states that the DME "supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively."

complications; or adverse effects associated with treatment. (Infusion Therapy Standards of Practice, 2015).⁹²

Currently, standards for home infusion therapy have been established by the current AOs; however, they are not necessarily consistent. In order to assure consistency in the areas identified in the Act, we are establishing basic standards that all AOs would be required to meet or exceed. We are proposing universal standards for Medicare-participating qualified home infusion therapy suppliers to ensure the quality and safety of home infusion therapy services for all beneficiaries that these suppliers serve.

In preparation for developing these standards and to gain a clear understanding of the current home infusion therapy supplier private sector climate, we reviewed the requirements established by section 5012 of the Cures Act, performed an extensive review of the standards from all six AOs that accredit home infusion suppliers (The Joint Commission, Accreditation Commission for Health Care, Compliance Team, Community Health Accreditation Partner, Healthcare Quality Association on Accreditation, and National Association of Boards of Pharmacy), and reviewed various other government and industry publications listed in this proposed rule. In addition to the standards, we reviewed the following documents related to coverage:

- Government Accountability Office—10–426 report, which describes the state of coverage of home infusion therapy components under Medicare fee-for-service prior to the enactment of the Cures Act (GAO, 2010).⁹³

- Medicare and Home Infusion white paper written by the National Home Infusion Association (NHIA), which provided an overview of Medicare coverage provided for Home Infusion Therapy services prior to the enactment of the Cures Act, as well as results of a study conducted by Avalere Health on the potential savings that could result from Medicare coverage of infusion therapy provided in the home (National Home Infusion Therapy Association, NDS).⁹⁴

⁹² Infusion Therapy: Standards of Practice, Journal of Infusion Nursing, Wolters Kluwer: Jan/Feb 2016 pp S25–S26

⁹³ Government Accountability Office. (2010). Home Infusion Therapy. Differences between Medicare and Private Insurers' coverage. (GAO Publication No. 10–426). Washington, DC: U.S. Government Printing Office.

⁹⁴ National Home Infusion therapy Association. Medicare and Home Infusion White Paper. Retrieved from <https://www.nhia.org/resource/legislative/documents/NHIAWhitePaper-Web.pdf>.

- American Society of Health System Pharmacists Guidelines on Home Infusion Pharmacy Services, which provided an in-depth overview of specialized, complex pharmaceuticals, best practices on providing home infusion therapy in the home or alternative site settings, and the plans to execute and manage the therapy (American Society of Health-System Pharmacists. ASHP guidelines on Home Infusion Pharmacy Service, 2014).⁹⁵

- The requirements of numerous Medicare Advantage plans, Medicare FFS, and private insurance plans.

Upon review of these materials, we believe that there is a sufficient private-sector framework already in place to address many of the areas that would typically be included in the establishment of basic health and safety standards for home infusion therapy. For example, existing AO standards include requirements related to plan of care, monitoring, patient assessment, quality improvement, and infection control. While the exact content of the AO standards vary, we believe that the standards are adequate to ensure patient health and safety. The AO representing the largest number of home infusion therapy suppliers requires that home infusion pharmacies provide certain services to ensure safe and appropriate therapy, in compliance with nationally recognized standards of practice. Patient training and education activities, as part of their required admission procedures, include the use of medical and disposable equipment, medication storage, emergency procedures, vascular access device management, recognition of a drug reaction, and when to report any adverse drug event. As such, we conclude that it is appropriate at this time to propose requirements for only those elements specifically identified in section 1861(iii) of the Act. Through the CMS accreditation organization process, we would monitor home infusion therapy suppliers to assure that services are provided in a safe and effective manner, and would consider future rulemaking to address any areas that may need improvement in the future. We are seeking public comment on this approach and invite comments related to the home infusion therapy proposed standards. Specifically, are the standards sufficient for Medicare beneficiaries, should CMS consider additional standards and would

⁹⁵ American Society of Health-System Pharmacists. ASHP guidelines on Home Infusion Pharmacy Service, 2014. Retrieved from: <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/home-infusion-pharmacy-services.ashx?la=en&hash=255092A51D0AE4746C151C51AC7BF82217AC2F76>.

additional standards impose additional burden?

2. Home Infusion Therapy Supplier Requirements (Proposed Part 486, Subpart I)

We propose to add a new 42 CFR part 486, subpart I, to incorporate the home infusion therapy supplier requirements. The proposed regulations would provide a framework for CMS to approve home infusion therapy accreditation organizations and give them the authority to approve Medicare certification for home infusion therapy suppliers. Proposed subpart I would include General Provisions (Basis and Scope, and Definitions) and Standards for Home Infusion Therapy (Plan of Care and Required Services).

a. Basis and Scope (Proposed § 486.500)

We propose to set forth the basis and scope of part 486 at § 486.500. Part 486 is based on sections 1861(iii)(2)(D) of the Act, which establishes the requirements that a home infusion therapy supplier must meet in order to participate in the Medicare program. These provisions serve as the basis for survey activities for the purposes of determining whether a home infusion therapy supplier meets the requirements for participation in Medicare. Section 1834(u) of the Act serves as the basis for the establishment of a prospective payment system for home infusion therapy covered under Medicare. In addition, 1834(u)(5) of the Act establishes the factors for the Secretary to designate organizations to accredit suppliers furnishing home infusion therapy and requires that organizations be designated not later than January 1, 2021.

b. Definitions (Proposed § 486.505)

At § 486.505, we propose to define certain terms that would be used in the home infusion therapy requirements. We propose to define the terms “applicable provider”, “home”, “home infusion drug”, and “qualified home infusion therapy supplier” in accordance with the definitions set forth in section 1861(iii) of the Act. Furthermore, section 1861(iii) of the Act includes a definition of the term “home infusion therapy” that is the basis of the proposed health and safety requirements set forth in this rule. In accordance with the Act, we propose the following definitions:

- “Applicable provider” would mean a physician, a nurse practitioner, and a physician assistant.
- “Home” would mean a place of residence used as the home of an individual, including an institution that

is used as a home. However, an institution that is used as a home may not be a hospital, CAH, or SNF as defined in sections 1861(e), 1861(mm)(1), and 1819 of the Act, respectively.

- “Home infusion drug” would mean a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

- “Qualified home infusion therapy supplier” would mean a supplier of home infusion therapy that meets all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act: (1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act; and (4) meets such other requirements as the Secretary determines appropriate.

c. Standards for Home Infusion Therapy

Proposed subpart I, as required by section 5012 of the Cures Act, would specify that the qualified home infusion therapy supplier ensure that all patients have a plan of care established by a physician.

(1) Plan of Care (Proposed § 486.520)

At § 486.520(a), we propose to require that all patients must be under the care of an “applicable provider” as defined at § 486.505. At § 486.520(b) we would require that the qualified home infusion therapy supplier ensure that all patients must have a plan of care established by a physician that prescribes the type, amount, and duration of home infusion therapy services that are furnished. The plan of care would also include the specific medication, the prescribed dosage and frequency as well as the professional services to be utilized for treatment. In addition, the plan of care would specify the care and services necessary to meet the patient-specific needs.

We also propose, at § 486.520(c), that the qualified home infusion therapy supplier must ensure that the plan of care for each patient is periodically reviewed by the physician. We do not propose to establish a specific time

frame for review requirements, but the expectation is that the physician is active in the patient’s care and can make appropriate decisions related to the course of therapy if changes are necessary in regards to the progress of the patient and goal achievement with the infusion therapy. We welcome comments regarding the proposed home infusion therapy plan of care requirements and if we should include specific review timeframes for the plan of care.

(2) Required Services (Proposed § 486.525)

Section 1861(iii)(2)(D)(II) of the Act specifically mandates that qualified home infusion therapy suppliers ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis. Infusion drugs are administered directly into a vein or under the skin, eliciting a more rapid clinical response than with oral medications. Consequently, an adverse effect or a medication error could result in a quicker and/or more severe complication. Therefore, at § 486.525(a), we propose to require the provision of professional services, including nursing services, furnished in accordance with the plan of care. We propose to require that home infusion therapy suppliers ensure that professional services are available on a 7-day-a-week, 24-hour-a-day basis in order to ensure that patients have access to expert clinical knowledge and advice in the event of an urgent or emergent infusion-related situation. This proposed requirement is imperative, as the success of home infusion therapy is often dependent upon the professional services being available during all hours and days of the week that allows for the patient to safely and effectively manage all aspects of treatment.

At § 486.525(b), we propose to require patient training and education, not otherwise paid for as durable medical equipment, and as described in 42 CFR 424.57(c)(12). This proposed requirement is consistent with section 1861(iii)(2)(B). In addition, the proposed patient training and education requirements are consistent with standards that are already in place, as established by the current AOs of home infusion therapy suppliers. This is a best practice, as home infusion therapy may entail the use of equipment and supplies with which patients’ may not be comfortable or familiar.

At § 486.525(c), we propose to require qualified home infusion therapy suppliers to provide remote monitoring and monitoring services for the provision of home infusion therapy

services and home infusion drugs furnished by a qualified home infusion therapy supplier. This proposed requirement is also consistent with section 1861(iii)(2)(B). Monitoring the patient receiving infusion therapy in their home is a vital standard of practice that is an integral part of providing medical care to patients in their home.⁹⁶ The expectation is that home infusion therapy suppliers would provide ongoing patient monitoring and continual reassessment of the patient to evaluate response to treatment, drug complications, adverse reactions, and patient compliance. Remote monitoring may be completed through follow-up telephone or other electronic communication, based on patient preference of communication. However, we do not propose to limit remote monitoring to these methods. Suppliers would be permitted to use all available remote monitoring methods that are safe and appropriate for their patients and clinicians and as specified in the plan of care as long as adequate security and privacy protections are utilized. Monitoring may also be performed directly during in-home patient visits. Additional discussion on remote monitoring and monitoring services can be found in section II.C.2.d. of this proposed rule. We invite the public to submit comments regarding the proposed home infusion therapy supplier service requirements.

C. Approval and Oversight of Accrediting Organizations for Home Infusion Therapy Suppliers

1. Background

Section 1861(iii)(3)(D)(III) of the Social Security Act (the Act), as added by section 5012(b) of the Cures Act, requires that a home infusion therapy supplier be accredited by an AO designated by the Secretary in accordance with section 1834 (u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and modifying the list of designated AOs. These statutory factors are: (1) The ability of the organization to conduct timely reviews of accreditation applications; (2) the ability of the organization take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act); (3) whether the organization has established reasonable fees to be charged to suppliers applying for accreditation; and, (4) such other factors as the Secretary determines appropriate.

⁹⁶ Infusion Therapy: Standards of Practice, Journal of Infusion Nursing, Wolters Kluwer: Jan/ Feb 2016 pp S25–S26.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit home infusion therapy suppliers furnishing home infusion therapy not later than January 1, 2021. However, at this time, there are six AOs that are providing accreditation to home infusion therapy suppliers. These AOs are: (1) The Joint Commission (TJC); (2) Accreditation Commission for Health Care (ACHC); (3) Compliance Team (TCT); (4) Community Health Accreditation Partner (CHAP); (5) Healthcare Quality Association on Accreditation; and (6) National Association of Boards of Pharmacy. These AOs are accrediting home infusion therapy suppliers as part of the deeming accreditation of home health agencies. However, these AOs have not been separately approved by Medicare for accreditation of home infusion therapy services.

We are proposing to publish a solicitation notice in the **Federal Register**, in which we would invite national AOs to apply to accredit home infusion therapy suppliers for the Medicare program. We are proposing that this solicitation notice would be published after the final rule is published, so that we can designate AOs to accredit home infusion therapy suppliers by no later than January 1, 2021 as required by 1834(u)(5)(B) of the Act. Any AOs that respond to this solicitation notice would be required to submit an application for CMS approval of their home infusion therapy accreditation program. The application submitted by an AO that respond to the solicitation notice would be required to meet all requirements set forth in proposed § 488.1010 and demonstrate that their substantive requirements are equal to or more stringent than our proposed regulations at part 485, subpart I.

Section 1861(iii)(3)(D) of the Act requires “qualified home infusion therapy suppliers” to be accredited by a CMS-approved AO. We are also proposing that, in order for the home infusion therapy suppliers accredited by the six AOs that currently provide non-Medicare approved home infusion therapy accreditation to continue receiving payment for the home infusion therapy services they provide, the 6 existing AOs must submit applications to CMS for Medicare approval of their home infusion therapy accreditation program. The accreditation currently being provided by these six AOs to the home infusion therapy suppliers is part of another accreditation program that has not been separately approved by CMS. These AOs have not submitted an application

to CMS for approval of a specific home infusion therapy accreditation program that meets the requirements of section 1861(iii) and section 1834(u)(5) of the Act; therefore, CMS has not been able to determine whether the home infusion therapy accreditation program standards used by these AOs meets or exceeds those of Medicare.

We are proposing that the home infusion therapy accreditation program submitted to CMS by these existing AOs be a separate and distinct accreditation program from the AO’s home health accreditation program. This would mean that these AOs must have a separate accreditation program with separate survey processes and standards for the accreditation of home infusion therapy suppliers. In addition, we would require that the application submitted by the six AOs that currently provide non-Medicare approved accreditation to home infusion therapy suppliers meet the requirements set forth in the proposed regulations at § 488.1010 and enforce the substantive health and safety standards proposed to be set out at 42 CFR part 485, subpart I.

Section 1834(u)(5)(C)(ii) of the Act states that in the case where the Secretary removes a home infusion therapy AO from the list of designated home infusion therapy AOs, any home infusion therapy supplier that is accredited by the home infusion therapy AO during the period beginning on the date on which the home infusion therapy AO is designated as a CMS-approved home infusion therapy AO and ending on the date on which the home infusion therapy AO is removed from such list, shall be considered to have been accredited by an home infusion therapy AO designated by the Secretary for the remaining period such accreditation is in effect. Under section 1834(u)(5)(D) of the Act, in the case of a home infusion therapy supplier that is accredited before January 1, 2021 by a home infusion therapy AO designated by the Secretary as of January 1, 2019, such home infusion therapy supplier shall be considered to be accredited by a home infusion therapy AO designated by the Secretary as of January 1, 2023, for the remaining period such accreditation is in effect. Home infusion therapy suppliers are required to receive accreditation before receiving Medicare payment for services provided to Medicare beneficiaries.

Section 1861(iii)(3)(D) of the Act defines “qualified home infusion therapy suppliers” as being accredited by a CMS-approved AO. CMS is proposing to establish regulations for the approval and oversight of AOs that

accredit home infusion therapy suppliers that address the following: (1) The required components to be included in a home infusion therapy AO’s initial or renewal application for CMS approval of the AO’s home infusion therapy accreditation program; (2) the procedure for CMS’ review and approval of the home infusion therapy AOs application for CMS approval of its home infusion therapy accreditation program; and (3) the ongoing monitoring and oversight of CMS-approved home infusion therapy AOs.

2. Proposed Process and Standards for Home Infusion Therapy Accreditation and the Approval and Oversight of Accrediting Organizations With CMS-Approved Accreditation Programs for Home Infusion Therapy Services

a. Establishment of Regulatory Requirements

We propose to establish new regulations in a new subpart L in 42 CFR part 488 that would govern CMS’ approval and oversight of AOs that accredit home infusion therapy suppliers. We believe these proposed new regulations would provide CMS with reasonable assurance that the home infusion therapy AO’s accreditation program requirements are consistent with the appropriate Medicare accreditation program requirements. Further, we believe that these proposed regulations would provide CMS with a way to provide oversight for AOs that accredit home infusion therapy suppliers, and provide CMS with authority over the home infusion therapy suppliers.

We are proposing to implement a comprehensive, consistent and standardized set of AO oversight regulations for accreditors of home infusion therapy suppliers. It is our intention to provide home infusion therapy AOs with the flexibility to innovate within the framework of these proposed regulations while assuring that their accreditation standards meet, or exceed the appropriate Medicare requirements, and their survey processes are comparable to those of Medicare. “Flexibility to innovate” means that AOs retain the freedom to develop their own accreditation standards and survey processes, so long as the AO ensures that they meet the proposed health and safety standards (contained in 42 CFR part 486, subpart B) and the AO meets the requirements of the proposed AO approval and oversight regulations.

The proposed regulations would reflect requirements similar to those in place for the oversight of national AOs

for Medicare-certified providers and suppliers which are codified at 42 CFR 488.1 through 488.9 and 42 CFR part 489, but would be modified, as appropriate, to be applicable for accreditors of home infusion therapy suppliers. We believe that it is important to have AO approval and oversight regulations that are as consistent as possible across all AOs and to treat all AOs in a similar manner.

b. Consideration of Existing Regulations

In formulating our approach to implementing the statutory requirements related to accreditation organizations, we had considered using the regulations at 42 CFR 488.1 to 488.13 for the approval and oversight of AOs that accredit home infusion therapy suppliers. However, we decided not to do so because Congress, by setting out separate accreditation organization approval standards for home infusion therapy suppliers at 1834(u)(5)(A) of the Act, intended approval for this accreditation program to be a discrete process. We believe that having a separate set of approval regulations applicable only to home infusion therapy suppliers will best reflect Congress's intent.

Only limited portions of the regulations at §§ 488.1 through 488.13 would apply to AOs that accredit home infusion therapy suppliers. For example, § 488.6, which provides that a supplier or provider that has been granted "deemed status" by CMS by virtue of its accreditation from a CMS-approved accreditation program is eligible to participate in the Medicaid program if they are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements would not apply to home infusion therapy suppliers because home infusion therapy suppliers cannot be deemed. The deeming process only applies to certain types of Medicare certified providers and suppliers, such as hospitals.

Section 488.7 titled "Release and use of accreditation surveys" and § 488.8 titled "Ongoing review of accrediting organizations" would apply to AOs that accredit home infusion therapy suppliers. However, § 488.9 titled "Validation surveys" would not apply to home infusion therapy suppliers because the State Survey Agency (SA) only performs validation surveys for Medicare providers that have an agreement with Medicare. Home infusion therapy suppliers are enrolled in the Medicare program but do not enter into an agreement with Medicare, therefore the SA will not perform

validation surveys of home infusion therapy suppliers. Also, section 1864(a) of the Act provides, that by agreement with the Secretary, the SA shall provide services to the following Medicare certified healthcare providers: Hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, or ambulatory surgical centers.

Section 488.10, titled "State survey agency review: Statutory provisions", § 488.11 titled "State survey agency functions" and § 488.12 titled "Effect of survey agency certification" would also not apply to home infusion therapy AOs. This is because, as stated previously, the SA does not perform validation surveys for AOs that accredit home infusion therapy providers. Section 488.13, titled "Loss of accreditation" provides that "if an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the SA will conduct a full review in a timely manner." This section would also not apply to AOs that accredit home infusion therapy suppliers because this regulation section requires use of the SA.

Section 488.14 titled, "Effect of QIO review" provides that "when a QIO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act." This section would not apply to home infusion therapy suppliers because it is only applicable only to hospitals.

Finally, § 488.18, titled "Documentation of findings" states that "the findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented." This section would not apply to AOs that accredit home infusion therapy suppliers because it involves the finding of the SA related only to SNFs and NFs.

In conclusion, a majority of sections contained in §§ 488.1 through 488.13 do not apply to home infusion therapy AOs and home infusion therapy suppliers. Therefore, we are proposing to create a separate set of regulations that are specifically applicable to home infusion therapy AOs and suppliers.

We seek comment on our decision not to use the existing regulation at §§ 488.1 through 488.13.

c. Consideration of a Validation Process for Accrediting Organizations That Accredit Home Infusion Therapy Suppliers

Our conventional validation process involves the participation of the CMS Regional Offices (ROs) to request the State Survey Agency to conduct an onsite validation (follow-up) survey within 60 days of an AO's onsite survey. The purpose of a validation survey is to evaluate the ability of that AO's survey process to identify serious, condition level deficiencies.

We are not proposing to establish a validation program requirement for home infusion therapy AOs and suppliers due to a number of resource constraints. Several factors limit our ability to establish and implement a validation program for home infusion therapy AOs. First, the SAs are not available to perform validation surveys for home infusion therapy AOs suppliers and other similar non-certified providers and suppliers. Section 1864(a) of the Act provides the SA, by agreement with the Secretary, provides services to the following Medicare certified healthcare providers: Hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, or ambulatory surgical centers.

Second, a validation program for home infusion therapy supplier AOs would require the use of contractors. Third, achieving sample sizes that are statistically significant from which to draw reliable conclusions about AO performances across all home infusion therapy suppliers would be problematic as there are a limited number of home infusion therapy suppliers. Due to the factors stated previously, we are not proposing to include validation requirements in the proposed new regulations for the oversight of AOs that accredit suppliers at this time. We seek public comment on the decision not to propose a validation process at this time.

Even though we would not have a formal validation process in place, we would be able to monitor the performance of the home infusion therapy AOs as part of the ongoing AO oversight process provided for in the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050. For

example, under proposed § 488.1030 we would have the ability to perform performance reviews to evaluate the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis; comparability reviews to assess the equivalency of a home infusion therapy AO's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements; and standards reviews when a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards. We may also perform CMS-approved home infusion therapy accreditation program review if a comparability or performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program with the requirements of this subpart. (See proposed § 488.1005 below for a definition of substantial non-compliance).

In addition, proposed § 488.1035 would require the home infusion therapy AOs to submit information to CMS which will help us monitor the AO's performance. This information would also help to ensure that the home infusion therapy suppliers accredited by the AO provide care that meets the proposed health and safety standards contained in 42 CFR part 486, subpart B. This information includes the following:

- Copies of all home infusion therapy supplier accreditation surveys, together with any survey-related information.
- Notice of all accreditation decisions.
- Notice of all complaints related to the AO's accredited suppliers.
- Information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation.
- Annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.
- Notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process.

d. Application Requirement for AOs That Currently Provide Accreditation for Home Infusion Therapy Suppliers

In this rule, we are proposing to establish regulations for the approval and oversight of AOs for home infusion therapy suppliers. We are also proposing the health and safety standards which home infusion therapy suppliers must meet, and which the home infusion AOs must meet or exceed in their accreditation standards. These health and safety standards are set forth at 42 CFR part 486, subpart I. The AOs that currently accredit home infusion therapy suppliers have not heretofore been governed by any CMS regulations related to home infusion therapy accreditation or health and safety standards. These AOs have each created their own set of accreditations standards. These accreditation standards vary from AO to AO.

Section 1834(u)(5)(C) of the Act requires home infusion therapy suppliers to be accredited in order to receive payment for the services they provide. We propose to require that the home infusion therapy accreditation program submitted to CMS for approval by each of the AOs that currently accredit home infusion therapy suppliers be separate and distinct accreditation programs that are not part of the AOs home health accreditation program. We would further require that the AOs home infusion therapy accreditation standards meet or exceed the proposed health and safety standards for home infusion therapy suppliers. Finally, we would require that the application meet the requirements of proposed 42 CFR 488.1010.

We solicit comments on these proposals.

e. Oversight of Home Infusion Therapy Accrediting Organizations

As noted previously, we are proposing to create a new set of regulations titled, "Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations" at 42 CFR part 488, subpart L. These proposed regulations would set forth the application and reapplication procedures for national AOs seeking approval or re-approval of authority to accredit home infusion therapy suppliers; ongoing CMS oversight processes for approved AOs that accredit home infusion therapy suppliers; and, appeal procedures for AOs that accredit home infusion therapy suppliers. In this section of the proposed rule, we describe our proposed regulatory provisions.

The following sections discuss the proposed regulations, in their proposed order.

(1) Basis and Scope (§ 488.1000)

We propose at § 488.1000 to set forth the statutory authority related to this set of proposed regulations. Sections 1834(u)(5) and 1861(iii) of the Act would be the statutory basis for these proposed regulations. These sections of the Act provide the Secretary with the authority necessary to carry out the administration of the Medicare program. Section 1861 of the Act defines services, supplier types and benefits, and over whom Medicare may have authority. Section 1861(d) defines the term "supplier." Section 1834(u)(5) of the Act governs accreditation of home infusion therapy suppliers.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that home infusion therapy suppliers be accredited by an organization designated under section 1834(u)(5) of the Act. Section 1834(u)(5) of the Act requires that the Secretary establish factors in designating accrediting organizations and designate accrediting organizations to accredit suppliers furnishing home infusion therapy by January 1, 2021.

Proposed § 488.1000(a) would set forth the statutory authority for the accreditation of home infusion therapy suppliers by the home infusion therapy AOs. Title 42 CFR 488.1000(b) would set forth the scope of the proposed regulation, which is the application and reapplication procedures for national AOs seeking approval or re-approval of authority to accredit home infusion therapy suppliers; ongoing CMS oversight processes for approved of home infusion therapy AOs; and, appeal procedures for AOs of home infusion therapy suppliers.

(2) Definitions (§ 488.1005)

We are proposing to use the following definitions at § 488.1005:

- Accredited home infusion therapy supplier means a supplier that has demonstrated substantial compliance with a CMS-approved national home infusion therapy AO's applicable CMS-approved home infusion therapy accreditation program standards, which meet or exceed those of Medicare, and has been awarded accreditation by that AO.

- Qualified home infusion therapy supplier means an entity that meets the following criteria which are set forth at 1861(iii)(3)(D)(i): (1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensures the safe and effective

provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and (4) meets such other requirements as the Secretary determines appropriate.

- Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare accreditation requirements has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient, as codified at § 488.1.

- National accrediting organization means an organization that accredits supplier entities under a specific program and whose accredited supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is active, fully implemented, and operational. This definition is codified at § 488.1.

- Reasonable assurance means an AO has demonstrated to CMS' satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements. This definition is codified at § 488.1.

- Rural area means an area as defined at section 1886(d)(2)(D) of the Act.

- Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in the newspaper, magazine articles or other media, that would, if found to be present, adversely affect the health and safety of patients and raises doubts as to a supplier's compliance with any of the Medicare home infusion therapy accreditation requirements. This definition is codified at § 488.1.

(3) Application and Reapplication Procedures for National Accrediting Organizations (§ 488.1010)

Proposed § 488.1010 would contain application and re-application procedures for all national AOs seeking CMS-approval of an accreditation program for home infusion therapy suppliers. Proposed § 488.1010(a) would provide a comprehensive listing of the information, supporting documentation, certifications, written statements and other data that prospective AOs for home infusion therapy suppliers would be required to include in their application for approval to accredit home infusion therapy suppliers. The requirements under this section would apply to both initial applications for CMS-approval as well as applications

for re-approval of an existing CMS-approved home infusion therapy accreditation program. This section would also require the AOs for home infusion therapy suppliers to furnish CMS with information that demonstrates that their accreditation program requirements meet or exceed the applicable Medicare requirements.

Proposed § 488.1010(a)(1) would require AOs for home infusion therapy suppliers seeking initial or renewed CMS-approval of their home infusion therapy accreditation program to demonstrate that they meet the definition of a "national accrediting organization." Section 1865 of the Act requires that accrediting organizations be national in scope.

We believe that because home infusion therapy suppliers are located throughout the country, it is necessary for AOs to demonstrate their ability to provide accreditation services in a variety of regions across the country. In the May 22, 2015 final rule entitled, "Medicare and Medicaid Programs: Revisions to Deeming Authority, Survey, Certification and Enforcement Procedures" (80 FR 29802), we stated that the term "national in scope" indicated a program already fully implemented, operational, and widely dispersed geographically throughout the country. However, we also stated that we would not establish a minimum or a specific geographic distribution for provider entities that the program must have already accredited. It is our intent that this proposed section would require a home infusion therapy AO to demonstrate that their accreditation program meets the "national in scope" description as previously defined.

Proposed § 488.1010(a)(2) would require AOs to specifically identify the Medicare supplier type for which they are requesting CMS-approval or reapproval. We believe it is necessary for an AO to establish separate accreditation requirements for each supplier type they accredit. There are many AOs that provide accreditation programs for multiple types of provider and supplier types. When we receive an application from such an AO, we would not know which type of accreditation program the AO has submitted for CMS approval. For example, the AO could be submitting a renewal application for one of its existing accreditation programs. Therefore, it is helpful to CMS if the AO identifies the type of accreditation for which they are seeking approval at the beginning of the application.

Proposed § 488.1010(a)(3) would require AOs to demonstrate their ability to take into account the capacities of home infusion therapy suppliers in

rural areas (as defined in section 1834(u)(5)(A)(ii) of the Act. Rural home infusion therapy suppliers may have limitations or access to care issues that do not apply to suburban and urban home infusion therapy suppliers. These limitation may include, but are not limited to the number of home infusion therapy suppliers available in rural areas and limited home infusion therapy services offered in rural areas. While we certainly would not permit AOs that accredit any type of supplier to modify their accreditation standards for suppliers in rural areas, these factors must be taken into account as in accordance with section 1834(u)(5)(A)(ii) of the Act.

Proposed § 488.1010(a)(4) would require the home infusion therapy AO to provide information that documents their knowledge, expertise, and experience in the healthcare field for which they offer accreditation and for which they are requesting approval. We believe that to successfully develop accreditation program standards that can provide CMS with reasonable assurance that accredited home infusion therapy suppliers meet or exceed each of the applicable Medicare requirements, evaluate compliance, support entities in their efforts to identify and implement necessary corrective actions and monitor ongoing compliance, an AO must possess subject matter expertise and experience in that field.

Proposed § 488.1010(a)(5) would require the AO to submit a detailed crosswalk (in table format) that identifies, for each of the applicable Medicare health and safety requirements, the exact language of the accrediting organization's comparable accreditation requirements and standards. This requirement would allow CMS to evaluate whether the accreditation program standards meet or exceed the applicable Medicare requirements. We note that an AO for home infusion therapy suppliers could set standards that exceed the Medicare requirements in the accreditation program it submits to CMS for approval. However, at a minimum, AOs for home infusion therapy suppliers would have to provide evidence that their accreditation program utilizes standards and procedures that met or exceeded applicable Medicare requirements.

Proposed § 488.1010(a)(6) would require each AO for home infusion therapy suppliers to provide a detailed description of its survey process. This requirement is intended to allow CMS to gain a better understanding of an AO's proposed survey process and ensure that its survey and enforcement

processes are comparable to Medicare's health and safety standards (contained in 42 CFR part 486, subpart I). The specific type of information to be provided under this section is set forth in proposed § 488.1010(a)(6)(i) through (vii) and includes, but is not limited to, the following: (1) A detailed description of the survey process; (2) type and frequency of surveys performed; (3) copies of the AO's survey forms; (4) documentation that the survey reports identify the comparable Medicare home infusion therapy health and safety requirements for each finding of non-compliance with accreditation standards; (5) timeline and procedures for monitoring home infusion therapy suppliers found to be out of compliance; (6) process for addressing deficiencies; and (7) the ability of the AO to conduct timely review of accreditation applications.

We propose at § 488.1010(a)(6)(viii) to require the AOs for home infusion therapy suppliers to acknowledge, that as a condition for CMS approval, the AO agrees to provide CMS with information extracted from each accreditation onsite survey, offsite audit or other evaluation strategy as part of its data submission required under § 488.1010(a)(21)(ii). Upon request, the AO must also provide CMS with a copy of the most recent accreditation onsite survey, offsite audit, or other evaluation strategy together and any other information related to the survey process as CMS may require, including, but not limited to corrective action plans.

Proposed § 488.1010(a)(6)(ix) would require the AOs for home infusion therapy suppliers to provide a statement acknowledging that they will notify CMS within two business days, using a CMS specified format, when an accreditation survey or complaint investigation identifies the presence of an immediate jeopardy situation. For purposes of this section, the term "immediate jeopardy" is defined in proposed § 488.1005.

We propose at § 488.1010(a)(7) to require the AOs for home infusion therapy suppliers to establish procedures related to performance of onsite surveys, offsite audits, and other survey activities. Proposed § 488.1010(a)(7)(i) would require the home infusion therapy AOs that performs onsite surveys to make sure that they are unannounced and that they establish procedures to prevent against unannounced surveys from becoming known to the supplier in advance of the visit. The purpose of unannounced onsite surveys is to prevent the supplier from performing significant preparations for the survey to the extent

that their environment would be so modified that it does not represent the normal daily operating conditions of the home infusion therapy supplier's office. If a provider is given advanced notice of a survey, they may attempt to make extensive preparations for the survey to the extent that they may attempt to hide patient safety issues such as a broken or malfunctioning medication infusion pump, areas of risk such as infection control, and ensuring that the patient receives the correct type and dosage of medication, poor quality of care such as failure to properly cleanse the insertion site before inserting IV access, and failure to perform periodic IV site care, or non-compliance that would normally be present.

Proposed § 488.1010(a)(7)(ii) would require home infusion therapy AOs that use offsite audits, or other evaluation strategies to evaluate the quality of services provided by a home infusion therapy supplier, to follow up these offsite audits with periodic onsite visits. We believe that it is very important for the AOs that accredit home infusion therapy suppliers to follow-up off-site survey reviews with periodic on-site visits to ensure that the home infusion therapy supplier is complying with all accreditation standards and meeting all health and safety regulations. The requirements of this section are consistent with existing CMS policy related to the performance of unannounced surveys specified in Chapter 2 of the CMS State Operations Manual (SOM). Chapter 2 of the State Operations Manual (SOM) applies to Medicare-certified providers and suppliers. Our intent for referencing Chapter 2 of the SOM is to show that the proposed provisions related to onsite surveys for home infusion therapy suppliers are consistent with the requirements for Medicare-certified providers and suppliers. Also, it is our intent is to have consistent regulations for the approval and oversight of AOs, to the extent possible, across all AOs.

We propose at § 488.1010(a)(8), to require an AO for home infusion therapy suppliers to provide a description of the criteria for determining the size and composition of the onsite survey or offsite audit teams or teams used for other accreditation evaluation strategies. These teams would perform onsite surveys at individual home infusion therapy supplier locations, offsite audits, and any other types of accreditation review activity that is performed by the AO. The AO's criteria should include, but not be limited to, the following information:

- The expected number of individual home infusion therapy supplier locations to be surveyed using an onsite survey.
- The expected number of home infusion therapy suppliers to be surveyed using off-site audits.
- A description of other types of accreditation review activities to be used.
- The reasons for each type of survey (that is, initial accreditation survey, reaccreditation survey; and complaint surveys).

Adherence to the requirements of this section would help CMS ensure that each home infusion therapy AO has established criteria for determining the appropriate size and composition of its survey teams. It is important that an AO assemble survey teams that are large enough and have the required knowledge, experience and training to properly and adequately survey home infusion therapy suppliers. We believe that surveys performed by competent, well trained surveyor teams would provide CMS with reasonable assurance that accredited home infusion therapy suppliers meet or exceed the applicable quality standards.

We propose at § 488.1010(a)(9) to require that an AO for home infusion therapy suppliers provide CMS with information regarding the overall adequacy of the number of surveyors, auditors, and other staff available to perform all survey related activities. Under this section, the home infusion therapy AO would also be required to provide an explanation as to how it would maintain an adequate number of trained surveyors on staff. The home infusion therapy AO must also describe its ability to increase the size of survey, audit, and other survey program staff to match growth in the number of accredited home infusion therapy suppliers while maintaining re-accreditation intervals for existing accredited home infusion therapy suppliers. The intent of these proposed requirements is to ensure that AOs for home infusion therapy suppliers maintain sufficient staffing levels over time which would enable them to meet the needs of their clients and also perform timely and accurate surveys. We recognize that within a given accreditation program, there can be variations in the size and complexity of individual home infusion therapy suppliers. Therefore, we believe that adding a regulatory requirement to specify a uniform size and composition of an AO survey teams would not be appropriate.

We propose at § 488.1010(a)(10) to require that an AO for home infusion

therapy suppliers provide CMS with detailed information about the individuals who perform survey activities, including onsite surveys, offsite audits and other review processes, for the purpose of ensuring accredited home infusion therapy suppliers maintain adherence to the accreditation program requirements. More specifically, proposed § 488.1010(a)(10)(i) would require the AOs to furnish information about the numbers of professional and technical staff available for accreditation related activities, as well as the educational background and experience requirements for its surveyors, auditors and reviewers. Proposed § 488.1010(a)(10)(ii) would require the AO to provide information about the educational, past experience and employment requirements surveyors must meet. Proposed § 488.1010(a)(10)(iii) would require the AO to provide information about the content and length of the orientation program for newly hired surveyors, auditors and reviewers.

These requirements would help ensure that AOs for home infusion therapy suppliers hires survey team staff members that possess the requisite knowledge, expertise, training, and experience specific to home infusion therapy suppliers. We believe it is imperative that surveys be performed by properly educated and trained staff in order to be valid and accurate. This proposed section is also intended to help ensure that the home infusion therapy AO maintains an adequate number of properly trained surveyors so that it would be able to meet the demand for all surveys, both initial and re-accreditation, to be performed for all clients.

We propose at § 488.1010(a)(11) to require each AO for home infusion therapy suppliers to describe the content, frequency and types of in-service training provided to survey and audit personnel. This requirement would help ensure that AO personnel who perform surveys, audits and other review-related activities maintain the skills and knowledge necessary to perform their work with competency. We believe that surveys performed by competent, well trained surveyor teams would provide CMS with reasonable assurance that accredited home infusion therapy suppliers meet or exceed the applicable quality standards.

We propose at § 488.1010(a)(12) to require AOs for home infusion therapy suppliers to provide documentation which describes the evaluation systems used to monitor the performance of individual surveyors, survey teams, and

staff that perform audit activities. This proposed requirement would provide CMS with insight into how each home infusion therapy AO measures the performance of their surveyors, survey teams and staff that perform audit activities. This requirement would provide CMS with the ability to assess whether an AO has a credible process for ongoing evaluations of its surveyors, survey teams, and staff that perform audit activities.

We believe that the performance evaluation of a home infusion therapy AO's surveyors, survey team and other staff that perform survey and audit activities can have a significant impact on the effectiveness of the home infusion therapy AO's survey processes.

We propose at § 488.1010(a)(13) to require the AO for home infusion therapy suppliers to provide the organization's policies and procedures for avoiding and handling conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions. This proposed provision would help CMS to determine if home infusion therapy AO has policies to avoid potential conflicts of interest that could undermine the integrity of its accreditation program.

We propose at § 488.1010(a)(14) to require the AO for home infusion therapy suppliers to provide CMS with documentation of its policies and procedures for handling disputes filed by a home infusion therapy supplier regarding survey or audit findings, or an adverse decision. The intent of this proposed section is to ensure that a home infusion therapy AO has procedures in place to ensure that those suppliers who wish to dispute the AO's survey findings or appeal an adverse decision are provided with notice of their organizational and statutory appeal rights.

We propose at § 488.1010(a)(15) to require that home infusion therapy AOs provide CMS with copies of the policies and procedures to be used when an accredited home infusion therapy supplier either—(1) removes or ceases furnishing services for which they are accredited; or (2) adds home infusion therapy services for which they are not accredited. This proposed requirement would ensure there is timely communication between the accredited home infusion therapy supplier and the AO, when changes in the supplier's circumstances occur that would have an impact on the status of their accreditation.

We propose at § 488.1010(a)(16) to require the home infusion therapy AOs

to provide CMS with the organization's policies and procedures for responding to and investigating complaints and grievances against accredited suppliers. These policies and procedures should include a specific procedure for coordinating with and making referrals, when applicable, to the appropriate licensing bodies, ombudsman's offices and CMS. It is our intent that each CMS-approved home infusion therapy AO has policies and procedures in place for handling complaints and grievances. We believe it is important that any complaints against an accredited home infusion therapy supplier be investigated promptly and fairly. It is also important that the appropriate referrals be made when necessary.

We propose at § 488.1010(a)(17) to require that the home infusion therapy AOs furnish a description of the AO's accreditation status decision-making process. Proposed § 488.1010(a)(17)(i) would require the organization to furnish its process for addressing a home infusion therapy supplier deficiencies with meeting accreditation program requirements. This section would also require the home infusion therapy AO to provide a description of the procedures used to monitor the correction of deficiencies identified during the accreditation survey and audit process. It is important for CMS to ensure that the home infusion therapy AOs are properly addressing the home infusion therapy supplier's deficiencies and requiring appropriate corrective action.

We propose at § 488.1010(a)(17)(ii) to require that the home infusion therapy AOs furnish a description of all types and categories of accreditation decisions associated with the program, including the duration of each of the organization's accreditation decisions.

Proposed § 488.1010(a)(17)(iii) would require the home infusion therapy AO to provide information about its procedures for the granting, withholding or removal of accreditation status for home infusion therapy suppliers that fail to meet the AO's standards or requirements. This proposed section would also require the home infusion therapy AO to identify the procedures related to assignment of less than full accreditation status or other actions taken by the home infusion therapy AO in response to non-compliance with its standards and requirements. Since the granting of full or less than full accreditation status is an essential component of a home infusion therapy AO's accreditation decision process, we believe that it is necessary for CMS to receive information on the policies and

procedures pertaining to these types of decisions as well.

We propose at § 488.1010(a)(17)(iv) to require the home infusion therapy AO to furnish a statement acknowledging that the organization agrees to notify CMS (in a manner specified by CMS in subregulatory guidance) of any decision to revoke or terminate, withdraw, or revise the accreditation status of a home infusion therapy supplier within 3 business days from the date the organization takes an action. “Revocation” or “termination” represents an involuntary cessation of a home infusion therapy supplier’s accreditation. A revocation or termination of accreditation could include an action taken when a home infusion therapy AO concludes that a home infusion therapy supplier is substantially non-compliant with accreditation standards and has not corrected its deficient practices within the timeframe specified by the home infusion therapy AO. A home infusion therapy AO could also revoke or terminate a home infusion therapy supplier’s accreditation due to the non-payment of accreditation fees. We define the term “revised” accreditation status as a change in the accreditation status of a home infusion therapy supplier based on the formal accreditation status categories used by a home infusion therapy AO. These changes could include adverse changes that fall short of revocation, as well as positive changes reflecting improved compliance. This is in contrast to a “withdrawal” which is a voluntary decision on the part of the home infusion therapy supplier to end its participation in the AO’s accreditation program.

Our intent with this proposed requirement is to require that home infusion therapy AOs notify CMS when they have taken a final action concerning a change in the accreditation status of a home infusion therapy supplier. If a home infusion therapy supplier has filed a request for an administrative appeal of the AO’s decision to revoke or terminate accreditation, the action on the part of the home infusion therapy AO to revoke or terminate accreditation cannot be finalized until after the conclusion of the administrative appeals process. In this case, the home infusion therapy AO would be required to send notice of their final action to CMS no later than three business days after that appeals process has concluded and a final AO determination has been made.

We propose at § 488.1010(a)(18) to require a home infusion therapy AOs to provide CMS with a list of all home

infusion therapy suppliers currently accredited by that home infusion therapy AO. This list must include the type and category of accreditation held by each home infusion therapy supplier and the expiration date of each supplier’s current accreditation.

We propose at § 488.1010(a)(19) to require that the home infusion therapy AOs provide CMS with a schedule of all survey activity (including but not limited to onsite surveys, offsite audits and other types of survey strategies), expected to be conducted by the home infusion therapy AO during the 6-month period following submission of the application. This proposed requirement would apply to both initial and renewal applications. Under this proposed section, the home infusion therapy AO would be required to provide us with its survey activity schedule for the 6-month period following submission of their application for approval to survey and accredit home infusion therapy suppliers. We would use the survey schedule to plan our survey observation as part of our review of the home infusion therapy AO’s application.

We propose at § 488.1010(a)(20) to require that the home infusion therapy AO submit a written statement or document that demonstrates the organization’s ability to furnish CMS with the electronic data the home infusion therapy AO must report to CMS as required by proposed § 488.1035. The information and data to be provided under this section would assist us in providing effective oversight of the approved home infusion therapy accreditation programs. This information is necessary for effective assessment and validation of the home infusion therapy AO’s survey process.

These proposed regulations will require the AO to submit documentation to CMS on a periodic basis. The intent of this requirement is to ensure that the AO is able to provide CMS with the required data electronically. CMS is cutting down on the use of printed documents and maximizing the use of electronic document storage.

We propose at § 488.1010(a)(21) to require that the home infusion therapy AO provide a description of the organization’s data management and analysis system with respect to its surveys and accreditation decisions. Proposed § 488.1010(a)(21)(i) would require the home infusion therapy AO to furnish a detailed description of how the home infusion therapy AO uses its data to assure compliance of its home infusion therapy accreditation program with the corresponding Medicare requirements.

We propose at § 488.1010(a)(21)(ii) to require the home infusion therapy AO to submit a written statement in which the home infusion therapy AO acknowledges that it agrees to submit timely, accurate, and complete data, which CMS determines necessary for evaluation of the home infusion therapy AO’s performance, and which would not be unduly burdensome to submit. The data to be submitted, according to proposed § 488.1010(a)(21)(ii)(B) would include, accredited home infusion therapy supplier identifying information, survey findings, quality measures, and notices of accreditation decisions. The home infusion therapy AO would further agree to submit the necessary data according to the instructions and timeframes CMS specifies through subregulatory guidance.

This data would allow CMS to obtain information about how the home infusion therapy AO would use its data management systems to meet or exceed Medicare home infusion therapy accreditation requirements as set forth in this subpart. The proposed data would also assist us in providing effective oversight of the approved home infusion therapy accreditation program.

We propose at § 488.1010(a)(22) to require the home infusion therapy AO to furnish the three most recent annual audited financial statements from their organization. The purpose of this proposed requirement would be to verify that the home infusion therapy AO’s staffing, funding, and other resources are adequate to perform the required surveys, audits and related activities in order to maintain the home infusion therapy accreditation program on a national basis. This requirement is also intended to insure that a home infusion therapy AO has the financial stability to ensure ongoing, stable operations and longevity.

Proposed § 488.1010(a)(23) would require the home infusion therapy AOs to provide a written statement, in which the home infusion therapy AO acknowledges, as a condition for approval, that the organization agrees to the items set forth in § 488.1010(a)(23)(i) through (vi).

Proposed § 488.1010(a)(23)(i) would require the home infusion therapy AO to provide a written statement acknowledging that, as a condition for approval, that if the home infusion therapy AO decides to voluntarily terminate its accreditation program, the home infusion therapy AO must provide written notification to CMS and all home infusion therapy suppliers accredited by that AO. This written

notice must be provided at least 90 calendar days in advance of the effective date of the home infusion therapy AOs decision to voluntarily terminate its CMS-approved accreditation program. This notice must contain the all of following information:

- Notice that the home infusion therapy AO is voluntarily terminating its home infusion therapy accreditation program.

- The effective date of the termination.

- The implications for the home infusion therapy supplier's payment status once their current term of accreditation expires in accordance with the requirements set forth at § 488.1045(a).

Proposed § 488.1010(a)(23)(ii) would require the home infusion therapy AO to provide a written statement acknowledging that, as a condition for approval, that, a home infusion therapy AO must provide written notification of an involuntary withdrawal of CMS approval of its home infusion therapy accreditation program to all its accredited home infusion therapy suppliers. This written notice must be provided by the home infusion therapy AO to all of its accredited home infusion therapy suppliers no later than 30 calendar days after the public notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of the accreditation program in accordance with the requirements at § 488.1045(b). This **Federal Register** notice must state the implications for the providers' or suppliers' payment status once their current term of accreditation expires. Home infusion therapy suppliers would no longer be eligible to receive Medicare payments upon expiration of the current term of accreditation. Therefore, it is critical that the home infusion therapy supplier seek accreditation immediately through another CMS-approved home infusion therapy accreditor.

Proposed § 488.1010(a)(23)(ii)(A) would require the home infusion therapy AO to acknowledge that they must send a second written notification, as a reminder to all accredited home infusion therapy suppliers within ten calendar days of the organization's removal from the list of CMS-designated home infusion therapy AOs. We believe that this second reminder to the accredited home infusion therapy suppliers who are in danger of having a lapse of accreditation is very important. This notice would remind the home infusion therapy suppliers that they must seek another home infusion therapy accreditor to avoid a

lapse in accreditation, and subsequently a lapse in Medicare payment.

Proposed § 488.1010(a)(23)(ii)(B) would require the home infusion therapy AO to acknowledge that they will notify CMS, in writing, (either electronically or in hard copy format) within 2 business days of identification of an immediate jeopardy situation that has been identified in any accredited home infusion therapy supplier. An immediate jeopardy situation is presented when a provider or supplier exhibits a deficiency that poses serious risk of harm or death to the home infusion therapy supplier's patients, staff or visitors, or poses a hazard to the general public. Immediate jeopardy situations are of such a serious nature that it is important that they be identified and removed as quickly as possible. We propose the 2-day notification requirement because CMS must notified of immediate jeopardy situations as quickly as possible so that we can monitor these serious situations and take action as appropriate.

We propose at § 488.1010(a)(23)(iii) to require the home infusion therapy AO to provide CMS with an annual summary of accreditation activity data and trends, including, but not limited to, deficiencies, complaints, terminations, withdrawals, denials, accreditation decisions, and other survey related activities as specified by CMS. We believe that it is important for CMS to monitor this information as part of our oversight of the home infusion therapy AOs performance.

Proposed § 488.1010(a)(23)(iv), would require a home infusion therapy AO to work collaboratively with CMS in the event that CMS terminates the home infusion therapy AO's approved status, to direct its accredited home infusion therapy suppliers to the remaining CMS-approved home infusion therapy AOs within a reasonable period of time. We would require the terminated home infusion therapy AO to perform this task because its accredited home infusion therapy suppliers would be left with no accreditation as a result of the termination of the home infusion therapy AOs CMS-approval. Therefore, we believe that the terminated home infusion therapy AO has some responsibility to help their accredited home infusion therapy suppliers seek alternative accreditors as soon as possible.

Proposed § 488.1010(a)(23)(v), would require the home infusion therapy AOs to notify CMS of any significant proposed changes in its CMS-approved accreditation program requirements or survey process. Under this section, the home infusion therapy AO would be

required to submit their notice of revised program requirements or changes in the survey process to CMS in writing no less than 60 days in advance of the proposed implementation date. As required by proposed § 488.1030(c)(1), the home infusion therapy AO would be required to agree not to implement the proposed changes without prior written notice of continued program approval from CMS, except as provided for at § 488.1030(c)(4).

Proposed § 488.1010(a)(23)(vi), would require the home infusion therapy AOs to provide a statement acknowledging that if they receive a written notice from CMS which states that there has been a change in the applicable Medicare home infusion therapy substantive health and safety requirements, the home infusion therapy AO must provide CMS with proposed corresponding changes in the home infusion therapy accreditation requirements for its CMS-approved home infusion therapy accreditation program. This requirement is intended to ensure that the AO's accreditation standards continue to meet or exceed those of Medicare, and that the AO's survey process remains comparable with that of Medicare.

Section 488.1010(a)(23)(vi) provides that in the event that CMS makes a change in the applicable home infusion therapy accreditation requirements, the home infusion therapy AO must comply with several requirements. First, proposed § 488.1010(a)(23)(vi)(A) would require the home infusion therapy AO to submit its responsive proposed changes in their accreditation requirements and survey processes to CMS within 30 calendar days of the date of the written CMS notice to the home infusion therapy AO or by a date specified in the notice, whichever is later. However, CMS will give due consideration to a home infusion therapy AO's request for an extension of the deadline as long as it is submitted prior to the due date. Second, proposed § 488.1010(a)(23)(vi)(B) would require that the home infusion therapy AO not implement its proposed responsive changes without prior written notice of continued program approval from CMS, except as provided for at § 488.1030(b)(1)(v).

Proposed § 488.1010(a)(24) would require the home infusion therapy AOs to provide CMS with a listing of the organization's proposed fees for home infusion therapy accreditation. The home infusion therapy AO must notify CMS of any plans for reducing the burden and cost of accreditation to small or rural home infusion therapy suppliers. While CMS does not

undertake to set or regulate the fees charges by a home infusion therapy AO, we do review fees charged by AOs to determine whether they are reasonable as directed by sections 1834(u)(5)(A)(iii) of the Act.

Proposed § 488.1010(b) would require home infusion therapy AOs to agree to submit any additional information, documentation, or attestations, including items not previously listed that CMS may deem necessary to make a determination for approval or denial of the home infusion therapy AO's application. Should we require this additional information, we would notify the home infusion therapy AO of the request and provide the home infusion therapy AO with a reasonable timeframe to submit the requested information.

We propose at § 488.1010(c) to allow a home infusion therapy AO to withdraw its initial application for CMS's approval of its home infusion therapy accreditation program at any time before we publish the final **Federal Register** notice described at § 488.1020(b). The intent of this provision is to provide home infusion therapy AOs that have encountered difficulty meeting the requirements described at § 488.1010(a) during the application process with the option to voluntarily withdraw their application before CMS publishes the final decision in the **Federal Register** as required by proposed § 488.1020(b). Proposed § 488.1020(b) would require that the final notice, published by CMS, specify the basis for our decision. Because the **Federal Register** is a public forum, we believe it is likely that home infusion therapy AOs would choose to voluntarily withdraw their application instead of having information about the non-compliance of their home infusion therapy accreditation program made publicly available. This may be especially true for those home infusion therapy AOs that wish to reapply for approval of their accreditation program in the future. A voluntary withdrawal of an application by the home infusion therapy AO would terminate the application review process prior to publication of the final decision in the **Federal Register**.

Proposed § 488.1010(d) would require CMS to complete its review of an application submitted by a home infusion therapy AO within 210 calendar days from the date that CMS determines that the application is complete. We propose that to determine completeness, each application would be assigned to a technical review team upon receipt by CMS. This team would perform a completeness review to determine if the application contains all

documents and supplemental information required by proposed § 488.1010(a). Lastly, we propose that if the application is not complete, the review team would contact the home infusion therapy AO and request that they submit any missing information or documents in accordance with § 488.1010(b).

We seek public comment on the proposal related to the proposed application requirements set forth in proposed § 488.1010. We further seek comments on the burden related to the requirements of the application procedure.

(4) Resubmitting a Request (§ 488.1015)

Proposed § 488.1015(a) would require that except as provided in paragraph (b), a home infusion therapy AO whose request for CMS's approval or re-approval of a home infusion therapy accreditation program was denied, or an organization that has voluntarily withdrawn an initial application, could resubmit its application if the organization had: (1) Revised its accreditation program to address the issues related to the denial of its previous request or its voluntary withdrawal; and (2) resubmitted the application in its entirety.

Proposed § 488.1015(b) would provide that a home infusion therapy AO that had asked for reconsideration of an application denial by CMS could not submit a new application until the pending reconsideration was administratively final. This provision would ensure that review of accreditation matters on reconsideration are pending before only one administrative agency and one administrative level at a time.

We seek public comments on the requirements of proposed § 488.1015.

(5) Public Notice and Comment (§ 488.1020)

Proposed § 488.1020(a) would require CMS to publish a notice in the **Federal Register** upon receipt of a complete application package. The notice would identify the organization, the type of home infusion therapy suppliers covered by the accreditation program, and provides for at least a 30-day public comment period (which begins on the date of publication of the **Federal Register** notice). The purpose of the **Federal Register** notice is to notify the public that a national AO has filed an application for approval of a home infusion therapy accreditation program and to seek public comment in response to this application. The requirement for the publication of a notice in the **Federal Register** when an application is

received is an existing regulatory procedural requirement for all other AO types. We have added this requirement to the home infusion therapy AO approval and oversight regulations for consistency.

Proposed § 488.1020(b) would require that when CMS approves or re-approves an application for approval of a home infusion therapy AO's accreditation program, a final notice would be published in the **Federal Register**. This notice would have to specify the basis for CMS' decision. Proposed § 488.1020(b)(1), would require that our final notice include at a minimum, the following information: (1) How the accreditation program met or exceeded Medicare accreditation program requirements; (2) the effective date of the CMS approval, which is not later than the publication date of the notice; and (3) the term of the approval (6 years or less).

If CMS makes a decision to disapprove a home infusion therapy AOs application, our final notice would state the deficiencies found in the application and the reason why the AOs accreditation program did not meet or exceeded Medicare accreditation program requirements. However, an AO has the option of voluntarily withdrawing its application at any time up until the publication of the final notice.

We propose at § 488.1020(b)(2) that if CMS did not approve a home infusion therapy AO's application for approval of its home infusion therapy accreditation program, the final notice would explain how the home infusion therapy AO failed to meet Medicare home infusion therapy accreditation program requirements. This notice would indicate the effective date of the decision.

We seek comment on the requirements of proposed § 488.1020, including on the appropriate term for approval of an AO.

(6) Release and Use of Accreditation Surveys (§ 488.1025)

Proposed § 488.1025 would require a home infusion therapy AO to include, in its accreditation agreement with each home infusion therapy supplier, an acknowledgement that the home infusion therapy supplier agrees to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require, including the home infusion therapy supplier's corrective action plans. Proposed § 488.1025(a) would provide that CMS may determine that a home infusion therapy supplier does not meet the applicable Medicare

conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

Proposed § 488.1025(b) would prohibit CMS from disclosing home infusion therapy survey reports or survey related information according to section 1865(b) of the Act. However, CMS would be permitted to publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information is related to an enforcement action taken by CMS.

CMS would use the home infusion therapy supplier accreditation survey information for purposes such as: (1) Confirmation of the home infusion therapy supplier's eligibility for Medicare participation; (2) to review and approve the home infusion therapy AO's recommendations regarding accreditation; (3) to review the home infusion therapy AO's investigations of complaints; and (4) to review the corrective action taken by the AO when deficiencies are found on survey.

We seek public comments on the requirements of proposed § 488.1025.

(7) Ongoing Review of Accrediting Organizations (§ 488.1030)

Proposed § 488.1030 would clarify that a formal accreditation program review could be opened on an ongoing basis. Specifically, this section would describe standardized requirements related to the ongoing federal review of home infusion therapy AOs and their approved accreditation programs. This proposed section would clarify that CMS oversight of accreditation programs is consistent across home infusion therapy AOs. We are committed to treating all home infusion therapy AOs subject to our oversight in the same manner. Under proposed § 488.1030, we could conduct the following three types of reviews of an AOs home infusion therapy accreditation programs: (1) Performance review; (2) comparability review; and (3) CMS-approved accreditation program review.

Proposed § 488.1030(a) would allow CMS to perform a performance review, in which we would evaluate the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis. Specifically, we would review the following aspects of a home infusion therapy AO's for home infusion therapy program performance: The organization's survey activity, and the organization's continued fulfillment of the requirements stated in § 488.1010.

Proposed § 488.1030(b) would allow CMS to perform a comparability review to assess the equivalency of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program requirements with comparable Medicare home infusion therapy accreditation requirements. Proposed § 488.1030(b)(1) would allow CMS to perform a comparability review when CMS imposes new or revised Medicare accreditation requirements. When this occurs, proposed § 488.1030(b)(1) would require CMS to provide written notice to the home infusion therapy AOs when changes have been made to the Medicare home infusion therapy accreditation requirements. Proposed § 488.1030(b)(2) would require the home infusion therapy accrediting organization to make revision to its home infusion therapy accreditation standards or survey process so as to incorporate the new or revised Medicare accreditation requirements.

Proposed § 488.1030(b)(3) would further require that the written notice sent by CMS to the home infusion therapy AO specify a deadline (not less than 30 days) by which the home infusion therapy AO must prepare and submit their proposed home infusion therapy accreditation program requirement revisions and the timeframe for implementation. Proposed § 488.1030(b)(4) would allow a home infusion therapy AO to submit a written request for an extension of the submission deadline as long as this request was submitted prior to the original deadline.

Proposed at § 488.1030(b)(5) would require that, after completing the comparability review, CMS would provide written notification to the home infusion therapy AO, specifying whether or not their revised home infusion therapy accreditation program standards continued to meet or exceed all applicable Medicare requirements. We propose at § 488.1030(b)(6) that if, no later than 60 days after receipt of the home infusion therapy AO's proposed accreditation standard changes, CMS did not provide the written notice to the home infusion therapy AO, then the revised home infusion therapy program accreditation standards would be deemed to meet or exceed all applicable Medicare requirement and the accreditation program would have continued CMS-approval without further review or consideration.

Proposed § 488.1030(b)(7) would provide that if a home infusion therapy AO was required to submit a new application because CMS imposed new regulations or made significant substantive revisions to the existing

regulations, CMS would provide notice of the decision to approve or disapprove the application within the time period specified in § 488.1010(d).

We propose at § 488.1030(b)(8) that if a home infusion therapy AO failed to submit its proposed changes within the required timeframe, or failed to implement the proposed changes that had been determined by CMS to be comparable, CMS could open an accreditation program review in accordance with § 488.1030(d).

When a home infusion therapy AO proposes to adopt new home infusion therapy accreditation standards or changes, in its survey process, we propose at § 488.1030(c)(1) to require the home infusion therapy AO to provide notice to CMS no less than 60 days prior to the planned implementation date of the proposed changes. Proposed § 488.1030(c)(2) would prohibit the home infusion therapy AO from implementing these changes before receiving CMS' approval except as provided in § 488.1030(c)(4). Proposed § 488.1030(c)(3) would require that this written notice contain a detailed description of the changes to be made to the organization's home infusion therapy accreditation standards, including a detailed crosswalk (in table format) that states the exact language of the revised accreditation requirements and the corresponding Medicare requirements for each. The requirements of §§ 488.1030(c)(2) and 488.10(c)(3) would ensure that the home infusion therapy AO provides CMS with advance notice of any proposed changes to their home infusion therapy accreditation requirements and survey processes. This notice would allow CMS time to review these proposed changes to ensure that the revised home infusion therapy accreditation standards and survey processes continue to meet or exceed all applicable Medicare home infusion therapy requirements and continue to be comparable to all applicable Medicare home infusion therapy survey processes, and provide a response to the home infusion therapy AO. This section would also prohibit home infusion therapy AOs from implementing any of the proposed changes in their home infusion therapy accreditation requirements and survey processes, until CMS approval has been received. We seek comment on this proposal.

Proposed § 488.1030(c)(4) would require CMS to provide written notice to the home infusion therapy accrediting organization indicating whether the home infusion therapy accreditation program, including the proposed revisions, continued or does not

continue to meet or exceed all applicable Medicare home infusion therapy requirements. If CMS found that the accrediting organization's home infusion therapy accreditation program, including the proposed revisions did not continue to meet or exceed all applicable Medicare home infusion therapy requirements. CMS would have to state the reasons for these findings.

Proposed § 488.1030(c)(5) would require CMS to provide this written notice to the home infusion therapy AO by the 60th calendar day following receipt of the home infusion therapy AO's written proposed changes as to whether the home infusion therapy AO's revised home infusion therapy accreditation program standards and survey processes have been deemed to meet or exceed all applicable Medicare home infusion therapy requirements and have continued CMS approval without further review or consideration. This proposed section would further specify that if CMS failed to provide the required written notice to the home infusion therapy AO by the 60 day deadline, the home infusion therapy AO's revised accreditation program standards would be deemed to meet or exceed all applicable Medicare requirements and have continued CMS approval without further review or consideration.

Proposed § 488.1030(c)(5) would permit CMS to open an accreditation program review, in accordance with proposed § 488.1030(d), if a home infusion therapy AO implemented changes to their home infusion therapy accreditation requirements or survey process that were not determined nor deemed by CMS to be comparable to the applicable Medicare requirements.

We propose at § 488.1030(d) to permit CMS to initiate an accreditation program review when a comparability or performance review reveals evidence that a home infusion therapy AO's CMS-approved home infusion therapy accreditation program is in substantial non-compliance with the requirements of the proposed home infusion therapy health and safety regulations contained in 42 CFR part 486, subpart B. Proposed § 488.1030(d)(1) would require CMS to provide written notice to the home infusion therapy AO when a home infusion therapy accreditation program review is initiated. Proposed § 488.1030(d)(1)(i) through (iv) would set forth the requirements for this written notice, which should contain the following information: (i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable; (ii) a description of the

process to be followed during the review, including a description of the opportunities for the home infusion therapy AO to offer factual information related to CMS' findings; (iii) a description of the possible actions that may be imposed by CMS based on the findings of the accreditation program review; and, (iv) the actions the home infusion therapy AO would have to take to address the identified deficiencies, and the length of the accreditation program review probation period, which will include monitoring of the home infusion therapy AO's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date that CMS has approved the home infusion therapy AOs plan of correction (which is the AO written plan for correcting any deficiencies in its home infusion therapy accreditation program that were found by CMS on a program review).

At § 488.1030(d)(2), we propose that CMS would review and approve the home infusion therapy AO's plan of correction for acceptability within 30 days after receipt. Proposed § 488.1030(d)(3) would provide that CMS will monitor the implementation of the home infusion therapy accrediting organization's plan of correction for a period not to exceed 180 days from the date of approval. During the 180-day review period, CMS would monitor implementation of the accepted plan of correction as well as progress towards correction of identified issues and areas of non-compliance that triggered the accreditation program review.

We propose at § 488.1030(d)(4) to authorize CMS to place the home infusion therapy AO's CMS-approved accreditation program on probation for a subsequent period of up to 180 calendar days, if necessary. The additional period of time may be necessary if CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of an existing CMS-approved accreditation program, that the home infusion therapy AO has failed to meet any of the requirements of § 488.1010, or has made significant progress correcting identified issues or areas of non-compliance, but requires additional time to complete full implementation of corrective actions or demonstrate sustained compliance. If a home infusion therapy AO's term of approval expires before the 180-day period is completed, the probationary period will be deemed to end upon the day of expiration of the home infusion therapy AO's term of approval. In the

case of a renewal application where we have placed the home infusion therapy accreditation program on probation, we propose that any approval of the applications must be conditional while the program remains on probation.

If we place a home infusion therapy AO's accreditation program on probation, proposed § 488.1030(d)(4)(i) would require CMS to issue a written determination to the home infusion therapy AO, within 60 calendar days after the end of any probationary period. The written determination must state whether or not the CMS-approved home infusion therapy accreditation program continued to meet the requirements of this section and the reasons for the determination.

If we determined that withdrawal of approval from a CMS-approved accreditation program was necessary, proposed § 488.1030(d)(4)(ii) would require CMS to send written notice to the home infusion therapy AO which contained the following information: (1) Notice of CMS' removal of approval of the home infusion therapy AOs accreditation program; (2) the reason(s) for the removal; and (3) the effective date of the removal determined in accordance with § 488.1030(d)(4)(ii).

If CMS withdrew the approval of a home infusion therapy AO accreditation program, proposed § 488.1030(d)(4)(iii) would require CMS to publish a notice of its decision to withdraw approval of the accreditation program in the **Federal Register**. This notice would have to include the reasons for the withdrawal, and a notification that the withdrawal would become effective 60 calendar days after the date of publication in the **Federal Register**. The publication of this **Federal Register** Notice is notice would be necessary to put interested stakeholders, such as the home infusion therapy suppliers that are accredited by the affected AO on notice about the withdrawal of CMS-approval of their AO, because this will have an effect on the status of their accreditation.

Proposed § 488.1030(e) would allow CMS to immediately withdraw the CMS approval of an home infusion therapy AO's home infusion therapy accreditation program, if at any time CMS makes a determination that the continued approval of that home infusion therapy accreditation program poses an immediate jeopardy to the patients of the entities accredited under the program; or the continued approval otherwise constitutes a significant hazard to the public health. We propose at § 488.1030(f) to mandate that any home infusion therapy AO whose CMS approval of its home infusion therapy accreditation program has been

withdrawn must notify, in writing, each of its accredited home infusion therapy suppliers of the withdrawal of CMS approval and the implications for the home infusion therapy suppliers' payment status no later than 30 calendar days after the notice is published in the **Federal Register**. This requirement would protect the home infusion therapy suppliers that have received their accreditation from a home infusion therapy AO that has had its CMS approval of their home infusion therapy accreditation program removed.

We seek public comments on the requirements of proposed § 488.1030. We further seek public comment related to the burden associated with the requirements of proposed § 488.1030.

(8) Ongoing Responsibilities of a CMS-Approved Accreditation Organization (§ 488.1035)

Proposed § 488.1035 would require a home infusion therapy AO to provide certain information to CMS and carry out certain activities on an ongoing basis. More specifically proposed § 488.1035(a) would require the home infusion therapy AO to provide CMS with all of the following in written format (either electronic or hard copy):

- Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements);
- Notice of all home infusion therapy accreditation decisions.
- Notice of all complaints related to home infusion therapy suppliers.
- Information about all home infusion therapy accredited suppliers against which the home infusion therapy AO has taken remedial or adverse action, including revocation, withdrawal, or revision of the home infusion therapy supplier's accreditation.
- Summary data specified by CMS that relate to the past year's home infusion therapy accreditation activities and trends which is to be provided on an annual basis.
- Notice of any proposed changes in its home infusion therapy accreditation standards or requirements or survey process.

Proposed § 488.1035(b) would require a home infusion therapy AO to submit an acknowledgment of receipt of CMS' notification of a change in CMS requirements within 30 days from the date of the notice. Proposed § 488.1035(c) would require that a home infusion therapy AO permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

Proposed § 488.1035(d) would require that within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy AO must provide CMS with written notice of the deficiency and any adverse action implemented by the home infusion therapy AO. Proposed § 488.1035(e) would require that within 10 calendar days after our notice to a CMS-approved home infusion therapy AO that CMS intends to withdraw approval of the home infusion therapy AO, the home infusion therapy AO must provide written notice of the withdrawal to all of the organization's accredited home infusion therapy suppliers.

We seek public comment on the requirements of proposed § 488.1035. We further seek public comments related to the burden associated with the requirements of proposed § 488.1035.

(9) Onsite Observations of Accrediting Organization Operations (§ 488.1040)

We propose at § 488.1040(a) and (b) to permit CMS to conduct an onsite inspection of the home infusion therapy AOs operations and offices at any time to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to: (1) Interviews with various home infusion therapy AO staff; (2) review of documents, and survey files, audit tools and related records; (3) observation of meetings concerning the accreditation process; (4) auditing meetings concerning the accreditation process; (5) observation of in-progress surveys and audits; (6) evaluation of the home infusion therapy AO's survey results and accreditation decision-making process.

CMS would perform onsite visits to a home infusion therapy AOs offices only for specific reasons. For example, when an AO had filed an initial or renewal application for approval of its home infusion therapy accreditation program, CMS would perform an onsite visit to the AOs offices as part of the application review process. If CMS has opened a program review and put the home infusion therapy AO on probation for a 180 day period, we would perform an onsite visit to the AOs offices to check of the AOs progress in implementing the plan of correction.

If CMS decides to perform an onsite visit to the home infusion therapy AOs offices, we would notify the AO. We

would coordinate with the AO staff to schedule the onsite visit at mutually agreed upon date and time.

The intended purpose of this section is to provide CMS with an opportunity to observe, first hand, the daily operations of home infusion therapy AOs and to ensure that the home infusion therapy accreditation program is fully implemented and operational as presented in the written application. Onsite inspections would strengthen our continuing oversight of the home infusion therapy AO performance because they provide an opportunity for us to corroborate the verbal and written information submitted to CMS by the home infusion therapy AO in their initial and renewal applications. In addition, onsite inspections would allow CMS to assess the home infusion therapy AO's compliance with its own policies and procedures.

We seek public comments on the requirements of proposed § 488.1040. We also seek comments regarding the burden related to § 488.1040.

(10) Voluntary and Involuntary Termination (§ 488.1045)

The proposed provisions related to the voluntary and involuntary termination of CMS approval of a home infusion therapy AO's accreditation program are set out at proposed § 488.1045. Proposed § 488.1045(a) would address voluntary termination of a home infusion therapy AO's accreditation program by the home infusion therapy AO. A home infusion therapy AO that decides to voluntarily terminate its CMS-approved accreditation program must provide written notice to CMS and each of its accredited home infusion therapy suppliers at least 90 days in advance of the effective date of the termination. This written notice must state the implications for the home infusion therapy supplier's payment should there be a lapse in their accreditation status.

Proposed standard § 488.1045(b) would address CMS involuntary termination of a home infusion therapy AO's CMS-approved accreditation program. Once CMS publishes the notice in the **Federal Register** announcing its decision to terminate the accrediting organization's home infusion therapy accreditation program, the home infusion therapy AO would have to provide written notification to all home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice was published in the **Federal Register**. This notice would state that CMS is withdrawing its

approval of the home infusion therapy AO's accreditation program and the implications for their payment, should there be a lapse in their accreditation status.

Proposed § 488.1045(c) addresses the requirements that would apply to both voluntary and involuntary terminations of CMS approval of the home infusion therapy AO. Proposed § 488.1045(c)(1) would provide that the accreditation status of affected home infusion therapy suppliers would be considered to remain in effect until their current term of accreditation expired. In the case where a home infusion therapy AO has been removed as a CMS-approved AO, any home infusion therapy supplier that is accredited by the organization during the period beginning on the date the organization was approved by CMS until the date the organization was removed, shall be considered accredited for its remaining accreditation period.

Proposed § 488.1045(c)(2) would provide that for any home infusion therapy supplier, whose home infusion therapy AO's CMS approval has been voluntarily or involuntarily terminated by CMS, and who wishes to continue to receive reimbursement from Medicare, must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date which states that the home infusion therapy supplier has submitted an application for accreditation under another CMS-approved home infusion therapy accreditation program. This section further states that failure to comply with this 60-calendar day requirement prior to expiration of their current accreditation status could result in a suspension of payment.

Proposed § 488.1045(c)(3) would require that the terminated home infusion therapy AO must provide a second written notification to all accredited suppliers ten calendar days prior to the organization's accreditation program effective date of termination.

The proposed notice provisions at § 488.1045(c)(2) and (3) could help prevent home infusion therapy suppliers from suffering financial hardship that could result from a denial of payment of Medicare claims if their home infusion therapy accreditation lapses as a result of the voluntary or involuntary termination of a CMS-approved home infusion therapy AO program.

We propose at § 488.1045(d), that if a home infusion therapy supplier requests a voluntary withdrawal from accreditation, it will not be possible for the withdrawal to become effective until the home infusion therapy AO completes three required steps. First,

the AO would have to contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intended to voluntarily withdraw from the accreditation program. Second, the home infusion therapy AO would have to advise home infusion therapy supplier, in writing, of the statutory requirement at 1861(iii)(3)(D)(i)(III) of the Act for requiring accreditation for all home infusion therapy suppliers. Third, the home infusion therapy AO would have to advise the home infusion therapy supplier of the possible payment consequence for a lapse in accreditation status. Proposed § 488.1045(d)(3) would require the home infusion therapy AO to submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier five business days after the request for voluntary withdrawal was ultimately processed and effective.

We believe that it is important that the home infusion therapy seek confirmation that the home infusion therapy supplier has indeed requested a voluntary termination of their accreditation. This confirmation would prevent the erroneous termination of the accreditation of a home infusion therapy supplier that did not request it or had subsequently withdrawn their request for voluntary termination.

We believe that it is also important for the home infusion therapy AO to provide the required written notice to the home infusion therapy supplier that requests a voluntary withdrawal from accreditation, so that the home infusion therapy supplier has been fully informed of the requirements for accreditation according to section 1861(iii)(3)(D)(i)(III) and the payment consequences of being unaccredited. If there is a lapse in the accreditation status of the home infusion therapy supplier, they will not be eligible to receive payment from Medicare for services furnished to Medicare beneficiaries. A home infusion therapy infusion therapy supplier that is unaware of this payment consequence could suffer financial hardship due to furnishing services to Medicare beneficiaries for which they cannot be reimbursed after a lapse in accreditation.

We seek public comments on the requirements of proposed § 488.1045. We also seek comments regarding the burden related to § 488.1045.

(11) Reconsideration (§ 488.1050)

We propose at § 488.1050 to set forth the appeal process through which a home infusion therapy AO may request

reconsideration of an unfavorable decision made by CMS. At proposed § 488.1050(b)(1), the home infusion therapy AO would have to submit a written request for reconsideration within 30 calendar days of the receipt of the CMS notification of an adverse determination or non-renewal. Proposed § 488.1050(b)(2) would require the home infusion therapy AOs to submit a written request for reconsideration which specifies the findings or issues with which the home infusion therapy AO disagreed and the reasons for the disagreement. Proposed § 488.1050(b)(3) would allow a home infusion therapy AO to withdraw their request for reconsideration at any time before the administrative law judge issues a decision.

We propose at § 488.1050(c)(1) to establish requirements for CMS when a request for reconsideration has been received from a home infusion therapy AO. Specifically, CMS would be required to provide the home infusion therapy AO with: The opportunity for an administrative hearing with a hearing officer appointed by the Administrator of CMS; the opportunity to present, in writing and in person, evidence or documentation to refute CMS' notice of denial, termination of approval, or non-renewal of CMS approval and designation. Section 488.1050(c)(2) would require CMS to send the home infusion therapy AO written notice of the time and place of the informal hearing at least 10 business days before the scheduled hearing date.

We propose at § 488.1050(d)(1) to establish rules for the administrative hearing such as who may attend the hearing on behalf of each party, including but not limited to legal counsel, technical advisors, and non-technical witnesses that have personal knowledge of the facts of the case. This proposed section would also specify the type of evidence that may be introduced at the hearing. Specifically, we would specify and clarify, at proposed § 488.1050(d)(4), that the hearing officer would not have the authority to compel by subpoena the production of witnesses, papers, or other evidence. Proposed § 488.1050(d)(5) would provide that the legal conclusions of the hearing officer within 45 calendar days after the close of the hearing. Proposed § 488.1050(d)(6) would require the hearing officer to present his or her findings and recommendations in a written report that includes separately numbered findings of fact. According to proposed § 488.1050(d)(7), the decision of the hearing officer would be final.

We seek public comments on the requirements of proposed § 488.1050.

C. Payment for Home Infusion Therapy Services

1. Proposed Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020

Section 50401 of the BBA of 2018 (Pub. L. 115–123) amended section 1834(u) of the Act by adding a new paragraph (7) that establishes a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of the same items and services, as defined in section 1861(iii)(2)(A) and (B) of the Act, and outlined in section IV.A.2 in this proposed rule, related to the administration of home infusion drugs. The temporary transitional payment would begin on January 1, 2019 and end the day before the full implementation of the home infusion therapy benefit on January 1, 2021, as required by section 5012(d) of the 21st Century Cures Act.

a. Transitional Home Infusion Drugs

Section 1834(u)(7)(A)(iii) of the Act defines the term “transitional home infusion drug” using the same definition as ‘home infusion drug’ under section 1861(iii)(3)(C) of the Act, which is a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. However, section 1834(u)(7)(A)(iii) of the Act includes an exception to the definition of ‘home infusion drug’ if the drug is identified under section 1834(u)(7)(C) of the Act. This provision specifies the HCPCS codes for the drugs and biologicals covered under the Local Coverage Determinations (LCDs) for External Infusion Pumps. In addition, subsequent infusion drug additions to the LCDs and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified), are also included in the definition of a ‘transitional home infusion drug.’

b. Infusion Drug Administration Calendar Day

Section 1834(u)(7)(E)(i) of the Act states that payment to an eligible home infusion supplier or qualified home infusion therapy supplier for an infusion drug administration calendar

day in the individual’s home refers to payment only for the date on which professional services, as described in section 1861(iii)(2) of the Act, were furnished to administer such drugs to such individual. This includes all such drugs administered to such individual on such day. We believe this to mean that payment is only for the day on which the nurse is in the patient’s home when an infusion drug is being administered. As section 1861(iii)(2)(A) of the Act refers to the professional services, including nursing services, we believe this to mean skilled services as set out at 42 CFR 409.32. For the professional services to be necessary for the safe and effective administration of home infusion drugs, they must be furnished by skilled professionals in accordance with individual state practice acts. We understand that there may be professional services furnished that do not occur on a day the drug is being administered. However, payment for such home infusion therapy services is built into the single payment for the day on which the nurse is in the patient’s home and the drug is being infused. Accordingly, under section 1834(u)(7)(D) of the Act, the temporary transitional payment is set equal to 4 hours of infusion in a physician’s office even though the nurse may be in the patient’s home for a much shorter timeframe. In other words, payment is made only for the day on which the administration of the infusion drug occurs even if professional services were furnished on a different day. Therefore, we propose to define in regulation that payment for an infusion drug administration calendar day is for the day on which home infusion therapy services are furnished by skilled professional(s) in the individual’s home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. An infusion drug administration visit that begins in one calendar day and spans into the next calendar day would be considered one visit using the date the visit ended as the service date. We are soliciting comment on the proposed definition of infusion drug administration calendar day in regulation, as detailed in section IX of this proposed rule.

c. Eligible Home Infusion Suppliers, Eligible Individuals, and Relationship to Home Health

Section 1842(u)(7)(F) of the Act defines eligible home infusion suppliers

as suppliers that are enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies, and that maintain all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered. This means that existing DME suppliers that are enrolled as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers, as are potential pharmacy suppliers that enroll and comply with the Medicare program’s supplier standards (found at 42 CFR 424.57(c)) and quality standards to become accredited for furnishing external infusion pumps and supplies.⁹⁷ Home infusion therapy services are furnished by eligible home infusion suppliers in the individual’s home to an individual who is under the care of an applicable provider and where there is a plan of care established and periodically reviewed by a physician prescribing the type, amount, and duration of infusion therapy services. In section VI.C.2.f below, regarding the home infusion therapy benefit for CY 2021 and subsequent years, we are soliciting comments regarding the interaction between home infusion therapy services and home health services. However, for purposes of this proposed temporary transitional payment for home infusion therapy services for CYs 2019 and 2020, we anticipate the relationship between home infusion therapy and home health to be as described in section VI.C.2.f of this proposed rule.

d. Payment Categories

As outlined in section 1834(u)(7)(C) of the Act, identified HCPCS codes for transitional home infusion drugs are assigned to three payment categories for which a single payment amount will be established for home infusion therapy services furnished on each infusion drug administration calendar day. Payment category 1 includes antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, and chelation drugs. Payment category 2 includes subcutaneous immunotherapy infusions. Payment category 3 includes certain chemotherapy drugs. Table 55 provides the complete list of J-codes associated with the infusion drugs that

⁹⁷ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>.

fall within each of the payment categories.

TABLE 55—INFUSION DRUG J-CODES ASSOCIATED WITH TEMPORARY TRANSITIONAL PAYMENT CATEGORIES FOR HOME INFUSION THERAPY SERVICES

J-Code	Drug
Category 1:	
J0133	Injection, acyclovir, 5 mg.
J0285	Injection, amphotericin b, 50 mg.
J0287	Injection, amphotericin b lipid complex, 10 mg.
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg.
J0289	Injection, amphotericin b liposome, 10 mg.
J0895	Injection, deferoxamine mesylate, 500 mg.
J1170	Injection, hydromorphone, up to 4 mg.
J1250	Injection, dobutamine hydrochloride, per 250 mg.
J1265	Injection, dopamine hcl, 40 mg.
J1325	Injection, epoprostenol, 0.5 mg.
J1455	Injection, foscarnet sodium, per 1,000 mg.
J1457	Injection, gallium nitrate, 1 mg.
J1570	Injection, ganciclovir sodium, 500 mg.
J2175	Injection, meperidine hydrochloride, per 100 mg.
J2260	Injection, milrinone lactate, 5 mg.
J2270	Injection, morphine sulfate, up to 10 mg.
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg.
J2278	Injection, ziconotide, 1 microgram.
J3010	Injection, fentanyl citrate, 0.1 mg.
J3285	Injection, trestatinil, 1 mg.
Category 2:	
J1555 JB ⁹⁸	Injection, immune globulin (cuvitru), 100 mg.
J1559 JB	Injection, immune globulin (hizentra), 100 mg.
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg.
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg.
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg.
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin.
Category 3:	
J9000	Injection, doxorubicin hydrochloride, 10 mg.
J9039	Injection, blinatumomab, 1 microgram.
J9040	Injection, bleomycin sulfate, 15 units.
J9065	Injection, cladribine, per 1 mg.
J9100	Injection, cytarabine, 100 mg.
J9190	Injection, fluorouracil, 500 mg.
J9200	Injection, floxuridine, 500 mg.
J9360	Injection, vinblastine sulfate, 1 mg.
J9370	Injection, vincristine sulfate, 1 mg.

The payment category for subsequent transitional home infusion drug additions to the LCDs and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the Medicare administrative contractors.

e. Payment Amounts

As set out at new section 1834(u)(7)(D) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L. 115–123), each payment category will be paid at amounts in accordance with

the Physician Fee Schedule for each infusion drug administration calendar day in the individual's home for drugs assigned to such category without geographic adjustment. Table 56 provides the payment categories associated with the HCPCS codes.

TABLE 56—PAYMENT CATEGORIES FOR TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES

HCPCS code	Description	Units
Category 1:		
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)—up to one hour.	1
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)—each additional hour.	3
Category 2:		
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)—up to one hour.	1
96370	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)—each additional hour.	3
Category 3:		

⁹⁸ The JB modifier indicates that the route of administration is subcutaneous.

TABLE 56—PAYMENT CATEGORIES FOR TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES—Continued

HCPCS code	Description	Units
96413	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration—up to one hour.	1
96415	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration—each additional hour.	3

Section 1834(u)(7)(E)(ii) of the Act requires that in the case that two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category would be made.

f. Billing

For eligible home infusion suppliers to bill for home infusion therapy services for an infusion drug administration calendar day, we will create three new HCPCS G-codes for each of the three payment categories. The eligible home infusion supplier would submit, in line-item detail on the claim, a G-code for every visit made by the nurse to provide professional services to the patient in his/her home on a day in which a drug is being infused. Each visit reported would include the length of time in which professional services were provided (in 15 minute increments). However, only one payment would be made per infusion drug administration calendar day at the standard amount described by each of the payment categories noted previously, for a total payment equivalent to 4 hours per infusion drug administration calendar day. These G-codes could be billed separately from or on the same claim as the DME, supplies, and infusion drug; and would be processed through the DME MACs. The supplier furnishing the DME, pump, the infusion drug, and other supplies must also provide the professional services under the home infusion therapy benefit during the temporary transitional payment period.

For the purposes of this temporary transitional payment for home infusion therapy services, section 1834(u)(7)(D)(i) requires that payment amounts would be equal to the amounts determined under the Physician Fee Schedule established under section 1848 of the Act for services furnished during the year for codes and units for such codes specified without application of geographic wage adjustment under section 1848(e) of the Act. In the event that multiple drugs, which are not all assigned to the same payment category,

are administered on the same infusion drug administration calendar day, section 1834(u)(7)(E)(ii) requires that a single payment would be made that is equal to the highest payment category. In order to implement the requirements of section 1834(u)(7) of the Act for this temporary transitional payment, we would issue a Change Request (CR) prior to implementation of this temporary transitional payment, including the G-codes needed for billing, outlining the requirements for the claims processing changes needed to implement this payment.

2. Solicitation of Public Comments Regarding Payment for Home Infusion Therapy Services for CY 2021 and Subsequent Years

Upon the expiration of the home infusion therapy services temporary transitional payment, we would be fully implementing the home infusion therapy services payment system under section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act (Pub. L. 114–255). In anticipation of future rulemaking, we are soliciting comments regarding the payment system for home infusion therapy services beginning in CY 2021.

a. Relationship to DME

As mentioned previously, Medicare Part B covers certain infusion pumps and supplies (including certain home infusion drugs) that are necessary for the effective use of the infusion pump, through the DME benefit. To be covered under the Part B DME benefit, the drug must be reasonable and necessary for the treatment of illness or injury or to improve the function of a malformed body member, and the drug must be necessary for the effective use of the DME. However, there is no separate Medicare Part B DME payment for professional services associated with the administration of home infusion drugs, including nursing services, or for training and education, monitoring, and remote monitoring services. Therefore, we consider the home infusion therapy benefit principally to be a separate payment in addition to the existing payment made under the DME benefit,

thus explicitly and separately paying for the home infusion therapy services.

b. Definition of Infusion Drug Administration Calendar Day

Section 1834(u)(7)(E)(i) of the Act applies the same definition of “infusion drug administration calendar day” for both the home infusion therapy temporary transitional payment and the home infusion therapy services benefit. We anticipate retaining the definition of infusion drug administration calendar day, as proposed in section IV.C.2. of this proposed rule for the full implementation of the home infusion therapy services benefit. This means that payment for an infusion drug administration calendar day is for the day on which home infusion therapy services are furnished by skilled professionals in the individual’s home on the day of infusion drug administration. An infusion drug administration visit that begins in one calendar day and spans into the next calendar day would be considered one visit using the date the visit ended as the service date. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. We are soliciting comments on the definition as discussed in section IV.C.2. of this proposed rule.

c. Payment Basis, Limitation on Payment, Required and Discretionary Adjustments, and Billing Procedures

Section 1834(u)(1)(A) of the Act requires the establishment of a unit of single payment for each infusion drug administration calendar day. Section 1834(u)(1)(A)(iii) of the Act limits the unit of single payment by requiring that it must not exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services furnished in a calendar day if furnished in a physician’s office, and the single payment must not reflect more than five hours for a particular therapy in a calendar day. Additionally, section 1834(u)(1) of the Act includes provisions for payment adjustments to

the unit of single payment for home infusion therapy. Section 1834(u)(1)(B) of the Act requires adjustments to reflect factors such as patient acuity and complexity of drug administration, and a geographic wage index and other costs that may vary by region. While the three payment categories used for the temporary transitional payment in CYs 2019 and 2020 reflect the therapy type and complexity of the drug administration under the Physician Fee Schedule, we are soliciting comments on other ways to account for therapy type and complexity of administration, as well as ways to capture patient acuity.

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted by a geographic wage index; therefore, we are considering using the Geographic Practice Cost Indices (GPCIs) to account for regional variations in wages and adjust the payment for the professional services. A GPCI has been established for every Medicare payment locality for each of the three components of a procedure's relative value unit (RVU) (for example, the RVUs for work, practice expense, and malpractice). The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.⁹⁹ Finally, section 1834(u)(1)(C) of the Act allows for discretionary adjustments which may include outlier situations and other factors as deemed appropriate by the Secretary, and are required to be made in a budget neutral manner. We request feedback on situations that may incur an outlier payment and potential designs for an outlier payment calculation.

For CY 2021 and subsequent years, although not required by law, the Part B qualified home infusion therapy supplier could potentially submit a claim for home infusion therapy services on a Part B practitioner claim and processed through the A/B MACs, rather than the DME MACs. We are soliciting comment on whether submitting a Part B practitioner claim processed through the A/B MACs is reasonable given that other types of suppliers and providers of services (such as physicians and HHAs), and not just DME suppliers, can meet the requirements under section 1861(iii) of the Act, such as accreditation, to provide home infusion therapy services. In addition, when Part B practitioner claims are processed through the A/B MACs a mechanism is already in place for the geographic wage adjustment, as

required for the home infusion therapy payment system, and we are considering the use of GPCI as described previously. In order to bill for the home infusion therapy services, beginning on January 1, 2021, a qualified home infusion therapy supplier will need to enroll in Medicare as a Part B Home Infusion Therapy supplier. Additionally, in order to furnish DME equipment and supplies, that same qualified home infusion therapy supplier must also be enrolled as a DME supplier since the home infusion therapy services are required to be for the furnishing of DME infusion drugs through a DME infusion pump. In other words, both enrollments would be necessary for the same supplier to bill for home infusion therapy services and the DME equipment and supplies. Therefore, in order to be paid for all elements of home infusion therapy, two claims would need to be submitted: (1) The first claim for the DME drug, equipment, and supplies on the 837P/CMS-1500 professional and supplier claims form submitted to the DME MAC; and (2) a second claim for the professional services on the 837P/CMS-1500 professional and supplier claims form submitted to the A/B MAC.

We invite comments on the unit of single payment, limitations on payment, and required and discretionary adjustments. We are also soliciting comments on whether it is reasonable to require two separate claims submissions to account for all components of home infusion therapy using the 837P/CMS-1500 professional and supplier claims form, and submitting claims to both the DME MACs and the A/B MACs for processing. Finally, we are soliciting any additional suggestions as to how qualified home infusion therapy suppliers should bill and be paid for services under the home infusion therapy benefit.

d. Definition of Professional/Nursing Services and Monitoring Related to the Administration of Home Infusion Drugs

In accordance with section 1861(iii)(2) of the Act, items and services covered under the home infusion therapy benefit are as follows:

- Professional services, including nursing services, furnished in accordance with the plan.
- Training and education (not otherwise paid for as DME),
- Remote monitoring, and monitoring services for the provision of home infusion drugs furnished by a qualified home infusion therapy supplier.

Section 1861(n) of the Act defines DME as equipment used in the patient's home. Furthermore, the regulations at

42 CFR 424.57(c)(12) state that the DME supplier "must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively." As the medications in the DME external infusion pump LCDs are considered supplies to the external infusion pump, and have been identified as drugs and biologicals that can be self-infused in the home, ongoing nursing supervision is not required once the patient and/or caregiver has been sufficiently taught to safely manage the pump. We recognize that the DME supplier standards require a DME supplier to document that it or another qualified party has at an appropriate time provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively (42 CFR 424.57(c)(12)). Therefore, the in-home nursing services under the home infusion therapy benefit would include a limited amount of teaching and training on the provision of home infusion drugs that is not already covered under the DME benefit in accordance.

In determining the reasonable and necessary number of infusion therapy visits, the home infusion therapy supplier must consider whether the training and education provided constitutes reinforcement of teaching provided previously in an institutional setting or in the home, or whether it represents initial instruction. Where the teaching represents initial instruction, the supplier should consider patient acuity, including the unique abilities of the patient, and complexity of the infusion. Where the teaching constitutes reinforcement, the supplier should evaluate the patient's retained knowledge and anticipated learning progress to determine the appropriate number of visits. Re-teaching or retraining for an appropriate period may be considered reasonable and necessary where there is a change in the infusion protocol or the patient's condition that requires re-teaching, or where the patient, family, or caregiver is not properly carrying out the task. The medical record should document the anticipated number of training and education visits required, patient/caregiver response to training, and if necessary, the reason that the re-teaching or retraining is required. Where it becomes apparent after a reasonable period of time that the patient/caregiver is not able to be trained, or if the patient/caregiver has been taught to safely and effectively use the infusion

⁹⁹ <https://www.cms.gov/apps/physician-fee-schedule/documentation.aspx>.

pump in the home, then further teaching and training would cease to be reasonable and necessary. In accordance with section 1861(iii)(1)(B), an individual must be under a plan of care established by a physician, prescribing the type, amount, and duration of infusion therapy services that are to be furnished in coordination with the furnishing of home infusion drugs under Part B. These home infusion drugs, defined under section 1861(iii)(3)(C) of the Act, must be administered intravenously, or subcutaneously for an administration period of 15 minutes or more through a pump that is an item of DME in order for home infusion therapy services to be reasonable and necessary for the treatment of the illness or injury. In order to satisfy the definition of DME, an item must be appropriate for use in the home. In this case, in order to be considered appropriate for use in the home, the patient must be able to safely and effectively operate the infusion pump. Therefore, if a patient is unable to safely and effectively operate the infusion pump in the home, then the patient would not be eligible for the home infusion therapy benefit.

It is important to reiterate that the professional services covered under this benefit are not intended to provide ongoing nursing supervision throughout each infusion. If applicable, the reason why a training was unsuccessful should be documented in the record. We invite comments regarding what constitutes a reasonable and necessary amount of training and education for the provision of home infusion drugs. We outline in this section additional, more detailed information on the professional and nursing services that would be covered, as well as remote monitoring services for the provision of home infusion drugs, as defined in 1861(iii)(3)(C) of the Act, relative to the therapy types currently included in the DME external infusion pump LCD.¹⁰⁰

(1) Central Vascular Access Device Maintenance

As many of the drugs and biologicals included in the DME external infusion pump LCD are given continuously, given on a long-term basis, or are vesicants or irritants that should not be given peripherally, many beneficiaries would likely have central vascular access devices (CVAD), such as peripherally inserted central catheters (PICC), central lines, or ports requiring training and education regarding

maintenance and hygiene, and site care and dressing changes. The qualified home infusion therapy supplier would be responsible for educating the patient on properly disinfecting access points and connectors, what to do in the event of a dislodgement or occlusion, and signs/symptoms of infection. This also includes teaching the patient about flushing the CVAD after the infusion to ensure all of the medication has been flushed through the tubing and catheter, and locking the catheter to prevent blood from backing into the catheter and clotting. Education regarding specific techniques and solutions (saline or heparin) may be given to minimize catheter occlusion.¹⁰¹

(2) Medication Education and Disease Management

The qualified home infusion therapy supplier would be responsible for ensuring that the patient has been properly educated about his/her disease, medication therapy, and lifestyle changes. This could include self-monitoring instruction (for example, nutrition, temperature, blood pressure, heart rate, daily weight, abdominal girth measurement, edema, urine output) and identification of complications or problems necessitating a call to the infusion nurse/pharmacist, or emergency protocols if they arise. The qualified home infusion therapy supplier would ensure proper understanding of the medication therapy including: Drug; route of administration; prescription (dosage, how often to administer, and duration of therapy); side effects and interactions with other medications; adverse reactions to therapy; goals of therapy; and indications of progress. Lifestyle education regarding behavior and food/fluid modifications/restrictions, symptom management, and infection control are also important aspects of this education. As some drugs covered under the DME benefit involve extensive lifestyle changes and dietary restrictions, training and education as included in the home infusion therapy benefit could entail any ancillary services such as visits with social workers or dieticians as needed, and documented in the medical record. For patients on continuous, potentially life long IV therapy, the nurse, social worker, or dietician would assess the need for further training and education regarding the concept of long-term drug infusion and address aspects of life-style

changes and realistic expectations for life with an infusion pump.

(3) Patient Evaluation and Assessment

Comprehensive patient assessment is imperative when providing home infusion therapy in order to ensure the accuracy of the medication administration and safety of the patient, and to determine whether changes in the home infusion therapy plan of care are necessary. The qualified home infusion therapy supplier would evaluate patient history, current physical and mental status, including patient response to therapy, any adverse effects or infusion complications, lab reports, cognitive and psychosocial status, family/care partner support, prescribed treatment, concurrent oral prescriptions, and over-the-counter medications. This includes obtaining any necessary blood-work and vital signs.

(4) Medication Administration

As the DME supplier is responsible, under the DME benefit,¹⁰² for training the patient and caregiver on pump operation, maintenance, and troubleshooting; the qualified home infusion therapy supplier would be responsible for all other aspects of medication administration, including inspection of medications, containers, supplies prior to use; proper drug storage and disposal; household precautions for chemotherapy drugs including spills, handling body wastes, and physical contact precautions; hand hygiene and aseptic technique; pre/post medication/hydration administration; and medication preparation.

(5) Remote Monitoring and Monitoring Services

Section 1861(iii)(3)(D)(i)(II) of the Act requires that the qualified home infusion therapy supplier “ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.” Therefore, the qualified home infusion therapy supplier would closely monitor lab values, patient response to therapy, and assess compliance. Direct communication and coordination with the patient, caregivers, applicable providers, and pharmacist regarding changes in the patient’s condition should be on-going so that any adjustment to treatment is made as needed and in a timely fashion.

Monitoring services, as indicated on the plan of care, would dictate either the

¹⁰⁰ <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD>.

¹⁰¹ Gabriel J (2013) Venous access devices part 2: preventing and managing complications of CVADs. *Nursing Times*; 109: 40, 20–23.

¹⁰² <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/DMEPOS Accreditation Standards CMB.pdf>.

need for daily monitoring of indicated vitals (through remote monitoring) or specify the interval for in-person evaluation and assessment of the patient. The use of remote monitoring services for those patients receiving home infusion therapy would likely be limited to patients receiving continuous infusion medications as identified in the plan of care. These patients are considered high risk patients and require daily monitoring, but generally do not need to be seen by a practitioner daily. This can be achieved, for example, through the use of a remote monitoring service that includes monitoring equipment through which the patient electronically submits self-obtained vital signs, such as weight, blood pressure, and heart rate. In this example, an off-site monitoring service would communicate any abnormal results to the home infusion therapy supplier for analysis and consultation with the provider overseeing the patient's care (that is, physician, nurse practitioner, or physician assistant) regarding potential treatment plan changes.

We invite comments on any additional interpretations of professional, nursing, training and education, and monitoring services that may be considered under the scope of the home infusion therapy benefit. We also specifically welcome comments on the use of remote monitoring under the home infusion therapy benefit.

e. The Role of Prior Authorization Under the Home Infusion Therapy Benefit

Section 1834(u)(4) of the Act states that the Secretary may apply prior authorization for home infusion services. Generally, prior authorization requires that a decision by a health insurer or plan be rendered to confirm that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary.¹⁰³ Prior authorization helps to ensure that a service, such as home infusion therapy, is being provided appropriately. Private health plans generally require prior authorization before home infusion therapy can begin. We would maintain the discretion to decide if certain drugs or frequency in visits require prior authorization before therapy can be covered. The emphasis would be on the appropriateness of the drug and the necessity of associated professional services and not the site of care. We are soliciting comments as to whether and how prior authorization

could potentially be utilized for home infusion therapy.

f. Home Infusion Therapy and the Relationship to/Interaction With Home Health

A beneficiary does not have to be considered confined to the home (that is, homebound) in order to be eligible for the home infusion therapy benefit. However, homebound beneficiaries requiring home health services also may be eligible for the home infusion therapy benefit. Therefore, there may be circumstances when a patient may utilize both the home health benefit and the home infusion therapy benefit concurrently.

HHAs are required to furnish necessary DME and coordinate home infusion services when a patient is under a home health plan of care. In accordance with the Home Health Conditions of Participation at 42 CFR 484.60, the HHA must assure communication with all physicians involved in the plan of care, as well as integrate orders and services provided by all physicians and disciplines. In order to qualify for the Medicare home health benefit, the beneficiary must—

- Be confined to the home;
- Be under the care of a physician;
- Receive services under a plan of care established and periodically reviewed by a physician;
- Be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology, or have a continuing need for occupational therapy; and
- Have had a face-to-face encounter related to the primary reason for home health care with an allowed provider type and within the required timeframe.

If a patient meets the requirements listed previously and a home health visit is furnished that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS payment and billed on the home health claim. When the HHA providing services under the Medicare home health benefit is also the same entity furnishing services as the qualified home infusion therapy supplier, and a home visit is exclusively for the purpose of furnishing items and services related to home infusion therapy, the HHA would submit a claim for payment as a home infusion therapy supplier and receive payment under the home infusion therapy benefit. If the home visit includes the provision of other home health services in addition to, and separate from, items and services related to the home infusion therapy, the HHA would submit both a home health claim and a home infusion

therapy claim, but must separate the time spent performing services covered under the HH PPS from the time spent performing services covered under the home infusion therapy benefit. We anticipate this would be similar to the approach for furnishing negative pressure wound therapy using a disposable device as described in the regulations at 42 CFR 484.205(b).

We are soliciting feedback on the relationship between the Medicare home health benefit and the home infusion therapy benefit, including how payment would be made for a beneficiary who meets eligibility requirements for home health services and home infusion therapy services.

VII. Changes to the Accreditation Requirements for Certain Medicare-Certified Providers and Suppliers

A. Background

To participate in the Medicare program, Medicare-certified providers and suppliers of health care services, must be substantially in compliance with specified statutory requirements of the Act, as well as any additional regulatory requirements related to the health and safety of patients specified by the Secretary of the Department of Health and Human Services (HHS). Medicare certified providers and suppliers are enrolled in the Medicare program by entering into an agreement with Medicare. They include hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, and ambulatory surgical centers. These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for skilled nursing facilities (SNFs), conditions for coverage (CfCs) for ambulatory surgical centers (ASCs) and other suppliers, and conditions for certification for rural health clinics (RHCs). A Medicare-certified provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its participation in the Medicare program terminated.

In accordance with section 1864 of the Act, state health departments or similar agencies, under an agreement with CMS, survey health care providers and suppliers to ascertain compliance with the applicable CoPs, CfCs, conditions of certification, or requirements, and certify their findings to us. Based on these State Survey

¹⁰³ <https://www.healthcare.gov/glossary/prior-authorization/>.

Agency (SA) certifications, we determine whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

Section 1865(a) of the Act allows most health care facilities to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accreditation body. If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider or supplier accredited by the AO's CMS-approved accreditation program may be deemed by us to meet the Medicare conditions or requirements.

We are responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring providers or suppliers accredited by the AO meet the quality and patient safety standards required by the Medicare CoPs, requirements, CfCs, and conditions for certification. Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for and be approved by CMS for a period not to exceed six years.

The AO must reapply for renewed CMS approval of an accreditation program before the date its approval period expires. This allows providers or suppliers accredited under the program to continue to be deemed to be in compliance with the applicable Medicare CoPs, requirements, CfCs, and conditions for certification. Regulations implementing these provisions are found at 42 CFR 488.1 through 488.9.

We believe that it is necessary to revise the regulations for Medicare-certified providers and providers to add two new requirements for the AOs that accredit certified providers and providers. First, we are proposing at § 488.5 to require AOs for Medicare-certified providers and suppliers to include a written statement in their application which states that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the AO's CMS-approved accreditation program, the AO must continue the facility's current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first. We are also proposing to modify the AO oversight regulations at § 488.5 by adding new requirements for training for AO surveyors.

B. Proposed Changes to Certain Requirements for Medicare-Certified Providers and Suppliers at Part 488

1. Continuation of Term of Accreditation When a Medicare-Certified Provider or Supplier Decides to Voluntarily Terminate the Services of an Accrediting Organization (§ 488.5)

We propose to add a new regulation at § 488.5(a)(17)(iii), which would require that, with an initial or renewal application for CMS-approval of a Medicare certified provider or supplier accreditation program, an AO must include a written statement agreeing that when a fully accredited, deemed provider or supplier in good standing notifies its AO that it wishes to voluntarily withdraw from the AO's accreditation program, the AO would honor the provider's or supplier's current term of accreditation until the effective date of withdrawal identified by the facility, or the expiration date of the term of accreditation, whichever comes first. We make this proposal because we have received numerous complaints from accredited and deemed facilities in good standing with their current AO stating that once they provide notification to the AO of their intent to voluntarily withdraw their accreditation from that AO, the AO frequently terminates their accreditation immediately without regard to their current accreditation status, up to date payment of fees, contract status, or the facility's requested effective date of withdrawal. Accreditation is voluntary for Medicare certified providers and suppliers that participate in Medicare. It is not required for participation in Medicare. Therefore, we do not believe it is reasonable for AOs to penalize facilities because they choose to terminate the services of an AO. Medicare certified providers and suppliers may freely choose to demonstrate compliance with the Medicare conditions by receiving surveys from any CMS-approved AO of their choice, or the SA.

2. Training Requirements for Accrediting Organization Surveyors (§ 488.5(a)(7))

We are proposing to add a new requirement at § 488.5(a)(7) which imposes a new training requirement for surveyors of AO that accredit Medicare certified provider and supplier types by amending the provision at § 488.5(a)(7). We are proposing that all AO surveyors be required to complete the relevant program-specific CMS online trainings initially, and thereafter, consistent with requirements established by CMS for state surveyors. CMS provides a wide

variety of comprehensive trainings through an on-demand integrated surveyor training website. These online trainings are available and can be accessed by state and federal surveyors and the public, free of charge, 24 hours a day, 365 days a year. These online trainings are currently publically available for the SA surveyors.

As part of our oversight of the AOs performance, CMS has contracted with the SAs to perform validation surveys on a sample of providers and suppliers (such as hospitals, critical access hospital, ambulatory surgical centers, and home health agencies) accredited by the AOs that accredit Medicare certified providers and suppliers. Validation surveys must be performed by the SA within 60 days of the survey performed by the AO. As a validation survey is performed within 60 days of the AO survey, we believe that the conditions at the hospital or other facility being surveyed would be similar at the time of the validation survey.

The purpose of a validation survey is to compare the survey findings of the AO to the survey findings of the SA to see if there are any disparities. The amount of disparities found in the AO's survey is called the "disparity rate" and is tracked by CMS as an indication of the quality of the surveys performed by the AO.

CMS has determined that many of the AOs' disparity rates have been consistently high. This means that the AOs have consistently failed to find the same condition level deficiencies in the care provided by the hospital or other providers surveyed that were found by the SA during the validation survey.

We believe that the disparity in findings made by the AO surveyors and those of the SA surveyors can largely be attributed the difference in the training and education provided to the AO surveyors. Each AO is responsible for providing training and education to their surveyors. The surveyor training and education provided varies from AO to AO and is not consistent. CMS provides comprehensive online training to the SA surveyor staff on the CMS Surveyor Training website¹⁰⁴ which are specific to each type of provider of supplier type to be surveyed.

It is our belief that the AO's disparity rate would be decreased if all surveyors took the same training. We believe completion of the same surveyor training by both SA and AO surveyors would increase the consistency between the results of the surveys performed by the SAs and AOs and have a positive impact on the historically high disparity

¹⁰⁴ <https://surveyortraining.cms.hhs.gov/>.

rate. Therefore we are proposing that all AO surveyors be required to take the CMS online surveyor training offered on the CMS website. We would require each AO to provide CMS with documentation which provides proof that each of their surveyors has completed the CMS online surveyor training. If the AO fails to provide this documentation, CMS could place the AO on an accreditation program review pursuant to § 488.8(c).

VIII. Requests for Information

This section addresses two requests for information (RFI). Upon reviewing the RFIs, respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; neither RFI constitutes a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor each RFI announcement for additional information pertaining to the request. Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.¹⁰⁵ While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater

interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC “. . . for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally.” In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement,¹⁰⁶ which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-term:

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.
- Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.
- Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations

¹⁰⁵ These statistics can be accessed at: <https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php>.

¹⁰⁶ The draft version of the trusted Exchange Framework may be accessed at: <https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>.

accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives.

- The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required

discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185) and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children’s hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

- Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient’s practitioner, if the practitioner is known and has been clearly identified;
- Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the time of discharge; and
- Hospitals, CAHs, and HHAs would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient’s goals of care and treatment preferences.

We published another proposed rule (81 FR 39448) on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such

other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

We also published a final rule (81 FR 68688) on October 4, 2016, that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. In this rule, we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident’s receiving provider, whether it is an acute care hospital, an LTCH, a psychiatric facility, another LTC facility, a hospice, a home health agency, or another community-based provider or practitioner (42 CFR 483.15(c)(2)(iii)). We specified that necessary information must include the following:

- Contact information of the practitioner responsible for the care of the resident;
- Resident representative information including contact information;
- Advance directive information;
- Special instructions or precautions for ongoing care;
- The resident’s comprehensive care plan goals; and
- All other necessary information, including a copy of the resident’s discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the resident’s medications, as well as a recapitulation of the resident’s stay, a final summary of the resident’s status, and the post-discharge plan of care. In addition, in the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?

- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?

- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?

- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?

- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?

- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving

provider, supplier, or patient/resident cannot receive the information electronically?

- Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicare beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data were really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is

a developer-friendly, standards-based application programming interface (API) that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Home Health Agency Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we stated that we intend to continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge

information on the CMS website.¹⁰⁷ In the FY 2019 IPPS/LTCH PPS proposed rule, we also continued our discussion of the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. This discussion in the FY 2019 IPPS/LTCH PPS proposed rule continued a discussion we began in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively). In all of these rules, we noted that section 2718(e) of the Public Health Service Act requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. In the FY 2015 IPPS/LTCH PPS proposed and final rules, we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS proposed rule, we took one step to further improve the public accessibility of charge information. Specifically, effective January 1, 2019, we are updating our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate.

In general, we encourage all providers and suppliers to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being

surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals and in other settings, and patients being surprised by facility fees, physician fees for emergency department visits, or fees for services that are part of the beneficiary's episode of care but that are not otherwise included in a hospital's chargemaster (for example, home health or physical therapy services that follow a hospital stay but are billed separately). We also are concerned that, for providers and suppliers that maintain a list of standard charges, the charge data may not be helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of current charge information.

We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including when services could be offered in more than one setting. Therefore, we are seeking public comment from all providers and suppliers, including home health agencies, on the following:

- How should we define "standard charges" in the home health setting? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should "standard charges" be defined to mean: average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the HHA based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should "standard charges" be defined and reported for both some measure of the average contracted rate and the chargemaster, price list or charge list? Or is the best measure of a HHA's standard charges its chargemaster, price list or charge list?

- What types of information would be most beneficial to patients, how can HHAs best enable patients to use charge and cost information in their decision-making, and how can CMS and HHAs help third parties create patient-friendly interfaces with these data?

- Should HHAs be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patients' choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how co-pays and co-insurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should HHAs play any role in helping to inform patients of what their out-of-pocket obligations will be?

- If HHAs were required to provide patients with information on what Medicare pays for a particular service performed by that HHA, what changes would need to be made by HHAs? What burden would be added as a result of such a requirement?

In addition, we are seeking public comment on improving a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do HHAs face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support HHAs that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management

¹⁰⁷ See, for example, Medicare Provider Utilization and Payment Data, available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html>.

and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics'

May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table (Table 57) presents the mean hourly wage rate, fringe benefits costs and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 57—MAY 2017 NATIONAL INDUSTRY—SPECIFIC OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES—NAICS 621600—HOME HEALTH CARE SERVICES

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (100%) (\$/hr)	Adjusted hourly wage (\$/hr)
Registered Nurse (RN)	29-1141	\$33.77	\$33.77	\$67.54
Physical therapists HHAs	29-1123	46.19	46.19	92.38
Speech-Language Pathologists (SLP)	29-1127	43.93	43.93	87.86
Occupational Therapists (OT)	29-1122	43.70	43.70	87.40

This proposed rule makes reference to associated information collections that are not discussed in the regulation text contained in this document. These proposed changes are associated with the Information Collection Request (ICR) for CMS-10545—Outcome and Assessment Information Set (OASIS) OASIS-C2/ICD-10, approved under OMB control number 0938-1279. We note that on March 12, 2018 we published a notice in the **Federal Register** seeking public comment on a revision to CMS-10545 (OMB control number 0938-1279), which would modify the OASIS and refer to the revised item set as the OASIS-D upon implementation of the revised data set on January 1, 2019 (83 FR 10730). We are soliciting public comment on additional changes related to when certain OASIS items are required to be completed by HHA clinicians due to the proposed implementation of the patient-driven groupings model (PDGM) for CY 2020, as outlined in section III.F of this proposed rule; and the changes to due to the proposed removal of HH QRP measures beginning with the CY 2021 HH QRP, as outlined in section V.E of this proposed rule.

B. ICRs Regarding the OASIS

We believe that the burden associated with the OASIS is the time and effort associated with data collection and reporting. As of April 1, 2018, there are approximately 11,623 HHAs reporting OASIS data to CMS.

In section V.E.1 of the proposed rule, we are proposing to remove the Depression Assessment Conducted Measure from the HH QRP beginning

with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. The removal of this measure will not impact collection of information because OASIS Item M1730, which is used to calculate this measure, is also used as a risk adjuster to calculate other OASIS-based outcome measures currently adopted for the HH QRP.¹⁰⁸

In section V.E.2 of the proposed rule, we are proposing to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This measure is calculated using OASIS Item M2401, row a at the time point of Transfer to an Inpatient Facility (TOC) and Discharge from Agency—Not to an Inpatient Facility (Discharge). Specifically, we are proposing to remove this one data element at the TOC and Discharge time points.

¹⁰⁸ The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), Improvement in Management of Oral Medications (NQF #0176), and Improvement in Status of Surgical Wounds (NQF #0178).

In section V.E.3 of the proposed rule, we are proposing to remove the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This measure is calculated using OASIS Item M1910 at the time point of SOC/ROC. Specifically, we are proposing to remove this one data element at the SOC/ROC time point.

In section V.E.4 of the proposed rule, we are proposing to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 3. A measure does not align with current clinical guidelines or practice. This measure is calculated using OASIS Items M1051 and M1056 at the time points of TOC and Discharge. Specifically, we are proposing to remove these two data elements at the TOC and Discharge time points.

In section V.E.5 of the proposed rule, we are proposing to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. The removal of this measure will not impact collection of information because OASIS Items M1340 and M1342 are

used as risk adjusters to calculate other OASIS-based outcome measures currently adopted for the HH QRP and OASIS Items M1340 and M1342 are also used for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance that is used by HH surveyors during the survey process.^{109 110}

In sections V.E.6 and V.E.7 of the proposed rule, we are proposing to remove the Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505) Measure and the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. Because these are both claims-based measures, their removal will not impact collection of information.

Therefore, we are proposing the net reduction of 1 data element at SOC, 1 data element at ROC, 3 data elements at TOC and 3 data elements at Discharge associated with OASIS item collection as a result of the measure removal proposals from the HH QRP.

The OASIS instrument is used for meeting the home health Conditions of Participation, requirements under the HH QRP, and for payment purposes under the HH PPS. As outlined in section III.F of this proposed rule, to calculate the case-mix adjusted payment amount for the PDGM, we are proposing to add collection of two current OASIS items (10 data elements) at the FU time point:

- M1033: Risk for Hospitalization (9 data elements)
- M1800: Grooming (1 data element)

As outlined in section III.F of this proposed rule, several OASIS items would not be needed in case-mix adjusting the period payment for the PDGM; therefore, we are proposing to make 19 current OASIS items (48 data elements) optional at the FU time point:

- M1021: Primary Diagnosis (3 data elements)
- M1023: Other Diagnosis (15 data elements)
- M1030: Therapies (3 data elements)
- M1200: Vision (1 data element)
- M1242: Frequency of Pain Interfering (1 data element)
- M1311: Current Number of Unhealed Pressure Ulcers at Each Stage (12 data elements)
- M1322: Current Number of Stage 1 Pressure Ulcers (1 data element)
- M1324: Stage of Most Problematic Unhealed Pressure Ulcer that is Stageable (1 data element)
- M1330: Does this patient have a Stasis Ulcer? (1 data element)
- M1332: Current Number of Stasis Ulcer(s) that are Observable (1 data element)
- M1334: Status of Most Problematic Stasis Ulcer that is Observable (1 data element)
- M1340: Does this patient have a Surgical Wound (1 data element)
- M1342: Status of Most Problematic Surgical Wound that is Observable (1 data element)
- M1400: Short of Breath (1 data element)
- M1610: Urinary Incontinence or Urinary Catheter Presence (1 data element)
- M1620: Bowel Incontinence Frequency (1 data element)
- M1630: Ostomy for Bowel Elimination (1 data element)
- M2030: Management of Injectable Medications (1 data element)

- M2200: Therapy Need (1 data element)

Therefore, we are proposing the net reduction of 38 data elements at FU associated with OASIS item collection as a result of the implementation of the PDGM for CY 2020.

In summary, under our proposals, there would be a net reduction of 1 data element at SOC, 1 data element at ROC, 38 data elements at FU, 3 data elements at TOC and 3 data elements at Discharge associated with OASIS item collection as a result of the measure removal proposals from the HH QRP and the proposed implementation of the PDGM starting January 1, 2020.

We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, we estimate that there would be a reduction in clinician burden per OASIS assessment of 0.3 minutes at SOC, 0.3 minutes at ROC, 11.4 minutes at FU, 0.9 minutes at TOC and 0.9 minutes at Discharge.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2016 show that the SOC/ROC OASIS is completed by RNs (approximately 87 percent of the time), PTs (approximately 12.7 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). We estimated a weighted clinician average hourly wage of \$70.75, inclusive of fringe benefits, using the hourly wage data in Table 57. Individual providers determine the staffing resources necessary.

Table 58 shows the total number of assessments submitted in CY 2017 and estimated burden at each time point.

TABLE 58—CY 2017 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time point	CY 2017 assessments completed	Estimated burden (\$)
Start of Care	6,420,299	-\$2,271,180.77
Resumption of Care	1,062,962	-376,022.81
Follow-up	3,688,651	-49,584,691.07
Transfer to an inpatient facility	1,925,270	-2,043,192.79
Death at Home	41,183	0
Discharge from agency	5,249,483	-5,571,013.83
Total	18,387,848	-59,846,101.27

* Estimated Burden (\$) at each Time-Point = (# CY 2017 Assessments Completed) × (clinician burden [min]/60) × (\$70.75 [weighted clinician average hourly wage]).

¹⁰⁹ The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF

#0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), and Improvement in Management of Oral Medications (NQF #0176).

¹¹⁰ Measure specifications can be found in the Home Health Potentially Avoidable Events

Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

Based on the data in Table 58 for the 11,623 active Medicare-certified HHAs in April 2018, we estimate the total average decrease in cost associated with proposed changes with OASIS item collection at \$5,148.94 per HHA annually, or \$59,846,101.27 for all HHAs annually. This corresponds to an estimated reduction in clinician burden associated with changes to collection of information associated with the OASIS of 72.8 hours per HHA annually, or 845,881.3 hours for all HHAs annually. This decrease in burden would be accounted for in the information collection under OMB control number 0938-1279.

C. ICRs Regarding Home Infusion Therapy

At § 486.520, Plan of Care, we propose that all patients must have a plan of care established by a physician that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. This requirement directly implements section 5012 of the 21st Cures Act. Accredited home infusion therapy suppliers are already required by their accrediting bodies to provide all care in accordance with a plan of care that specifies the type, amount, and duration of infusion therapy services to be furnished to each patient; therefore this proposed requirement would not impose a burden upon accredited agencies. Furthermore, all existing home infusion therapy suppliers are already accredited due to existing payment requirements established by private insurers and Medicare Advantage plans. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(3), this requirement exists even in the absence of a federal requirement; therefore, the associated burden is not subject to the PRA.

D. ICRs Regarding the Approval and Oversight of Accrediting Organizations for Home Infusion Therapy

1. Background

We are proposing to establish a new set of regulations related to the approval and oversight of accrediting organizations that accredit home infusion therapy suppliers. If finalized, these new regulatory requirements would impose burden on those new AOs that seek approval of their Home Infusion Therapy accreditation program. This burden would include, but is not limited to the time and costs associated with the following activities: (1) Preparation and filing of an initial application seeking CMS approval of the AOs home infusion therapy

accreditation program; (2) participation in the application review process (that is, meetings, provide additional information and materials that may be required, participate in a site visit, etc.); (3) seeking new accreditation clients; (4) performing on-site surveys, off-site survey audits or the performance of other types of survey activities; (5) participation in CMS ongoing accreditation program review activities; (6) performance of periodic re-accreditation activities; (7) investigation of complaints and performing complaint surveys; (8) administration of the appeals process for providers that have been denied accreditation; (9) staff training, in-services and continuing education; and (10) ensuring that surveyor staff have the proper education, training, and credentials.

The following is a discussion of the potential ICR burdens associated with the proposed home infusion therapy supplier accreditation oversight regulations and well as any PRA exceptions that may apply.

2. Applicable PRA Exception

We believe that the information collection burden associated with the preparation and submission of an initial or renewal application for approval and designation as an home infusion therapy AO and the participation in other accreditation related activities does not meet the definition of “collection of information” as defined in 5 CFR 1320.3(c) because it is “not imposed on 10 or more persons.” This information collection burden would be imposed only on those national AOs that accredit home infusion therapy suppliers.

At this time, there are five CMS-approved AOs and one non-CMS-approved AO that provide accreditation for home infusion therapy suppliers (that is, The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation, and National Association of Boards of Pharmacy). However, these AOs offer home infusion therapy accreditation as part of the deeming accreditation of home health agencies or the home infusion therapy accreditation provided is CMS approved.

In this proposed rule, we have proposed to require that these AO must apply for CMS approval of a home infusion therapy accreditation that is separate and distinct from its home health accreditation program. When we do solicit AOs to accredit home infusion therapy suppliers, we do not anticipate receiving more than the six applications

which would be submitted by the existing AOs seeking approval of a home infusion therapy accreditation program, because this is a specialized area of accreditation.

It is possible that the number of AOs that we designate to accredit home infusion therapy suppliers may increase to 10 or more in the future, when we begin accepting applications for home infusion therapy AOs. However, we do not anticipate that the number of AOs that would accredit home infusion therapy suppliers would increase to 10 or more in the foreseeable future.

Should the number of AOs that accredit home infusion therapy suppliers rise to 10 or more, we would prepare and submit an information collection request (ICR) for the burden associated with the accreditation process, as well as obtain OMB approval, prior to accepting additional applications.

E. ICR Regarding Modifications to 42 CFR 488.5

We have proposed to modify the AO approval and oversight regulations for Medicare certified providers and suppliers by adding 2 new requirements. The first proposed new requirement is to added to § 488.5(a)(7) and is a requirement that in their application for CMS approval, the AOs that accredited Medicare certified providers and suppliers must include a statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter. The second requirement is to be added as § 488.5(a)(18)(iii) and would require that the AOs for Medicare certified providers and suppliers include a written statement in their application for CMS approval agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization’s CMS-approved accreditation program, the accrediting organization must continue the facility’s current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

1. Burden Associated With CMS Online Training for AO Surveyors

CMS provides a number of online surveyor training modules that are available to the State Survey Agency surveyors. We have proposed to require the AO surveyors to take this training in an attempt to decrease the historically

high disparity rate between the AOs survey results and those of the validation surveys performed by the State Survey Agency surveyors.

There are a total of 163 online training programs that are available the State Survey Agency surveyors on the CMS Surveyor Training website. This website provides courses that are general in nature such as “Principles of Documentation Learning Activity—Long Term Care” and “Basic Writing Skills for Surveyor Staff”, infection control, patient safety, Emergency Preparedness. The CMS Surveyor Training website also offers courses related to specific healthcare settings, services, and regulations such as hospitals, CAHs, ASCs, CLIA, Community Mental Health Centers, EMTALA, Federally Qualified Health Centers (FQHCs), Home Health Agencies and OASIS, Hospices, Nursing Homes and the MDS, Outpatient Physical Therapy/Outpatient Speech Therapy. These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace at which the trainee completes the training.

We estimate that each SA surveyor takes approximately 10 of these courses. We further estimate that it would take approximately 3–5 hours to complete each of these courses. Therefore a SA surveyor would incur a time burden of 30–50 hours for the completion of these CMS surveyor training courses. We believe that the surveyors for AOs that accredit Medicare certified providers would need to take the same number and type of surveyor training courses as the SA surveyors (that is—approximately 10 courses). This means that each of the AOs surveyors that takes this training would incur a time burden in the amount of 30–50 hours.

The AOs that accredit Medicare certified providers and suppliers would incur a cost burden for the wages of their surveyors for the time they spend taking these online surveyor training courses. Most surveyors are clinicians such as Registered Nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). As noted above, we estimated that it would take approximately 30–50 hours for each AO surveyor to complete 10 online surveyor courses. Therefore, the AO would incur wages in the amount of \$1,060.80 to \$1,768.00 per each surveyor that completes the CMS online surveyor training. The AO would also incur additional costs for fringe benefits and overhead in the amount of \$1,060.80 to

\$1,768.00 per each surveyor that completes the CMS online surveyor training.

We are not able to accurately estimate to total time and cost burden to each AO for the wages incurred for the time spent by all surveyors of that AO that take the CMS online surveyor training courses, because we do not know exactly how many surveyors each AO has. However, if we estimate that each AO has 15 surveyors, the estimated time burden to each AO associated with this requirement would be 450 to 750 hours ((30 hours × 15 surveyors = 450 hours per all surveyors) and (50 hours × 15 surveyors = 750 hours per all surveyors)). The estimated cost burden to each AO for Medicare certified providers and supplies associated with this requirement would be \$31,824 to \$53,040 ((\$1,060.80 × 15 = \$15,912) and (\$1,768.00 × 15 = \$26,520) and (\$15,912 to \$26,520 for fringe benefits and overhead)).

There are currently 9 AOs that accredit Medicare certified providers and suppliers. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 4,050 to 6,750 ((450 hours per all surveyors/AO × 9 AOs = 4,050 hours across all AOs) and (750 hours per all surveyors/AO × 9 AOs = 6,750 hours across all AOs). The estimated cost across all AOs that accredit Medicare certified providers and suppliers would be \$763,776 (\$15,912 × 9 AOs = \$143,208) and (\$26,520 × 9 AOs = \$238,680) and (\$381,888 for fringe benefits and overhead).

However, we believe that the information collection burden associated with the requirement that the surveyors of AOs that accredit Medicare certified providers and suppliers does not meet the definition of “collection of information” as defined in 5 CFR 1320.3(c) because it is “not imposed on 10 or more persons.” This information collection burden would be imposed only on those AOs that accredit Medicare certified providers and suppliers. At this time, there are nine CMS-approved AOs that accredit Medicare certified providers and suppliers (that is, AAAASF, AAAHC, ACHC, AOA–HFAP, Community Health Accreditation Partner (CHAP), CIHQ, DNV–GL, The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT)). Should the number of AOs that accredit Medicare certified providers and suppliers rise to 10 or more, we will seek OMB approval for the burden

associated with the accreditation process.

2. Burden Associated With the Requirement for AOs To Continue a Medicare-Certified Provider’s or Supplier’s Accreditation

This proposal would require the AOs for Medicare certified providers and suppliers to include a written statement in their application for CMS approval of their accreditation program, agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization’s CMS-approved accreditation program, the accrediting organization must continue the facility’s current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

We believe that the AO would incur limited burden associated with this task, because this regulation simply requires that the AOs include a written statement in their application stating that they agree to continue the facility’s current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization’s CMS-approved accreditation program. All AOs that accredit Medicare certified providers and suppliers are required to submit an initial application to CMS when they first seek CMS approval and to submit renewal applications to CMS every 6 years thereafter. In accordance with 42 CFR 488.5, the AOs are required to provide a number of written acknowledgements with their application. We believe that the AO could add the required written statements to the other written acknowledgements that are included with their applications. As the AO would already be preparing the other acknowledgements required to be submitted with their application, it would be little if any additional burden for the AO to add the required written statements to their application.

We estimate that the required written statement would consist of only 1–2 sentences and would take no more than 5 minutes to prepare. We further believe that clinicians such as registered nurses would prepare the required statement to be included in the AOs application. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a

non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the AOs associated with the preparation of the written statement would be approximately \$17.68 (15 minutes \times \$35.36 per hour = \$8.84 plus \$8.84 in fringe benefits and overhead = \$17.68).

There are 9 AOs that accredit Medicare certified providers and suppliers. The estimated time burden across all of these AOs would be 45 minutes (15 minutes \times 9 AOs = 135 minutes per all AOs). The estimated cost burden across all AOs that accredit Medicare certified providers and suppliers would be \$159.12 (\$8.84 \times 9 AOs = \$79.56 per all AOs + \$79.56 for fringe benefits and overhead).

However, we believe that the information collection burden associated with the requirement that the AOs that accredit Medicare certified providers and suppliers provide a written statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider or supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, does not meet the definition of "collection of information" as defined in 5 CFR 1320.3(c) because it is "not imposed on 10 or more persons." This information collection burden would be imposed only on those AOs that accredit Medicare-certified providers and suppliers. At this time, there are nine CMS-approved AOs that accredit Medicare-certified providers and suppliers (that is, AAAASF, AAAHC, ACHC, AOA-HFAP, Community Health Accreditation Partner (CHAP), CIHQ, DNV-GL, The Joint Commission (TJC), The Compliance Team (TCT)). Should the number of AOs that accredit Medicare certified providers or suppliers rise to 10 or more, we will seek OMB approval for the burden associated with the accreditation process.

F. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

We invite public comments on these information collection requirements. If

you wish to comment, please identify the rule (CMS-1689-P) and, where applicable, the ICR's CFR citation, CMS ID number, and OMB control number.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

See this rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. Home Health Prospective Payment System (HH PPS)

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area

compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Section 50208 of the BBA of 2018 (Pub. L. 115-123) requires the Secretary to implement a new methodology used to determine rural add-on payments for CYs 2019 through 2022.

Section 1895(b)(2) of the Act and section 1895(b)(3)(A) of the Act, as amended by section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, require the Secretary to implement a 30-day unit of service, effective for CY 2020, and calculate a 30-day payment amount for CY 2020 in a budget neutral manner, respectively. In addition, section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the BBA of 2018 requires the Secretary to eliminate the use of the number of therapy visits provided to determine payment, also effective for CY 2020.

Finally, the HHVBP Model applies a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and expenditures.

2. Home Infusion Therapy

Section 1861(iii) of the Act, as added by the Cures Act, sets forth three elements for home infusion therapy suppliers in three areas: (1) Ensuring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient-specific needs, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided, and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home. These

provisions serve as the basis for suppliers to participate in Medicare.

Section 1834(u) of the Act serves as the basis for the establishment of a prospective payment system for home infusion therapy covered under Medicare. Section 1834(u)(7) of the Act, as added by BBA of 2018 requires the Secretary to provide a temporary transitional payment to eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs for CYs 2019 and 2020. Under this payment methodology (as described in section VI.C. of this proposed rule), the Secretary would establish three payment categories at amounts equal to the amounts determined under the Physician Fee Schedule established under section 1848 for services furnished during CY 2019 for codes and units of such codes, determined without application of the geographic adjustment.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate organizations to accredit qualified home infusion therapy suppliers furnishing home infusion therapy no later than January 1, 2021. Qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an accrediting organization designated and approved by the Secretary; and meet other such requirements as the Secretary deems appropriate.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The net transfer impact related to the changes in payments under the HH PPS for CY 2019 is estimated to be \$400 million (2.1 percent). The net transfer impact in CY 2020 related to the change in the unit of payment under the proposed PDGM is estimated to be \$0 million as section 51001(a) of the BBA of 2018 requires such change to be implemented in a budget-neutral manner. The net transfer impact in CY 2019 related to the Temporary Transitional Payment for Home Infusion Therapy is estimated to be \$60 million. The savings impacts related to the HHVBP model as a whole are estimated at \$378 million. The cost impact related to OASIS item collection as a result of the proposed implementation of the PDGM and proposed changes to the HH QRP is estimated to be a net \$60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020. Finally, the estimated cost impact to each potential home infusion therapy AO is \$23,258. We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS’s practice in interpreting the RFA is to consider effects economically “significant” only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs’ visits are Medicare paid visits and therefore the majority of HHAs’ revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule would have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule is not applicable to hospitals. Therefore, the Secretary has determined this proposed rule would not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. This rule is not anticipated to have an effect on State, local, or tribal

governments, in the aggregate, or on the private sector of \$150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments. If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique commenters on this year's proposed rule would be the similar to the number of reviewers of last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which would review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 5.3 hours for the staff to review half of this proposed rule, which consists of approximately 160,000 words. For each HHA that reviews the rule, the estimated cost is \$569.11 (5.3 hours × \$107.38). Therefore, we estimate that the total cost of reviewing this regulation is \$767,729.39 (\$569.11 × 1,349 reviewers).

1. HH PPS

a. HH PPS for CY 2019

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2019. Accordingly, the following analysis describes the impact in CY 2019 only. We estimate that the net impact of the policies in this rule is approximately \$400 million in increased payments to HHAs in CY 2019. We applied a wage index budget neutrality factor and a case-mix weight budget neutrality factor to the rates as discussed in section III.C.3 of this proposed rule. Therefore, the estimated impact of the 2019 wage index and the recalibration of the case-mix weights for CY 2019 is \$0 million. The \$400 million increase reflects the distributional effects of the CY 2019 home health payment update of 2.1 percent (\$400 million increase), a 0.1 percent increase in payments due to decreasing the FDL ratio in order to target to pay no more than 2.5 percent of total payments as outlier payments (\$20 million increase) and a 0.1 percent decrease in payments due to the new rural add-on policy mandated by the BBA of 2018 for CY 2019 (\$20 million decrease). The \$400 million in increased payments is reflected in the last column of the first row in Table 59 as a 2.1 percent increase in expenditures when comparing CY 2018 payments to estimated CY 2019 payments.

With regards to options for regulatory relief, the rural add-on policy for CYs 2019 through 2022 is statutory and we do not have the authority to alter the methodology used to categorize rural counties or to revise the rural add-on percentages.

b. HH PPS for CY 2020 (Proposed PDGM)

We estimate no net impact of the proposed policies related to the implementation of the PDGM for the CY 2020 HH PPS, as the transition to the 30-day unit of payment is required to be budget neutral. However, since the PDGM eliminates the use of therapy thresholds as a factor in determining payment, HHAs that provide more nursing visits, and thus experience lower margins under the current payment system which may incentivize overutilization of therapy, may experience higher payments. Conversely, HHAs that provide more therapy visits compared to nursing visits, and thus may profit more from the current payment system, may experience lower payments.

c. Proposed Elimination of Recertification Requirement To Estimate How Much Longer Home Health Services Will Be Required

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require, as a condition of payment, that a physician must certify (and recertify, when home health services are furnished over a period of time) that the individual is eligible for home health services. The regulations at § 424.22(b)(2) set forth the content and basis for recertification requirements and states that the recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. This requirement has been longstanding policy that predates the Paperwork Reduction Act of 1995 requirements. Therefore, there is no corresponding Collection of Information that was submitted to the Office of Management and Budget (OMB) for review and approval for the burden estimate for the recertification requirement that the certifying physician must estimate how much longer home health services will be required.

In section III.G. of this proposed rule, we are proposing to eliminate the regulatory requirement as set forth at 42 CFR 424.22(b)(1), that the certifying physician, as part of the recertification process, include an estimate of how much longer home health services will be required at each home health recertification. While all other recertification content requirements under § 424.22 will remain unchanged, the certifying physician would not be required to provide his/her estimation as to how much longer the patient will require home health services on recertifications on and after January 1, 2019. Therefore, we believe this would result in a reduction of burden for certifying physicians by reducing the amount of time physicians spend on the recertification process and we are providing an estimate on the reduction in burden in this proposed rule. All salary information is based on the May 2017 wage data for physicians and surgeons from the Bureau of Labor Statistics (BLS) website at (<https://www.bls.gov/oes/current/oes291069.htm>) and includes a fringe benefits and overhead worth 100 percent of the base salary.

Using CY 2017 claims, we estimate that of the total number of Medicare home health claims (5.8 million), 37 percent were recertifications (2.1 million) completed by 284,615

certifying physicians.¹¹¹ Of those 2.1 million recertifications, we estimate that the time needed to recertify patient eligibility will decrease by 2 minutes per recertification with a total reduction of 69,930 physician hours for all recertifications as a result of eliminating the time estimation statement. Based on the physician's hourly wage of \$203.26 as described previously (\$101.63 with 100 percent fringe benefits and overhead), this results in an overall annualized cost savings of \$14.2 million beginning in CY 2019.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment applies in CY 2018 based on PY1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (2020) data. In the CY 2016 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately \$380 million (80 FR 68716). In the CY 2017 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately \$378 million (81 FR 76795). We do not believe the changes proposed in this rule would affect the prior estimates.

3. Home Infusion Therapy

a. Health and Safety Standards

Section 5012 of the Cures Act (Pub. L. 114–255), which amended section 1861(s)(2) of the Social Security Act (the Act), established a new Medicare home infusion therapy benefit. Section 1861(iii) of the Act, as added by section 5012 of the Cures Act defines, the Medicare home infusion therapy benefit and covers professional services including nursing services, training and education, and remote monitoring and monitoring services associated with administering certain infusion drugs in a patient's home. This benefit would ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries. Section 1861(iii) of the Act, as added by the Cures Act, sets forth elements for home infusion therapy suppliers in three areas: (1) Ensuring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient-specific needs, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided, and (3)

having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home.

We propose to implement the following requirements for home infusion therapy suppliers—

- Ensure that all patients must have a plan of care established by a physician that prescribes the type, amount and duration of infusion therapy services that are furnished. The plan of care would specify the care and services necessary to meet the patient specific needs.
- Ensure that the plan of care for each patient is periodically reviewed by the physician.
- Ensure that patients have infusion therapy support services at all times through the provision of professional services, including nursing services, furnished in accordance with the plan of care on a 7-day-a-week, 24-hour-a-day schedule.
- Provide patient training and education.
- Provide remote monitoring and monitoring services for the provision of home infusion therapy and home infusion drugs.

All current standards established by AOs already address the proposed requirements set forth in this rule. Furthermore, all existing home infusion therapy suppliers are already accredited by an existing AO for home infusion therapy to meet requirements established by private insurers and Medicare Advantage plans. Therefore, we assume that there would be no new burden imposed on home infusion therapy suppliers in order to meet the proposed health and safety standards. Additionally, we assume that these proposed health and safety provisions would not impose a new burden on home infusion therapy AOs that are likely to apply to be Medicare approved AOs for home infusion therapy because their existing standards would already meet or exceed those that would be established in this rule.

b. Home Infusion Therapy Payment

We estimate that the net impact of the policies in this rule is approximately \$60 million in increased Medicare payments to home infusion suppliers in CY 2019. This increase reflects the cost of providing infusion therapy services to existing DME home infusion therapy beneficiaries (at a 4-hour rate), as the temporary transitional payment applies only to existing Medicare qualified home infusion suppliers (that is, DME suppliers that are enrolled as pharmacies that provide external infusion pumps and supplies are

considered eligible home infusion suppliers, as are potential pharmacy suppliers that enroll and comply with the Medicare program's supplier standards (found at 42 CFR 424.57(c)) and quality standards to become accredited for furnishing external infusion pumps and supplies). Prior to the implementation of the temporary transitional payment, home infusion suppliers have not been separately reimbursed for providing these services under the DME benefit. For the temporary transitional payment we do not anticipate an increase in beneficiaries receiving home infusion therapy services as referral patterns are not likely to change significantly due to the inability for other provider types (for example, physicians, HHAs) to become home infusion therapy suppliers prior to CY 2021 and given that existing DME suppliers already provide home infusion therapy services without separate reimbursement.

c. Accreditation of Quality Home Infusion Therapy Suppliers

The requirement for accreditation of home infusion therapy suppliers will cause both the home infusion therapy AOs and the home infusion therapy suppliers to incur costs related to the accreditation process. This section provides a discussion of the estimated time and cost burdens that home infusion therapy suppliers may incur as part of the accreditation process. It also discusses the estimated time and cost burdens that may be incurred by the home infusion therapy AOs to comply with the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050. As the following discussion demonstrates, we have estimated that each home infusion therapy AO would incur an estimated cost burden in the amount of \$23,258 for compliance with the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050.

(1) Burden Incurred by Home Infusion Therapy AOs

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit suppliers furnishing home infusion therapy not later than January 1, 2021. To date, we have not solicited nor approved any AOs to accredit home infusion therapy suppliers as required by section 1834(u)(5)(B) of the Act. Therefore, in this rule we have proposed to publish a solicitation notice in the **Federal Register** seeking national AOs to accredit home infusion therapy suppliers. We propose to publish this

¹¹¹ CY 2017 OASIS assessments matched to Medicare FFS claims (as of March 2, 2018).

solicitation after the publication of the final rule.

The AOs that respond to the solicitation notice would be required to submit an application to CMS requesting CMS-approval of a home infusion therapy accreditation program for Medicare. If CMS approves the AOs application, the home infusion therapy AO would also be required to meet, on an ongoing basis, the requirements set forth in proposed §§ 488.1010 through 488.1050. The following is a discussion of the burden associated with specific sections of the proposed home infusion therapy AO approval and oversight regulations at §§ 488.1010 through 488.1050.

(a) Burden for Home Infusion Therapy AOs Associated With Proposed § 488.1010

The AOs that accredit home infusion therapy suppliers would incur time and costs burdens associated with the preparation of the application they submit to CMS requesting approval of their home infusion therapy accreditation program. This would include the preparation, gathering or obtaining of all the documentation required in proposed § 488.1010(a)(1) through (24).

If the AO has never submitted an application to CMS, we estimate that it would take approximately 70 hours of time to gather, obtain or prepare all documentation required by proposed § 488.1010(a)(1) through (23). However, for an existing AO that has previously submitted an application to CMS for any type of accreditation program, we estimate that it would take approximately 45 hours to gather, obtain or prepare all required documentation. We believe that it would take less time for an AO that has previously submitted an application to CMS to prepare an application requesting approval of a home infusion therapy accreditation program because this AO would already be familiar with the application process and requirements. The proposed application requirements for home infusion therapy AOs, set forth at § 488.1010(a)(1) through (23), are consistent with those for Medicare-certified providers and suppliers which are set forth at § 488.5.

The home infusion therapy AO would incur costs associated with the preparation and submission of the home infusion therapy accreditation program application. The home infusion therapy AO would incur costs for the wages of all AO staff that work on the preparation of the application. We estimate that the AO would have 2 staff work on the preparation of the application. We

believe that the AO staff that works on the AOs application would be clinicians such as registered nurses or medical or health services manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>) and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>). Therefore, we estimate that the home infusion therapy AO would incur wages for 45 hours of time by a registered nurse and wages for 45 hours of time by a medical or health services manager in the amount of \$8,014.50 (45 hours × \$35.36 per hour = \$1,591.20) + (45 hours × \$53.69 = \$2,416.05 per hour) + (\$4,007.25 for fringe benefits and overhead).

As stated previously, we estimate that it would take approximately 70 hours for an AO that has never submitted an application before to prepare and submit their home infusion therapy accreditation program application to CMS. We estimate that the home infusion therapy AO would incur wages for 70 hours of time by a registered nurse and 70 hours of time by a medical or health services manager in the amount of \$12,453 (70 hours × \$35.36 per hour = \$2,475.20) + (70 hours × \$53.59 = \$3,751.30) + (\$6,226.50 for fringe benefits and overhead).

In addition, AOs are required to submit 2 hard copies of their application to CMS in notebooks with dividers and an electronic copy of their application on a thumb drive. Because of this requirement, the home infusion therapy AO would incur costs for the notebooks, dividers, thumb drive, photocopying, paper and ink, and postage costs for mailing the notebooks with the hard copies of the application to the CMS Central Office. We estimate that these costs would be no more than \$250.

At this time, there are six AOs that accredit home infusion therapy suppliers (that is—The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). The home infusion therapy accreditation offered by these AOs is offered as part of the deeming accreditation of a home health accreditation program and has not been approved under the requirements of section 1834(u)(5)(A) of the Act. Therefore, we are proposing that, in order for the home infusion therapy

suppliers accredited by these AOs to continue to receive payment for the home infusion therapy services furnished to Medicare beneficiaries, these AOs must obtain Medicare approval for a home infusion therapy accreditation program. If all of these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, the cost incurred across all of these potential home infusion therapy AOs for the preparation and submission of their applications would be \$48,087 ($\$4,007.25 \times 6$ AOs = \$24,043.50) + (\$24,043.50 for fringe benefits and overhead).

To obtain this CMS approval, we are proposing that these AOs would be required to submit an application to CMS seeking approval of a home infusion therapy accreditation program that meets the requirements set forth in the proposed new home infusion therapy AO approval and oversight regulations set forth at §§ 488.1010.1 through 488.1010.24 and the proposed new home infusion therapy health and safety regulations at 42 CFR part 466, subpart I. We have further proposed that the home infusion therapy accreditation programs submitted to CMS for approval by the existing home infusion therapy AOs be consistent with the requirements of section 5102 of the 21st Century CURES Act and section 1861(iii) of the Act. We would also require that the home infusion therapy programs submitted by these AOs be separate and distinct from the AOs home health deeming accreditation program.

The AOs that currently provide home infusion therapy accreditation would incur the time and costs associated with the preparation of the CMS application and required supporting documentation. We estimate that it would take these AOs approximately 45 hours to prepare their applications and supporting documentation because they have previously submitted applications for approval of their home health accreditation programs. The existing AOs that accredit home infusion therapy suppliers would also incur costs for the wages for all AO staff involved with the preparation and submission of the application. The AO would also incur costs for printing the hard copies of the application, ink and paper, notebooks and dividers, and postage.

(b) Burden for Home Infusion Therapy AOs Associated With Proposed § 488.1030

In accordance with proposed § 488.1030(b) CMS would perform a comparability review if CMS makes

changes to the home infusion therapy AO approval and oversight regulations or home infusion therapy health and safety regulation. The purpose of the comparability review is to allow CMS to assess the equivalency of a home infusion therapy AO's accreditation standards with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare home infusion therapy accreditation requirements.

Proposed § 488.1030(b)(1) would provide that if CMS were to make changes to the home infusion therapy AO approval and oversight accreditation regulations or the home infusion therapy health and safety regulations, CMS would send a written notice of the changes to the home infusion therapy AOs. Proposed § 488.1030(b)(2) would provide that CMS would provide a deadline of not less than 30 day by which the AO must submit its revised home infusion therapy accreditation program standards to CMS.

Proposed § 488.1030(b)(2) would require the home infusion therapy AOs to revise their home infusion therapy accreditation standards so as to incorporate the changes made by CMS. The AO must submit their revised home infusion therapy accreditation program standards to CMS by the deadline specified in CMS' written notice. The AO may submit a request for an extension of the submission deadline, so long as the request is submitted prior to the original submission deadline.

The home infusion therapy AOs would incur a time burden associated with the time required for the AO staff to review CMS' notice of the revisions to the home infusion therapy AO approval and oversight accreditation standards or home infusion therapy health and safety standards. We estimate that it would take no more than 1 hour for the AO to review the notice from CMS notifying the AO of the changes to the AO approval and oversight regulations or health and safety regulation.

The home infusion therapy AOs would incur a cost burden for the wages of the AO staff that are involved with reviewing the CMS notice and the preparation of the home infusion therapy AO's revised accreditation program standards. We believe that the AO staff that would review the notice from CMS regarding changes to the CMS home infusion therapy regulations would be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the home infusion therapy AO would incur a cost burden in the amount of \$70.72 for the preparation of the response to CMS (1 hour × \$35.36 per hour = \$35.36) + (\$35.36 for fringe benefits and overhead).

The home infusion therapy would also incur a cost burden for the wages of the AO staff for the time spent preparing the AOs revised home infusion therapy accreditation standards. However, we are unable to accurately estimate this cost because the amount of wages incurred would be dependent on the amount of time spent by the AO staff preparing the AOs revised accreditation standards.

We believe that the AO staff that would prepare the home infusion therapy AOs revised home infusion therapy accreditation standards would be a clinician such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). If we were to estimate that it would take 5 hours for the home infusion therapy AO to prepare the revised home infusion therapy accreditation standards, the estimated cost burden to the AO would be \$353.60 (5 hours × \$35.36 per hour = \$176.80) + (\$176.80 for fringe benefits and overhead).

At this time, there are six AOs that accredit home infusion therapy suppliers (that is—The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). The home infusion therapy accreditation offered by these AOs is offered as part of the deeming accreditation of a home health accreditation program and has not been approved under the requirements of section 1834(u)(5)(A) of the Act. If all of these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, the cost incurred across all of these AOs for the preparation of revised accreditation standards would be \$2,121.60 (\$176.80 × 6 AOs = \$1,060.80) + (\$1,060.80 for fringe benefits and overhead).

As provided by proposed § 488.1030(b)(4), a home infusion therapy AO may request an extension of the deadline by which they must submit their revised accreditation home infusion therapy standards, so long as the extension request is submitted prior

to the submission deadline. If the home infusion therapy AO requested an extension of the submission deadline, the AO would incur burden for the time required to prepare and submit the deadline extension request, however, we believe this burden would be minimal. We believe that the extension request could be sent in the form of an email to CMS, would consist of no more than a few paragraphs and would take no more than 15 minutes to prepare and send.

The AO would incur a cost burden for the wages for the AO staff who prepares the extension request. We believe that this email would be sent by an administrative assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive administrative assistant is \$28.56 (<https://www.bls.gov/oes/current/oes436011.htm>). We estimate that the AO would incur a cost burden for wages related to the preparation and sending of the extension request to CMS in the amount of \$14.28. (\$28.56 × 15 minutes = \$7.14) + (\$7.14 for fringe benefits and overhead).

At this time, there are six AOs that accredit home infusion therapy suppliers (that is—The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). If all of these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, they could become CMS-approved home infusion therapy AOs. It is unlikely that all of the AOs would submit a request for an extension of the deadline to submit their revised accreditation standards to CMS. However, if this were to occur, the cost incurred across all of these AOs for the preparation of the extension requests by each home infusion therapy AO would be \$85.68 (\$7.14 × 6 AOs = \$42.84) + (\$42.84 for fringe benefits and overhead).

Proposed § 488.1030(b)(7) would provide that if CMS were to make significant substantial changes to the home infusion therapy AO approval and oversight accreditation standards or the home infusion therapy health and safety standards, we may require the home infusion therapy AOs to submit a new application for approval of their revised home infusion therapy accreditation programs. If this were to occur, the home infusion therapy AOs would incur a time burden for the time associated

the preparation of the AOs new application.

We estimate that it would take the home infusion therapy AO approximately 45 hours to prepare and submit their new application to CMS. This would include the time and costs required to gather and prepare the required supporting documentation to go with the application. We believe that the home infusion therapy AOs would already be familiar with the CMS application process and would be able to use their previous application and supporting documentation with updates, therefore, the reapplication process would be less burdensome.

The home infusion therapy AO would also incur costs associated with the preparation and submission of a new application. The home infusion therapy AO would incur costs for the wages of all AO staff that work on the preparation of the application. We estimate that the AO would have 2 staff persons work on the preparation of the application. Furthermore, we believe that the AO staff that works on the AOs application would be clinicians such as a registered nurse and a medical or health services manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>). Therefore, we estimate that the home infusion therapy AO would incur wages for 45 hours of time by a registered nurse and 45 hours of time by a medical or health services manager in the amount of \$8,014.50 (45 hours × \$35.36 per hour = \$1,591.20) + (45 hours × \$53.69 = \$2,416.05 per hour) + (\$4,007.25 for fringe benefits and overhead). The cost across all the 6 potential home infusion therapy AOs would be \$48,087 (\$4007.25 × 6 AOs = \$24,043.50) + (\$24,043.50 for fringe benefits and overhead).

In addition, AOs are required to submit 2 hard copies of their application to CMS in notebooks with dividers and an electronic copy of their application on a thumb drive. Because of this requirement, the home infusion therapy AO would incur costs for the notebooks, dividers, thumb drive, photocopying, paper and ink, and postage costs for mailing the notebooks with the hard copies of the application to the CMS Central Office. We estimate that these costs would be no more than \$250.

In accordance with proposed § 488.1030(c), CMS will perform a

standards review when the home infusion therapy AO makes updates to its accreditation standards and surveys processes. Proposed § 488.1030(c)(1) would require that when a home infusion therapy AO proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy AO must submit its revised accreditation standards and survey processes to CMS for review, at least 60 days prior to the proposed implementation date of the revised standards. Proposed § 488.1030(c)(3) would require that the home infusion therapy AO provide CMS with a detailed description of the changes that are to be made to the AO's home infusion therapy accreditation standards, requirements and survey processes and a detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each. Proposed § 488.1030(c)(4) would provide that CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. Proposed § 488.1030(c)(5) would provide that if a home infusion therapy AO implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with proposed § 488.1030(c)(d).

The burden to the home infusion therapy AO associated with the standards review includes the time required for the home infusion therapy AO to prepare its revised accreditation standards and detailed crosswalk for submission to CMS and submit them to CMS for review. This burden would also include the time required for the AO staff to read and respond to CMS' written response. It is important to note that we do not include in our burden estimate the time that would be spent by the home infusion therapy AO in making voluntary revisions to their accreditation standards that are not required by CMS nor prompted by a regulatory change.

The home infusion therapy AO would also incur costs for the wages of the AO staff involved with the preparation of

the AO's revised home infusion therapy accreditation standards and the detailed crosswalk for submission to CMS. The AO would also incur costs for wages for the time the AO staff spent reviewing CMS' response. However, the AO could send their revised accreditation standards to CMS via email, therefore the AO would not incur costs for postage.

We are not able to accurately estimate the total time and cost burden associated with the standards review because the time required for the home infusion therapy AO to prepare its revised home infusion therapy accreditation standards and detailed crosswalk would depend on the extent of the revision the AO has made to its home infusion therapy accreditation standards or survey processes. The burden would also depend of the content and length of CMS' response letter. However, we do estimate that the preparation of the home infusion therapy AOs revised accreditation standard and detailed crosswalk for submission to CMS would take no less than 5 hours.

We believe that the AO staff that would prepare the home infusion therapy AOs revised home infusion therapy accreditation standards and detailed crosswalk for submission to CMS would be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, if we were to estimate that this task would take 5 hours to complete, the cost burden to the home infusion therapy would be \$353.60 (5 hours × \$35.36 per hour = \$176.80) + (\$176.80 for fringe benefits and overhead).

We further estimate that it would take the home infusion therapy AO approximately 30 minutes for the home infusion therapy AO to review the CMS response to their submission of the revised home infusion therapy accreditation standards and detailed crosswalk. We believe that a clinician such as a registered nurse would review the CMS response letter. Therefore, the cost burden to the home infusion therapy AO associated with this task would be \$ 53.04 (45 minutes × \$35.36 per hour = \$26.52) + (\$26.52 for fringe benefits and overhead).

It is important to note that we have not calculated this burden across all of the potential home infusion therapy AOs. We have not done so because the submission of revised home infusion therapy accreditation standards by a home infusion therapy AO would only

occur on an occasional basis and would never be done by all 6 potential AOs at the same time.

In accordance with proposed § 488.1030(d), CMS may perform a home infusion therapy accreditation program review if a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program with the requirements of the proposed home infusion therapy AO approval and oversight regulation at 42 CFR part 488, subpart L. If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy AO indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice would provide all of the following information:

- A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.
- A description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy accrediting organization to offer factual information related to CMS' findings.
- A description of the possible actions that may be imposed by CMS based on the findings of the home infusion therapy accreditation program review.
- The actions the home infusion therapy accrediting organization must take to address the identified deficiencies.
- A timeline for implementation of the home infusion therapy accrediting organization's corrective action plan, not to exceed 180 calendar days after receipt of the notice that CMS is initiating a home infusion therapy accreditation program review.

Proposed § 488.1030(d)(3) would provide that CMS will monitor the performance of the AO's home infusion therapy and the implementation of the corrective action plan during a probation period of up to 180 days. Proposed § 488.1030(d)(4) would provide that if CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of the proposed regulations at §§ 488.1010 through

488.1050, CMS may place the home infusion therapy AO's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the period described in § 488.1030(d)(1)(iv).

The time burden associated with the home infusion therapy accreditation program review includes the time burden associated with the AO's review of CMS' written notice which indicates that the home infusion therapy AO's CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The time required for the review of the CMS letter will depend on the length of CMS' finding. However, we estimate it would take no more than 60 minutes to review this letter.

The AO would incur costs for the wages of the AO staff who performs the review of the CMS letter. We believe that an AO staff person with a clinical background such as a registered nurse would review the CMS letter. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, we estimate that the cost burden to the home infusion therapy AO associated with the review of the CMS letter would be approximately \$70.72 (1 hour × \$35.36 = \$35.36) + (\$35.36 for fringe benefits and overhead).

There is further burden associated with the requirement that the AO prepare and submit a written response to the CMS letter and a corrective action plan. However, we are unable to accurately estimate the time burden associated with this task because the amount of time required for the home infusion therapy AO to prepare the response letter and corrective plan would be dependent on the number and type of findings identified in CMS' letter.

However, we believe that an AO staff person with a clinical background such as a registered nurse would prepare the home infusion therapy AO's written response to the CMS letter and a corrective action plan. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). If we were to estimate that it would take the home infusion therapy AO 3 hours to prepare and submit a written response to the CMS letter and a corrective action plan, the estimated cost burden to the home infusion therapy AO associated with this task would be \$212.16 (3 hours × \$35.36 = \$106.08) + (\$106.08 for fringe

benefits and overhead). Proposed § 488.1030(d)(2) provides that CMS would review and approve the AO's plan of correction within 30 days of receipt. If CMS requires the home infusion therapy AO to make changes to their corrective action plan as a condition of approval, the AO would incur burden for the time required to make the required revisions to their plan of correction and resubmit it to CMS.

The home infusion therapy AO would incur a time burden for the time spent by the AO staff making corrections to the AOs corrective action plan. We are unable to accurately estimate how long it would take for the AO to revise its corrective action plan because the revision to be made to the corrective action plan would be dependent on the extent of the correction requested by CMS.

However, we believe that an AO staff person with a clinical background such as a registered nurse would make the corrections to the AOs corrective action plan. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). So, if we were to estimate that it would take the home infusion therapy AO 2 hours to prepare and submit a written response to the CMS letter and make any necessary revision to the corrective action plan, the estimated cost burden to the home infusion therapy AO associated with this task would be \$141.44 (2 hours × \$35.36 per hour = \$70.72) + (\$70.72 for fringe benefits and overhead). During the 180 day probationary period, CMS is likely to require the home infusion therapy AO to submit periodic progress reports and participate in periodic telephone to monitor the home infusion therapy AOs progress. The home infusion therapy AO would incur burden for the time required to prepare and submit an initial progress report. We estimate that the initial progress report would take approximately one hour to prepare. We further estimate that the burden associated with the preparation and submission of subsequent progress reports would be less than that for the initial progress report because the AO would be able to modify or update their initial or previous progress report. We estimate that it would take approximately 1 hour for the AO staff to prepare the initial progress report and 30 minutes for the AO staff to prepare subsequent progress reports. If CMS were to require the AO to submit one progress report per month during the entire 180 day probation period (6 months), the AO would have

to submit 1 initial progress report and 5 subsequent progress reports. Therefore, we estimate that the AO would incur a time burden in the amount of 3.5 hours for the submission of all progress reports during the 180 day probation period. The AO would also incur a cost burden for the wages of the AO staff person who is involved in the preparation and submission of the progress reports. We believe that the initial and subsequent progress reports would be prepared by person with a clinical background such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). We estimate that the home infusion therapy AO would incur a cost burden in the amount of \$247.52 for the preparation of the progress reports during the 180 day probation period ($3.5 \text{ hours} \times 35.36 \text{ per hour} = \123.76) + (\$123.76 for fringe benefits and overhead).

The home infusion therapy AO would also incur burden associated with the time required to participate in the periodic phone calls with CMS. We are not able to accurately estimate the amount of time that would be required for these periodic phone calls because we do not know how often the AO would be required to participate in phone calls with CMS or how long these phone calls would last. However, we do not believe that these phone calls would be held more often than monthly or last more than one hour. The AO would incur costs for the wages of all AO staff that participate in the periodic telephone calls. We are not able to accurately estimate the total cost burden for wages that would be incurred by the home infusion therapy AO at this time, because we do not know who from the AO would be attending these meetings.

If we were to estimate that these phone calls were to be held on a monthly basis during the 180 day probation period for a period of one hour period per call, the home infusion therapy AO would incur a time burden in the amount of 6 hours per each staff member that participates in these phone calls. We believe that the AO would have a minimum of 3 staff that are clinicians, such as registered nurses, participate on the call. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/ooh/healthcare/registered-nurses.htm>). Therefore, the cost burden to the home infusion therapy AO for participation in the monthly telephone calls would be \$1,272.96 ($3 \text{ AO staff} \times \$35.36 \text{ per hour} = \$106.08 \text{ per call per all staff}$ /\$106.08

per call per all staff $\times 6 \text{ calls} = \636.48 total wages per all staff per all calls) + (\$636.48 for fringe benefits and overhead)).

At or near the end of the first 180 day probationary period, CMS will make a decision as to whether the home infusion therapy AO has successfully come into compliance with the home infusion therapy regulations, or whether the AO has failed to do so. Proposed § 488.1030(d)(4) would provide that if CMS finds that the home infusion therapy AO has failed to properly implement the plan of correction and come into compliance with the requirements of the proposed home infusion therapy AO approval and oversight regulation or the proposed home infusion therapy health and safety regulations, CMS may place the home infusion therapy AO's on an additional probation period of up to 180 calendar days. If this were to occur, the AO would incur the same or similar time and cost burdens as in the initial 180 day probationary period. (See previous estimates for the estimated time and cost burden associated with the 180-day probationary period).

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1030(d) across all of the potential home infusion therapy AOs. We have not done so because the act of CMS placing a home infusion therapy AO on an accreditation program review would only occur on a sporadic and as needed basis. There would never be a situation in which all 6 potential AOs would be under an accreditation program review at the same time.

(c) Burden for Home Infusion Therapy AOs Associated With Proposed § 488.1035

Proposed § 488.1035 titled "Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization" would require that the home infusion therapy AO carry out certain activities and submit certain documents to CMS on an ongoing basis. Proposed § 488.1035(a) would require the home infusion therapy AO to submit the following documents to CMS: (1) Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements); (2) notice of all accreditation decisions; (3) notice of all complaints related to providers or suppliers; (4) information about all home infusion therapy accredited suppliers against which the

home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation; (5) the home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends; (6) notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process.

We believe that there would be little burden associated with this requirements for several reasons. First, while the home infusion therapy AOs would be required to provide copies of all survey reports and any survey-related information that CMS may require, the AOs would only be required to provide this information upon request. CMS may not request the home infusion therapy AO to submit this information if there are no compliance concerns. Second, we believe the home infusion therapy AO would keep these records in the normal course of their business as a home infusion therapy AO and would store the survey records in electronic format. As the AO already has this information prepared and stored in an electronic format, it would place little if any burden on the home infusion therapy AO to provide this information to CMS. We believe that the AO could send this information to CMS via email and attach the survey record electronic files to the email.

We estimate that it would take approximately 30 minutes to locate the required survey information files and approximately 15 minutes for the AO staff to prepare an email to CMS and attach the electronic files to the email. We believe that the person at the AO that would prepare the email sending the survey information to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/ooh/healthcare/registered-nurses.htm>). Therefore, the cost burden to the home infusion therapy AO associated with the preparation and submission of the survey reports and information to CMS would be \$53.04 (30 minutes to locate information requested by CMS \times \$35.36 per hour = \$17.68) + (15 minutes \times \$35.36 = \$8.84) + (\$26.52 for fringe benefits and overhead). The estimated cost across the potential 6 home infusion therapy AOs for these tasks would be \$318.24 ($\$53.04 \times 6 \text{ home infusion therapy AOs} = \318.24).

Proposed § 488.1035(a)(2) would require the home infusion therapy AO to provide CMS with notice of all accreditation decisions made for each home infusion therapy supplier that files an application for accreditation. This would consist of a list of each home infusion therapy supplier that had filed an application with the home infusion therapy AO for accreditation and the accreditation decision made by the AO.

We believe that these accreditation decisions would be made by the AO in the normal course of the AOs business of performing accreditation of home infusion therapy suppliers. We further believe that there would be little burden associated with the requirement that the AO provide CMS with a list of the accreditation decisions made by the AO as this is information that would be readily available to the AO and that could quickly and easily be provided to CMS via email. We estimate that it would take approximately 15 minutes for the home infusion AO to gather the required accreditation decision information in preparation for sending it to CMS.

We believe that this information can be sent to CMS via email and estimate that it would take an additional 15 minutes for the AO staff to prepare an email to CMS and attach the electronic files containing the accreditation decision information to the email. We believe that the person at the AO who would prepare the accreditation decision information and prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation and submission of the survey reports and information to CMS would be \$35.36 (15 minutes × \$35.36 per hour = \$8.84) and (15 minutes × \$35.36 = \$8.84) + (\$17.68 for fringe benefits and overhead). The estimated cost across the potential 6 home infusion therapy AOs for these tasks would be \$212.16 (\$35.36 × 6 home infusion therapy AOs = \$212.16).

Section 488.1035(a)(3) would require the AO to report complaint information to CMS. Complaint information is typically reported to CMS by other AOs by email on a monthly basis for the previous month. The contents of the complaint information reported to CMS would depend on whether the AO had received any complaints during the previous month. For example, if the AO

received no complaint during the previous month, this email could consist of a sentence stating that the AO had received no complaints. If the AO had received one or more complaints during the previous month, the AO would be required to provide information about the nature of each complaint, a description of the investigation performed, a description of how the complaint was resolved and the date resolved.

We believe that there would be little burden associated with the reporting of complaint information by the home infusion therapy AO to CMS for several reasons. First, we estimate that the home infusion therapy AOs will rarely receive complaints about their accredited home infusion therapy suppliers. Second, we believe that the home infusion therapy AO will store information about any complaints received in an electronic format. Therefore, complaint information can be reported by the home infusion therapy AO to CMS via email. We estimate that the preparation of the complaint information email would take only no more than 15 minutes to prepare and send.

We believe that the person at the AO who would prepare the complaint information email and sent it to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated monthly cost burden to the home infusion therapy AO associated with the submission of complaint information to CMS would be \$17.68 (15 minutes × \$35.36 per hour = \$8.84) + (\$8.84 for fringe benefits and overhead). The estimated yearly burden to the home infusion therapy AO for this task would be \$212.16 (\$17.68 per month × 12 months per year = \$212.16 per year).

The estimated monthly cost across the potential 6 home infusion therapy AOs for these tasks would be \$106.08 (\$17.68 × 6 home infusion therapy AOs = \$106.08). The estimated yearly cost across the 6 potential home infusion therapy AOs would be \$1,272.96 (\$17.68 × 6 AOs = \$106.08 per all AOs per month/\$106.08 per year × 12 months per year = \$1,272.96. Proposed § 488.1035(a)(4) would require the AO to provide CMS with information about all home infusion therapy accredited suppliers against which the home infusion therapy AO has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation. The

information to be sent to CMS would simply consist of a list of the home infusion therapy suppliers and the type of remedial or adverse action taken.

We expect that when a home infusion therapy AO takes remedial or adverse action against its accredited supplier, the AO would prepare documentation which states the action taken and the reason this action was taken. We further believe that the AO would store this information electronically. This would enable the AO to send the required information to CMS via email. Therefore, we believe that there would be little burden associated with this requirement.

We believe that the home infusion therapy AOs could send information about adverse or remedial actions they have taken against their accredited suppliers via email. We estimate that it would take approximately 30 minutes for a home infusion therapy AO to prepare a report about the adverse or remedial actions taken against its accredited suppliers and approximately 15 minutes to prepare an email to CMS, attach the electronic file with the required information and send it to CMS. The home infusion therapy AOs would be required to report this information to CMS on a monthly basis.

The AO would incur a cost burden for the wages of the AO staff for the time spent preparing the report of the adverse or remedial action taken against the AO's accredited home infusion therapy suppliers and the time spent preparing the email to CMS. We believe that the person at the AO who would prepare the report of adverse or remedial action taken and prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost monthly cost burden to the home infusion therapy AO associated with the submission of information about the adverse or remedial action taken by the home infusion therapy AO against its accredited home infusion therapy suppliers to CMS would be \$53.04 (30 minutes × \$35.36 per hour = \$17.68 + (15 minutes × \$35.36 per hour = \$8.84) + (\$26.52 for fringe benefits and overhead). The estimated yearly cost burden to the home infusion therapy AO for this task would be \$636.48 (\$53.04 per month × 12 months per year = \$636.48 per year).

The estimated monthly cost across the potential 6 home infusion therapy AOs for these tasks would be \$318.24 (\$53.04 × 6 home infusion therapy AOs =

\$318.24). The estimated yearly cost across the 6 potential home infusion therapy AOs would be \$3,818.88 ($\$53.04 \times 6 \text{ AOs} = \318.24 per all AOs per month/ $\$318.24$ per year $\times 12$ months per year = \$3,818.88).

Proposed § 488.1035(a)(5) would require the home infusion therapy accrediting organization to provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditation activities and trends. This summary data might include information such as the total number of complaints received during the year, the total number of immediate jeopardy situations found during the year, and the total number of deficiencies cited. We believe this is information that the AO would collect and document throughout the year in the normal course of business. We further believe that the home infusion therapy AO would prepare this year end summary data for their own informational, quality improvement, and research purposes.

We believe that there would be little, if any time burden associated with the submission of the documents and information required by proposed § 488.1035(a)(5) by the home infusion therapy AOs to CMS, because these are documents which the AO would keep in the normal course of business, therefore these documents would be easily accessible to the home infusion therapy AO. Title 5 CFR 1320.3(b)(2) states that the time, effort, and financial resources necessary to comply with a collection of information that would be incurred in the normal course of their activities (for example in compiling and maintaining business records) will be excluded from the burden if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary. Further, we believe that most, if not all of the home infusion therapy AOs would store these documents electronically and would be able to send them electronically to CMS via email.

The home infusion therapy AO would incur a time burden for the preparation and submission of the annual summary data to CMS. We estimate that it would take approximately 60 minutes for the home infusion therapy AO to locate the required annual summary data information and prepare it for submission to CMS. We further estimate that it would take an additional 15 minutes to prepare an email to CMS and attach the electronic files containing the summary data.

The home infusion therapy AO would incur a cost burden for the wages of the AO staff who prepares that summary data for submission to CMS and

prepares the email to in which the annual summary data are submitted to CMS. We believe that the person at the AO who would prepare the summary data for submission to CMS and also prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the submission of summary data to CMS would be $\$88.40$ ($60 \text{ minutes} \times \$35.36 \text{ per hour} = \35.36) + $\$17.68$ ($15 \text{ minutes} \times \$35.36 \text{ per hour} = \8.84) + $\$44.20$ for fringe benefits and overhead). The estimate cost burden across the 6 potential home infusion therapy AOs for this task would be $\$530.40$ ($\$88.40 \times 6 \text{ potential home infusion therapy AOs} = \530.40).

Proposed § 488.1035(b) would require that within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS. The time burden associated with this requirement would be the time required for an AO staff person to review the notification from CMS about the change in home infusion therapy accreditation program requirements and the time required for the AO staff person to compose and send an acknowledgement email to CMS.

We estimate the time required for the AO staff to review the notice of a change in CMS requirements would be 1 hour. We further estimate that the time that would be required to prepare and submit the acknowledgement of receipt of the CMS notice would be approximately 15 minutes because this notice could be sent to CMS via email and would only consist of 1–2 paragraphs.

The home infusion therapy AO would incur a cost burden for the wages of the staff for the time required to review the notice from CMS of the change in CMS requirements. The home infusion therapy AO would incur a cost burden for the wages of the staff for the time required to prepare the acknowledgement and submits it to CMS. We believe that the person at the AO who would prepare the email to CMS acknowledging receipt of the CMS notice would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>).

The estimated cost burden to the home infusion therapy AO associated with the review of the notice from CMS of changes to the CMS requirements would be $\$70.72$ ($1 \text{ hour} \times \$35.36 \text{ per hour}$) + $\$35.36$ for fringe benefits and overhead). The estimated cost burden associated with the preparation and submission of the acknowledgement by the home infusion therapy AO would be $\$17.68$ ($15 \text{ minutes} \times \$35.36 \text{ per hour} = \8.84) + $\$8.84$ for fringe benefits and overhead). The estimates cost across the 6 potential home infusion therapy AOs would be $\$530.40$ ($\$70.72 \times 6 = \424.32) + $\$17.68 \times 6 = \106.08 .

It is important to note that the home infusion therapy AOs would only have to perform these tasks if CMS were to make a change to the home infusion therapy standards. We believe that this would occur on an infrequent basis, therefore, the home infusion therapy AOs would incur these time and cost burdens on an infrequent basis.

Proposed § 488.1035(c) would require that the home infusion therapy AO permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. An example in which a surveyor would be needed to testify as a witness would be if there was litigation about CMS' termination of a home infusion therapy supplier's participation in the Medicare program and the surveyor that had performed a survey of that home infusion therapy supplier was needed to testify about the survey findings. The burden associated with this requirement would be the time the surveyor spent providing testimony, any travel expenses the home infusion therapy AO would be responsible to pay, and the wages paid to the surveyor during the time spent giving testimony.

The home infusion therapy AO would incur a time burden for the time required for the AO's surveyor to serve as a witness. This would include travel time to and from the location where the hearing is being held. The AO would also incur cost burdens for the wages paid to the surveyor during the time they are serving as a witness and also for any travel expenses the AO may be required to pay, that are not reimbursed.

It is important to note that the home infusion therapy AO surveyors would rarely, if ever, be required to act as a witness. Therefore, this is a burden that the home infusion therapy AOs would not be likely to incur.

Proposed § 488.1035(d) would require that, within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the

home infusion therapy AO must provide CMS with written notice of the deficiency and any adverse action implemented by the AO. The burden associated with this requirement is the time required to provide notice to CMS of the immediate jeopardy situation and the wages for the AO staff person for the time spent preparing and submitting this notice.

We believe that the AO would keep this information in the normal course of their business of providing home infusion therapy accreditation. Therefore, the AO should have these readily available. We further believe that the home infusion therapy AOs would keep records related to immediate jeopardy findings in an electronic format.

The AO would incur a time burden for the time required to report the immediate jeopardy information to CMS. We estimate that it would take the AO no more than 20 minutes to prepare an email to CMS in which they provide the required information about the immediate jeopardy situation that has been discovered. The AO can attach electronic files to the email that contain the required information. It is important to note that we do not count, as a burden, the time spent by the home infusion therapy AO in finding the immediate jeopardy situation or resolving it, because it is the duty of any CMS-approved AO to monitor its accredited providers or supplier to ensure they are providing care that meets the accreditation standards and that they do not have any situation that put the patients or general public in imminent danger of harm. The home infusion therapy AO would incur a cost burden for the wages of the AO staff that prepares the email to CMS which notified CMS of the immediate jeopardy situation. We believe that the person at the AO who would prepare the immediate jeopardy notification email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation and submission of the acknowledgement by the home infusion therapy AO would be \$23.60 ($\35.36 divided by 60 minutes per hour = $\$0.59$ per minute/20 minutes \times $\$0.59$ per minute = $\$11.80$) + ($\11.80 for fringe benefits and overhead).

The home infusion therapy AOs would have to perform these tasks and incur these time and costs burdens only if they discover an immediate jeopardy

situation with an accredited home infusion therapy supplier. We would like to point out that this would not be a regular time and cost burden that would be incurred by the home infusion therapy AOs, as the discovery of immediate jeopardy situations by AOs do not occur frequently.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1035(d) across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to report an immediate jeopardy situation to CMS would only occur on a sporadic basis. We do not believe that there would ever be a situation in which all 6 potential AOs would be required to report an immediate jeopardy situation simultaneously. Proposed § 488.1035(e) would require that within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy AO that CMS intends to withdraw approval of the AO's home infusion therapy accreditation program, the home infusion therapy AO must provide written notice of the withdrawal to all of the home infusion therapy AO's accredited suppliers. The time burden associated with this requirement would be the time spent by the AO staff to prepare the required notice that must be sent to all of the AOs accredited home infusion therapy suppliers and the time required for the AO to send this notice out to all of its accredited suppliers.

We estimate that it would take that home infusion therapy AO approximately 45 minutes to prepare the notice that they must send out to their accredited suppliers. We believe it would take an additional 2 minutes per letter to be sent by the home infusion therapy AO to its accredited suppliers to prepare these letters for mailing (that is—fold letter, place in envelope, affix correct amount of postage and place the letter into the outgoing mail). We are not able to accurately estimate the amount of time it would take for the AO to send this notice out to all of its accredited suppliers because this would be dependent on the number of accredited suppliers the AO has at the time. However, if we were to assume that a home infusion therapy AO had 50 accredited home infusion therapy suppliers, this task would take the AO staff 1.7 hours to complete (2 minutes \times 50 letters = 100 minutes/100 minutes divided by 60 minutes per hour = 1.7 hours).

The home infusion therapy AO would incur a cost burden for the wages of the AO staff person that prepares the required notification. We believe that

the person at the AO who would prepare the required notification would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be $\$53.04$ (45 minutes \times $\$35.36$ per hour = $\$26.52$) + ($\26.52 for fringe benefits and overhead)

The home infusion therapy would also incur a cost burden for the wages of the staff person for the time spent preparing the required notices for mailing and mailing them. We are unable to accurately estimate this cost burden because the time required to perform this task would be dependent on the number of accredited home infusion therapy supplier the AO has at the time. However, if we were to assume that a home infusion therapy AO had 50 accredited home infusion therapy suppliers, this task would take the AO staff 1.7 hours to complete (2 minutes \times 50 letters = 100 minutes/100 minutes divided by 60 minutes per hour = 1.7 hours). We believe that the person that would perform this task would be an Administrative Assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive administrative Assistant is \$28.56 (<https://www.bls.gov/oes/current/oes436011.htm>). Therefore, the home infusion therapy AO would incur a cost burden in the amount of \$97.92 for the completion of this task ($\$28.56$ per hour divided by 60 minutes per hour = $\$0.48$ per minute/60 minutes per hour divided by 10 = 6 minutes per 0.1 hour/6 minutes \times 7 = 42 minutes = 0.7 hour/60 minutes + 42 minutes = 102 minutes or 1.7 hours/ $\$0.48$ per minute \times 102 minutes = $\$48.96$) + ($\48.96 for fringe benefits and overhead). The home infusion therapy AO would incur an additional cost burden for miscellaneous costs. These costs would include the cost of the paper used to print the notices on, the printer ink used, the cost of the envelopes used, and the postage required to mail all the notices. We are unable to accurately estimate these costs as they are dependent on the number of notices that would be sent. We believe that these costs would not exceed \$250.

It is important to note that the home infusion therapy AO surveyors would rarely, if ever, be required to perform the tasks required by proposed § 488.1035(e) because we would rarely withdraw the CMS approval of a home

infusion therapy AO. We would do so if there were serious, unresolved compliance concerns that the AO was unable or unwilling to rectify, even after being placed on an accreditation program probationary period. We do not believe that it would be possible that all of the home infusion therapy AOs would incur these cost and time burdens at the same time.

(d) Burden for Home Infusion Therapy AOs Related to Proposed § 488.1040

Proposed § 488.1040 would require that as part of the application review process, the ongoing review process, or the continuing oversight of a home infusion therapy AO's performance, CMS may conduct onsite inspections of the home infusion therapy AO's operations and offices at any time to verify the home infusion therapy AO's representations and to assess the home infusion therapy AO's compliance with its own policies and procedures. Proposed § 488.1040(b) provides that the activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following: (1) Interviews with various AO staff; (2) review of documents, survey files, audit tools, and related records; (3) observation of meetings concerning the home infusion therapy accreditation process; (4) auditing meetings concerning the accreditation process; (5) observation of in-progress surveys and audits; and (6) evaluation of the AO's survey results and accreditation decision-making process.

We believe that there would be little burden associated with the onsite visits made by CMS to the home infusion therapy AO's operations and offices because most of the activities related to the onsite visit involve work performed by the CMS staff, which would not impose burden on the AO staff (such as review of records or observation of meeting held at the AOs offices). We estimate that the time burden to the home infusion therapy AO associated with these onsite visits would include the time required for the AO staff to greet the CMS team upon arrival and show them to the conference room, the time required to locate the records the CMS team requests for review, and the time required for CMS to conduct interviews of AO staff members. If the home infusion therapy AOs records are electronic, an AO staff member may need to remain with the CMS team during their record review to assist them with access to the AO's records.

We are not able to accurately estimate the total time that would be required for these activities because we have not yet accredited any home infusion therapy

AOs, nor have we had an opportunity to perform an onsite visit to a home infusion therapy AO. We do not yet know what type of accreditation standards and surveys processes the home infusion therapy AOs would use. Also, we do not know the amount and type of records we would seek to review during an onsite visit to a home infusion therapy AO or approximately how much time we would need to review these records. Likewise, we do not yet know how much interaction we would need to have with the home infusion therapy AO staff or which AO staff members we would choose to interview. The onsite AO visits we have performed for other types of AOs have lasted 1 to 2 days depending on the type of AO.

However, if we estimate that it would take 1 hour for the CMS team entrance conference, 8 hours for the CMS team to perform their records review and 1 hour for the CMS team conduct the exit conference, the home infusion therapy AO would incur a time burden in the amount of 1 hour for each AO staff person that attends the entrance conference, 8 hours for any staff that remains with the CMS team to assist them with the record review and 1 hour of time for each AO staff person that attends the exit conference. We believe that the AO staff that would be attending the entrance and exit conferences and assisting the CMS staff with their records review would most likely be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). We estimate that approximately 4 AO staff persons would attend the entrance and exit conferences and that one AO staff person would assist the CMS team with their record review.

Based on the a previously stated time estimate, we estimate that the home infusion therapy AO would incur a cost burden in the amount of \$282.88 for wages for four AO staff for attendance at the entrance conference. ($\$35.36$ per hour per each AO staff \times 1 hour = $\$35.36/\35.36 per hour \times 4 AO staff = $\$141.44$) + ($\141.44 for fringe benefits and overhead).

We further estimate that the AO would incur a cost burden in the amount of \$282.88 for the wages of the four AO staff for attendance at the exit conference. ($\$35.36$ per hour per each AO staff \times 1 hour = $\$35.36/\35.36 per hour \times 4 AO staff = $\$141.44$) + ($\141.44 for fringe benefits and overhead).

We also estimate that the AO would incur a cost burden in the amount of \$565.76 for the wages of the AO staff

person that would remain with the CMS team to assist them with their record review. (8 hours \times $\$35.36$ = $\$282.88$) + ($\282.88 for fringe benefits and overhead).

The total estimated cost burden to the home infusion therapy AO associated with the CMS onsite visit is $\$1,131.52$ ($\$282.88$ for entrance conference + $\$282.88$ for exit conference + $\$565.76$ for assisting CMS staff with record review = $\$1,131.52$). The estimated cost burden across all of the potential six home infusion therapy AOs would be $\$6,789.12$.

In this proposed rule, we have proposed that the six AOs that currently provide accreditation to home infusion therapy suppliers must submit an application to CMS for approval of a separate and distinct home infusion therapy accreditation program. A corporate onsite visit to the home infusion therapy AOs office is a part of the application review and approval process. Therefore, each of the AOs that submit an application to CMS for approval of a home infusion therapy program would incur the previously stated estimated burden related to the corporate onsite visit. However, after the initial application process has been completed, CMS would only make additional corporate onsite visits every 6 years when the home infusion therapy AOs submit their renewal application. Therefore, this would not be a frequent or ongoing burden incurred by the home infusion therapy AOs.

(e) Burden for Home Infusion Therapy AOs Related to Proposed § 488.1045

Proposed § 488.1045 contains regulations related to the voluntary and involuntary termination of the CMS approval of a home infusion therapy AO's home infusion therapy accreditation program. Proposed § 488.1045(a) would provide that a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 90 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

The requirement that the home infusion therapy AO provide notice of its decision to voluntarily terminate its CMS approved home infusion therapy accreditation program to CMS and all of its accredited home infusion therapy suppliers would cause the AO to incur the following time burdens: (1) The time required to prepare and send the required notice to CMS; and (2) the time required to prepare and send the

required notice to all of the AOs accredited home infusion therapy suppliers. We would require that the AO send the required notice of their decision to voluntarily terminate its CMS-approved accreditation program to CMS by U.S. mail. We would also require the AO to send the required notice to all of its accredited home infusion therapy suppliers by U.S. mail. We estimate that it would take approximately 60 minutes for the AO staff person to prepare the letter to CMS in which the AO notified CMS that the AO wishes to voluntarily terminate its CMS-approved home infusion therapy accreditation program, print the letter and mail it.

We further estimate that it would take the AO staff person another 4 hours to perform the following tasks: (1) Draft a letter its accredited home infusion therapy suppliers, giving notice that the AO is voluntarily terminating its CMS approved home infusion therapy accreditation program; (2) perform a mail merge to prepare a copy of the letter addressed to each accredited home infusion therapy supplier; (3) print out a letter to each accredited supplier and envelope; put the letters into the envelopes; (4) affix the correct amount of postage; and (5) put the envelopes in the outgoing mail. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be \$35.36 (60 minutes \times \$35.36 per hour = \$35.36).

The home infusion therapy AO would also incur a cost burden for the wages of the staff person for the time spent preparing and mailing the required notices to be sent to the AO's accredited home infusion therapy suppliers. As stated previously, we estimate that it would take approximately 4 hours of time for an AO staff person to prepare the required notification letter to the AOs accredited providers, print out a copy of the letter for each accredited home infusion therapy supplier and put these letters into the mail. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/>

[oes291141.htm](https://www.bls.gov/oes/current/oes291141.htm)). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice for mailing would be \$353.60 (4 hours \times \$35.36 per hour = \$176.80) + (\$176.80 for fringe benefits and overhead).

The home infusion therapy AO would incur an additional burden for miscellaneous costs associated with the preparation of the required notices to be sent to CMS and the AOs accredited home infusion therapy suppliers, including the cost of the paper on which the notices are printed, the printer ink used, the cost of the envelopes used, and the postage required to mail all of the notices. We are unable to accurately estimate these costs as they are dependent on the number of notices that would need to be sent. However we believe these costs would not exceed \$200. We seek comment on how to estimate this burden.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045 across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks only arise if a home infusion therapy AO voluntarily decides to terminate its CMS approved home infusion therapy accreditation program. This would occur rarely, if ever.

We do not believe that there would ever be a situation in which all six of the potential home infusion therapy AOs would decide to terminate their CMS approved accreditation programs simultaneously.

Proposed § 488.1045(b) states that once CMS publishes a notice in the **Federal Register** announcing the decision to involuntarily terminate the home infusion therapy AO's home infusion therapy accreditation program, the home infusion therapy AO must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program by no later than 30 calendar days after the notice is published in the **Federal Register**. This notice would announce that CMS is withdrawing its approval of the AOs home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at § 488.1010(f) once their current term of accreditation expires.

The time burden associated with proposed § 488.1045(b) would be the time it takes for the home infusion therapy AO to prepare and send the required written notification to all

accredited home infusion therapy suppliers which states that CMS is withdrawing the AOs approval of the home infusion therapy accreditation program and which also states the implications for the home infusion therapy suppliers payment status. We estimate that it would take no more than 4 hours for an AO staff person to perform the following tasks: (1) Draft the required notification letter; (2) perform a mail merge to prepare a copy of the letter that is addressed to each home infusion therapy supplier accredited by the AO; (3) print copies of the notification letters for each of the AOs accredited home infusion therapy suppliers; (4) put each notifications letter into an envelope; (5) affix the correct amount of postage to the envelope and (6) put the envelopes into the outgoing mail.

The home infusion therapy AO would incur a cost burden for the wages for the AO staff who performs the previously stated tasks. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be \$282.88 (4 hours \times \$35.36 per hour = \$141.44) + (\$141.44 for fringe benefits and overhead).

The home infusion therapy AO would incur an additional burden for miscellaneous costs associated with the preparation of the required notices to be sent to the AOs accredited home infusion therapy suppliers, including the cost of the paper on which the notices are printed, the printer ink used, the cost of the envelopes used, and the postage required to mail all of the notices. We believe that these costs would not exceed \$200.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045 across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks required by § 488.1045(b) would only arise if CMS decides to involuntarily terminate the CMS approval of the AO's home infusion therapy accreditation program. This would occur rarely, if ever. Also, we do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would decide to terminate their

CMS approved accreditation programs simultaneously.

Proposed § 488.1045(c)(3) would require that for both voluntary and involuntary terminations of a home infusion therapy AOs CMS approved home infusion therapy accreditation program, the home infusion therapy AO must provide a second written notification to all of its accredited home infusion therapy suppliers ten calendar days prior to the AO's accreditation program termination effective date. We estimate that the time and cost burdens associated with this requirement would be the same as our estimated burden for proposed § 488.1045(b) set forth previously.

Proposed § 488.1045(d) sets forth the required steps that a home infusion therapy AO must take when one of its accredited home infusion therapy suppliers has requested a voluntary withdrawal from accreditation. The withdrawal from accreditation by the home infusion therapy supplier may not become effective until the AO completes all of the following 3 steps: (1) The home infusion therapy AO must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program; (2) the home infusion therapy AO must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status; (3) the home infusion therapy AO must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by no later than 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

The burden associated with the requirement that the home infusion therapy AO contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program would include the time required for the AO to contact the home infusion therapy supplier to request written confirmation that the home infusion therapy supplier does indeed want to terminate their home infusion therapy accreditation. We estimate that the AO would most likely contact the home infusion therapy supplier to make this request by telephone or email. We estimate this would take no more than 15 minutes.

The AO would incur a cost burden for the wages of the AO staff person for the

time spent contacting the home infusion therapy supplier to confirm they intend to voluntarily withdraw from the home infusion therapy accreditation program. We believe that the person at the AO who would perform this task would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with contacting the home infusion therapy supplier to confirm that they do want to voluntarily terminate would be \$17.68 (15 minutes × \$35.36 per hour = \$8.84) + (\$8.84 for fringe benefits and overhead).

The home infusion therapy AO would also incur a time burden associated with the requirement that they send a written notice to the home infusion therapy supplier that is voluntarily terminating their home infusion therapy accreditation, which provides notice of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status. We estimate that it would take the home infusion therapy no more than 60 minutes to prepare the written notification.

We believe that the person at the AO who would prepare the required written notice to be sent to the home infusion therapy supplier that is voluntarily terminating its home infusion therapy accreditation would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required written notice would be \$70.72 (1 hours × \$35.36 per hour = \$35.36) + (\$35.36 for fringe benefits and overhead). We further estimate that the AO would incur postage costs in the amount of \$0.50 for each letter sent.

Finally, we estimate the burden associated with § 488.1045(d)(3) would include the time required for the home infusion therapy AO staff to prepare a final notice of voluntary withdrawal of accreditation by the home infusion therapy supplier and the time required to send this notice to CMS. We estimate that it would only take the AO staff 15 minutes or less to prepare the required notice for CMS, because this notice could be sent to CMS by email. We estimate it would take an additional 10

minutes of time for the AO staff to prepare the email and attach the written notice to the email.

The AO would incur a cost burden for the wages of the AO staff for the time spent preparing the notice and sending it to CMS. We believe that the person at the AO who would prepare the required written notice to be sent to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required written notice to be sent to CMS would be \$29.48 (15 minutes × \$35.36 per hour = \$8.84) + (10 minutes × \$35.36 per hour = \$5.90) + (\$14.74 for fringe benefits and overhead).

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1045(d) across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks would only arise if a home infusion therapy supplier would decide to voluntarily terminate its accreditation with the home infusion therapy AO. This would occur on an infrequent basis. We do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would have a home infusion therapy supplier decide to voluntarily terminate the accreditation with their home infusion therapy AOs simultaneously.

(f) Burden for Home Infusion Therapy AOs Associated With Proposed § 488.1050

Proposed § 488.1050(a) would provide that a home infusion therapy AO that is dissatisfied with a determination, made by CMS, that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy AO meet the applicable quality standards is entitled to reconsideration.

Proposed § 488.1050(b)(1) would require that a written request for reconsideration be filed within 30 calendar days of the receipt of CMS' notice of an adverse determination or non-renewal. Proposed § 488.1050(b)(2) would provide that the written request for reconsideration must specify the findings or issues with which the home infusion therapy AO disagrees and the reasons for the disagreement. Proposed

§ 488.1050(c)(1) provides the opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and proposed § 488.1050(c)(2) provides that written notice of the time and place of the hearing will be provided at least 10 business days before the scheduled date.

We estimate that it would take approximately 2 hours for a home infusion therapy AO to prepare its request for reconsideration. We believe that the person at the AO who would prepare the request for reconsideration would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the request for reconsideration would be \$141.44 (2 hours × \$35.36 per hour = \$70.72) + (\$70.72 for fringe benefits and overhead).

The remaining information that would be submitted in connection with a request for reconsideration or a reconsideration hearing, including any evidence or testimony provided is not considered “information” in accordance with 5 CFR 1320.3(h)(8), which excludes as “information” any “facts or opinions obtained or solicited at or in connection with public hearings.”

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under § 488.1050 across all of the potential home infusion therapy AOs. We have not done so because we believe that the filing of a request for reconsideration by a home infusion therapy AO would occur rarely, if ever. Further, we do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would decide to file a request for reconsideration at the same time. Therefore, there would never be an occurrence where all the home infusion therapy AOs would incur the previously stated burden simultaneously.

(g) Burdens for Home Infusion Therapy AOs Related to Survey Activities and Accreditation of Home Infusion Therapy Suppliers

The home infusion therapy AO would incur time and cost associated the accreditation of home infusion therapy suppliers. These would include the time and costs required to perform an onsite survey, offsite survey or other type of survey activity for each home infusion

therapy supplier that has hired that AO to provide accreditation. However, as we have not approved any home infusion therapy AOs, we do not yet know what type of home infusion therapy accreditation standards they will use, or what the home infusion therapy accreditation survey process will consist of. Therefore, we are unable to accurately estimate the time and cost burden associated with the survey of home infusion therapy suppliers.

However, we can state that if the home infusion therapy AO were to perform an onsite survey, it would incur wages for each of the surveyors that are sent to perform the survey for the amount of time spent performing the survey. The AO would also incur wages for the time spent by the surveyors or other home infusion therapy AO staff in reviewing the survey documents, making a decision about whether to grant accreditation to the home infusion therapy supplier that was surveyed and preparing the decision letter to the home infusion therapy supplier. The AO would also incur travel costs for the AO staff to travel to the home infusion therapy supplier’s location to perform the survey.

If the home infusion therapy AO were to do an offsite records audit survey, the AO would request that the home infusion therapy supply the AO with specific records. The AO would incur costs for the wages of the AO staff that performed the audit of the documents provided by the home infusion therapy supplier. The AO would also incur wages for the time spent by the surveyors or other home infusion therapy AO staff in making a decision about whether to grant accreditation to the home infusion therapy supplier that was audited and preparing the decision letter to the home infusion therapy supplier.

We seek comment on how to estimate this burden.

2. Burden to Home Infusion Therapy Suppliers Related to Home Infusion Therapy Health and Safety Standards

All existing home infusion therapy suppliers are already accredited by existing home infusion therapy AOs to meet requirements established by private insurers and Medicare Advantage plans. We are proposing that, in order for the existing home infusion therapy suppliers accredited by these AOs to continue to receive payment for the home infusion therapy services provided, these AOs must obtain Medicare approval for a home infusion therapy accreditation program. To obtain this CMS approval, we are proposing that these AOs would be

required to submit an application to CMS seeking approval of a home infusion therapy accreditation program that meets the requirements set forth in the proposed new home infusion therapy AO approval and oversight regulations and proposed new home infusion therapy health and safety regulations. We would also require that the home infusion therapy program submitted by these AOs be separate and distinct from the AOs home health deeming accreditation program.

It is likely that the home infusion therapy suppliers would need to be resurveyed after their home infusion therapy AO obtains CMS approval of a home infusion therapy accreditation program, under section 1861(iii)(3)(D)(i)(III) of the Act. We believe this resurvey would be necessary because the AOs would have to determine if the home infusion therapy suppliers they accredit meet their new Medicare-approved home infusion therapy accreditation program accreditation standards. However, if a current home infusion therapy AOs current home infusion therapy standards already meet or exceed the proposed home infusion therapy health and safety standards, so that a revision of that AOs home infusion therapy accreditation standards is not required, then a resurvey of that AO’s accredited home infusion therapy suppliers may not be necessary.

The home infusion therapy supplier would incur some time burden in order to come into compliance with the home infusion therapy AOs new home infusion therapy accreditation program requirements initially and thus prepare for the accreditation survey. However, all existing home infusion therapy suppliers are already accredited by existing home infusion therapy AOs to meet requirements established by private insurers and Medicare Advantage plans. Therefore, we assume that there would be little, if any new burden imposed on home infusion therapy suppliers in order to implement the proposed new health and safety standards.

The home infusion therapy supplier would be charged a fee by the AO for providing accreditation services. Fees for the home infusion therapy accreditation currently offered by the six AOs listed previously accreditation programs offered by the six AOs listed previously vary between \$5,950 and \$12,500 and, in general, currently cover all of the following items: Application fee, manuals, initial accreditation fee, onsite surveys or other auditing (generally once every 3 years), and travel, when necessary for survey

personnel. Accreditation costs also vary by the size of the provider or supplier seeking accreditation, its number of locations, and the number of services it provides.

We recognize that cost and time burdens associated with becoming accredited may be a barrier for small suppliers such as home infusion therapy suppliers. We propose to implement the following to minimize the burden of accreditation on suppliers, including small businesses:

- Multiple accreditation organizations—We expect that more than one AO would submit an application to become a designated Home Infusion Therapy AO. We believe that selection of more than one home infusion therapy AO would introduce competition resulting in reductions in accreditation costs.

- Required plan for small businesses—During the application process we would require prospective home infusion therapy AOs to include a plan that details their methodology to reduce accreditation fees and burden for small or specialty suppliers. This would need to include that the AO's fees are based on the size of the organization.

- Reasonable quality standards—The quality standards that would be used to evaluate the services rendered by each home infusion therapy supplier are being proposed in this rule. Many home infusion therapy suppliers already comply with the standards and have incorporated these practices into their daily operations. It is our belief that compliance with the quality standards would result in more efficient and effective business practices and would assist suppliers in reducing overall costs.

There are at least two important sources of uncertainty in estimating the impact of accreditation on home infusion therapy suppliers. First, our estimates assume that all home infusion therapy suppliers with positive Medicare payments would seek accreditation. We assume that home infusion therapy suppliers who currently receive no Medicare allowed charges would choose not to seek accreditation. It is also possible that many of the home infusion therapy suppliers with allowed charges between \$1 and \$1,000 may decide not to incur the costs of accreditation.

Second, it is difficult to predict what accreditation fees would be in the future. Our experience with other accreditation programs has led us to believe that the accreditation rates would go up, due to factors such as wage increases, and increased travel costs. To monitor accreditation fees, we

propose to require the AOs for home infusion therapy suppliers to submit their proposed fees to CMS for review for reasonableness. We would require home infusion therapy AOs to notify CMS anytime there is an increase in accreditation fees.

(d) Medicare-Certified Accreditation Organizations—Proposed Changes to 42 CFR 488.5

We have proposed to modify the AO approval and oversight regulations for Medicare-certified providers and suppliers by adding two new requirements. The first proposed new requirement is to be added to 42 CFR 488.5(a)(7) and is a requirement that in their application for CMS approval, the AOs that accredited Medicare-certified providers and suppliers must include a statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter. The second requirement is to be added as § 488.5(a)(18)(iii) and would require that the AOs for Medicare-certified providers and suppliers include a written statement in their application for CMS approval agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

(1) Burden Associated With the Online Training Requirement for AO Surveyors

CMS provides a number of online surveyor training modules that are available to the State Survey Agency surveyors. We have proposed to require the AO surveyors to take this training in an attempt to decrease the historically high disparity rate between the AOs survey results and those of the validation surveys performed by the State Survey Agency surveyors.

CMS offers 168 online surveyor training programs that are available for the State Survey Agency surveyors. This website provides courses that are general in nature such as "Principles of Documentation Learning Activity—Long Term Care", "Basic Writing Skills for Surveyor Staff", "Infection Control, Patient Safety, and Emergency Preparedness. The CMS Surveyor Training website also offers courses related to specific healthcare settings,

services, and regulations, such as hospitals, CAHs, ASCs, CLIA, CMHCs, EMTALA, FQHCs, HHAs and OASIS, Hospices, Nursing Homes and the MDS, Outpatient Physical Therapy/Outpatient Speech Therapy (OPT/OST). These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace preferred by the trainee.

We estimate that each SA surveyor takes approximately 10 courses on the CMS Surveyor Training website. We estimate that it would take approximately 3–5 hours to complete each of these courses. We believe that the surveyors for AOs that accredit Medicare-certified providers should take the same number and type of surveyor training courses as the SA surveyors (that is—approximately 10 courses). This means that each of the AOs surveyors that takes this training would incur a time burden in the amount of 30 to 50 hours.

The AOs that accredit Medicare-certified providers and suppliers would incur a cost burden for the wages of the surveyor for the time they spend taking these online surveyor training courses. Most surveyors are clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). As noted previously, we estimated that it would take approximately 30–50 hours for each AO surveyor to complete 10 online surveyor courses. Therefore, the AO would incur wages in the amount of \$1,060.80 to \$1,768 per each surveyor that completes the CMS online surveyor training (($\$35.36 \times 30 \text{ hours} = \$1,060.80$) and ($\$35.36 \times 50 \text{ hours} = \$1,768$)). The AO would also incur additional costs for fringe benefits and overhead in the amount of \$1,060.80 to \$1,768.00 per each surveyor that completes the CMS online surveyor training.

We are not able to accurately estimate to total time and cost burden to each AO for the wages incurred for the time spent by all surveyors of that AO that take the CMS online surveyor training courses, because we do not know exactly how many surveyors each AO has. However, if we estimate that each AO has 15 surveyors, the estimated time burden to each AO associated with this requirement would be 450 to 750 hours (($30 \text{ hours} \times 15 \text{ surveyors} = 450 \text{ hours}$ per all surveyors) and ($50 \text{ hours} \times 15 \text{ surveyors} = 750 \text{ hours}$ per all surveyors)). The estimated cost burden to each AO for Medicare-certified providers and supplies associated with

this requirement would be \$31,824 to \$53,040 ($(\$1,060.80 \times 15 = \$15,912)$ and $(\$1,768.00 \times 15 = \$26,520)$ and $(\$15,912$ to $\$26,520$ for fringe benefits and overhead)).

There are currently 9 AOs that accredit Medicare-certified providers and suppliers. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 4,050 to 6,750 ((450 hours per all surveyors/AO \times 9 AOs = 4,050 hours across all AOs) and (750 hours per all surveyors/AO \times 9 AOs = 6,750 hours across all AOs)). The estimated cost across all AOs that accredit Medicare-certified providers and suppliers would be \$143,208 to \$238,680 ($(\$15,912 \times 9 \text{ AOs} = \$143,208)$ and $(\$26,520 \times 9 \text{ AOs} = \$238,680)$). The cost for fringe benefits and overhead on these estimated wages across all AOs would be \$143,208 to 238,680.

(2) Burden Associated With the Statement Requirement for AOs

We are proposing that AOs approved in accordance with section 1865 of the Act, and regulated under part 488 subpart A, provide a written statement in their application in which they agree to continue a provider's or supplier's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

Proposed § 488.5(a)(18)(iii) would require the AOs for Medicare-certified providers and suppliers to include a written statement in their application for CMS approval of their accreditation program, agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

We believe that the AOs that accredit Medicare-certified providers and suppliers would incur limited burden associated with this requirement, because this proposed regulation simply requires that the AOs to include a statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if

a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program. We believe that this written statement to be provided by the AO would consist of only 1 to 2 paragraphs and would take no more than 15 minutes to prepare.

We believe that a clinician such as registered nurses would prepare the required statement to be included in the AOs application. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the estimated cost burden to the AOs that accredit Medicare-certified providers and suppliers associated with the preparation of the required statement would be approximately \$17.68 ((15 minutes \times \$35.36 per hour = \$8.84) + (\$8.84 for fringe benefits and overhead)).

There are nine AOs that accredit Medicare-certified providers and suppliers. The cost across all AOs for the completion of this task would be \$158.12 ($(\$8.84 \times 9 \text{ AOs} = \$79.56)$ + (\$79.56 for fringe benefits and overhead). However, AOs for Medicare-certified providers and suppliers are required to submit a renewal application only every six years. Therefore, the existing AOs would be required to submit the statement stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program with their next renewal application which is submitted after the publication of the final rule. While we have calculated the cost for the performance of this task across all AOs that accredit Medicare-certified providers and suppliers, it is important to note that the existing AOs are scheduled to submit their renewal applications at varying dates and times over a period of several years. Therefore there will be no time period in which all of these AOs will incur these expenses simultaneously.

D. Detailed Economic Analysis

1. HH PPS

This rule proposes updates for the CY 2019 HH PPS rates contained in the CY 2018 HH PPS final rule (82 FR 51676 through 51752). The impact analysis of this proposed rule presents the

estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2017. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

a. HH PPS for CY 2019

Table 59 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2019. For this analysis, we used an analytic file with linked CY 2017 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2017. The first column of Table 59 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2019 wage index and revised labor share. The fourth column shows the payment effects of the CY 2019 case-mix weights. The fifth column shows the effects of the new rural add-on payment provision in statute. The sixth column shows the effects of the revised FDL ratio used to calculate outlier payments, and the seventh column shows the effects of the CY 2019 home health payment update percentage.

The last column shows the combined effects of all the policies proposed in this rule. Overall, it is projected that aggregate payments in CY 2019 would increase by 2.1 percent. As illustrated in Table 59, the combined effects of all of the changes vary by specific types of

providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2019

wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2019 relative to CY 2018, the percentage of total HH PPS payments that were

subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

TABLE 59—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2019

	Number of agencies	CY 2019 wage index and labor share ¹ (%)	CY 2019 case-mix weights ² (%)	Rural add-on revisions (%)	Updated outlier FDL ratio 0.51 (%)	CY 2019 HH payment update percentage ³	Total (%)
All Agencies	10,547	0.0	0.0	-0.1	0.1	2.1	2.1
Facility Type and Control							
Free-Standing/Other Vol/NP	1,065	-0.3	-0.1	0.0	0.2	2.1	1.9
Free-Standing/Other Proprietary	8,366	0.1	0.0	-0.1	0.1	2.1	2.2
Free-Standing/Other Government	260	0.3	0.1	-0.1	0.2	2.1	2.6
Facility-Based Vol/NP	604	0.0	0.0	0.0	0.2	2.1	2.3
Facility-Based Proprietary	76	-0.3	0.1	-0.2	0.2	2.1	1.9
Facility-Based Government	176	-0.1	0.0	-0.3	0.2	2.1	1.9
Subtotal: Freestanding	9,691	0.0	0.0	-0.1	0.1	2.1	2.1
Subtotal: Facility-based	856	-0.1	0.0	-0.1	0.2	2.1	2.1
Subtotal: Vol/NP	1,669	-0.2	-0.1	0.0	0.2	2.1	2.0
Subtotal: Proprietary	8,442	0.1	0.0	-0.1	0.1	2.1	2.2
Subtotal: Government	436	0.1	0.0	-0.2	0.2	2.1	2.2
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	253	0.1	0.1	-0.3	0.2	2.1	2.2
Free-Standing/Other Proprietary	821	0.6	0.0	-0.7	0.1	2.1	2.1
Free-Standing/Other Government	176	0.5	0.1	-0.2	0.2	2.1	2.7
Facility-Based Vol/NP	273	0.2	0.1	-0.3	0.2	2.1	2.3
Facility-Based Proprietary	41	0.1	0.2	-0.5	0.1	2.1	2.0
Facility-Based Government	134	0.2	0.1	-0.4	0.2	2.1	2.2
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	812	-0.4	-0.1	0.0	0.2	2.1	1.8
Free-Standing/Other Proprietary	7,545	0.0	0.0	0.0	0.1	2.1	2.2
Free-Standing/Other Government	84	0.1	0.1	0.0	0.2	2.1	2.5
Facility-Based Vol/NP	331	-0.1	-0.1	0.0	0.2	2.1	2.1
Facility-Based Proprietary	35	-0.6	0.1	0.0	0.2	2.1	1.8
Facility-Based Government	42	-0.4	-0.1	-0.1	0.1	2.1	1.6
Facility Location: Urban or Rural							
Rural	1,698	0.4	0.0	-0.6	0.1	2.1	2.0
Urban	8,849	0.0	0.0	0.0	0.1	2.1	2.2
Facility Location: Region of the Country (Census Region)							
New England	363	-0.9	0.0	0.0	0.2	2.1	1.4
Mid Atlantic	482	-0.3	-0.2	0.0	0.2	2.1	1.8
East North Central	2,031	-0.3	0.1	0.0	0.1	2.1	2.0
West North Central	705	0.0	0.1	0.0	0.2	2.1	2.4
South Atlantic	1,647	0.0	-0.2	0.0	0.1	2.1	2.0
East South Central	423	0.1	-0.1	-0.5	0.1	2.1	1.7
West South Central	2,774	0.6	0.1	-0.3	0.1	2.1	2.6
Mountain	678	-0.3	0.1	0.1	0.2	2.1	2.2
Pacific	1,403	0.3	0.2	0.0	0.1	2.1	2.7
Other	41	0.9	-0.9	0.0	0.2	2.1	2.3
Facility Size (Number of First Episodes)							
<100 episodes	2,907	0.0	0.3	0.0	0.2	2.1	2.6
100 to 249	2,301	0.1	0.4	-0.1	0.1	2.1	2.6
250 to 499	2,218	0.1	0.3	-0.1	0.1	2.1	2.5
500 to 999	1,637	0.1	0.1	-0.1	0.1	2.1	2.3
1,000 or More	1,484	0.0	-0.1	-0.1	0.1	2.1	2.0

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.

¹ The impact of the CY 2019 home health wage index is offset by the wage index budget neutrality factor described in section III.C.4 of this proposed rule.

²The impact of the CY 2019 home health case-mix weights reflects the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor described in section III.B of this proposed rule.

³The CY 2019 home health payment update percentage reflects the home health payment update of 2.1 percent as described in section III.C.2 of this proposed rule.

Region Key:

New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; **Middle Atlantic** = Pennsylvania, New Jersey, New York; **South Atlantic** = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; **East North Central** = Illinois, Indiana, Michigan, Ohio, Wisconsin; **East South Central** = Alabama, Kentucky, Mississippi, Tennessee; **West North Central** = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; **West South Central** = Arkansas, Louisiana, Oklahoma, Texas; **Mountain** = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; **Pacific** = Alaska, California, Hawaii, Oregon, Washington; **Other** = Guam, Puerto Rico, Virgin Islands.

b. HH PPS for CY 2020 (Proposed PDGM)

Table 60 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2020. For this analysis, we used an analytic file with linked CY 2017 OASIS assessments and CY 2017 HH claims data (as of March 2, 2018) for dates of service that ended on or before December 31, 2017. The first column of Table 60 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of HHAs in the impact analysis. The PDGM, as required by Section 51001(a)(2)(A) of the BBA of 2018, will be implemented in a budget neutral manner and the third column shows the total impact of the proposed PDGM as outlined in

section III.F of this proposed rule. As illustrated in Table 60, the effect of the proposed PDGM varies by specific types of providers and location. We note that some individual HHAs within the same group may experience different impacts on payments than others. This is due to distributional differences among HHAs with regards to the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, the degree of Medicare utilization, and the ratio of overall visits that were provided as therapy versus skilled nursing.

As outlined in section III.F of this proposed rule, several OASIS items would no longer be needed to case-mix adjust the 30-day payment under the PDGM; therefore, we would make 19 current OASIS items (48 data elements) optional at the FU time point starting January 1, 2020. As also discussed in

section III.F. of this proposed rule, in order to calculate the case-mix adjusted payment amount for the PDGM, we would add the collection of two current OASIS items (10 data elements) at the FU time point starting January 1, 2020. Section VII of this proposed rule provides a detailed description of the net decrease in burden associated with these proposed changes in conjunction with the changes in burden that result from OASIS item collection changes due to the proposed removal of certain measures required under HH QRP, also effective for January 1, 2020 as outlined in section V.E of this rule. We estimate that the burden associated with OASIS item collection as a result of this proposed rule results in a net \$60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

TABLE 60—IMPACTS OF PDGM, CY 2020

	Number of agencies	PDGM (%)
All Agencies	10,480	0.0%
Facility Type and Control		
Free-Standing/Other Vol/NP	1,055	2.6
Free-Standing/Other Proprietary	8,309	-1.2
Free-Standing/Other Government	260	1.1
Free-Based Vol/NP	604	3.8
Free-Based Proprietary	76	4.4
Free-Based Government	176	4.6
Subtotal: Freestanding	9,624	-0.4
Subtotal: Free-based	856	3.9
Subtotal: Vol/NP	1,659	2.9
Subtotal: Proprietary	8,385	-1.2
Subtotal: Government	436	2.9
Facility Type and Control: Rural		
Free-Standing/Other Vol/NP	253	3.8
Free-Standing/Other Proprietary	820	3.9
Free-Standing/Other Government	176	1.9
Free-Based Vol/NP	273	4.1
Free-Based Proprietary	41	11.3
Free-Based Government	134	5.9
Facility Type and Control: Urban		
Free-Standing/Other Vol/NP	802	2.4
Free-Standing/Other Proprietary	7,489	-1.8
Free-Standing/Other Government	84	0.3
Free-Based Vol/NP	331	3.7
Free-Based Proprietary	35	0.1

TABLE 60—IMPACTS OF PDGM, CY 2020—Continued

	Number of agencies	PDGM (%)
Free-Based Government	42	3.4
Facility Location: Urban or Rural		
Rural	1,697	4.0
Urban	8,783	-0.6
Facility Location: Region of the Country (Census Region)		
New England	354	2.5
Mid Atlantic	479	3.1
East North Central	2,012	-1.1
West North Central	703	-3.9
South Atlantic	1,643	-5.3
East South Central	423	0.9
West South Central	2,750	4.1
Mountain	675	-5.2
Pacific	1,400	3.8
Other	41	11.0
Facility Size (Number of 1st Episodes)		
< 100 episodes	2,841	1.9
100 to 249	2,301	1.1
250 to 499	2,218	0.6
500 to 999	1,636	-0.3
1,000 or More	1,484	-0.2
Nursing/Therapy Visits Ratio		
1st Quartile (Lowest 25 Nursing)	2,620	-9.9
2nd Quartile	2,620	-0.8
3rd Quartile	2,620	6.5
4th Quartile (Top 25 Nursing)	2,620	17.0

Source: CY 2017 Medicare claims data (as of March 2, 2018) for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.

Note(s): The “PDGM” is the 30-day version of the model with no behavioral assumptions applied. From the impact file, this analysis omits 354,099 60-day episodes not grouped under the PDGM (either due to a missing SOC OASIS, because they could be assigned to a clinical grouping, or had missing therapy/nursing visits). After converting 60-day episodes to 30-day periods for the PDGM, a further 26 periods were excluded with missing NRS weights, and 2,386 periods with a missing urban/rural indicator. These excluded episodes results overall in 67 fewer HHAs being represented than in the standard impact tables.

Region Key:

New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; **Middle Atlantic** = Pennsylvania, New Jersey, New York; **South Atlantic** = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; **East North Central** = Illinois, Indiana, Michigan, Ohio, Wisconsin; **East South Central** = Alabama, Kentucky, Mississippi, Tennessee; **West North Central** = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; **West South Central** = Arkansas, Louisiana, Oklahoma, Texas; **Mountain** = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; **Pacific** = Alaska, California, Hawaii, Oregon, Washington; **Other** = Guam, Puerto Rico, Virgin Islands.

In response to the CY 2019 case-mix adjustment methodology refinements proposed in the CY 2018 HH PPS proposed rule (82 FR 35270), a few commenters requested that CMS include more information in the impact table for the proposed PDGM, specifically how

payments are impacted for patients with selected clinical conditions as was included in the Technical Report which is available at: <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

Therefore, we are including Table 61 which provides more information on the impact of the PDGM case-mix adjustment methodology for patients with selected clinical conditions.

TABLE 61—IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS

	Ratio of average PDGM payment to average current (30-day equivalent) payment
All Episodes (60-Day Count)	1.00
Clinical Group	
Behavioral Health	0.85
Complex	1.13

TABLE 61—IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS—Continued

	Ratio of average PDGM payment to average current (30-day equivalent) payment
MMTA	1.00
MS Rehab	0.96
Neuro Rehab	0.93
Wound	1.27
Functional Level	
Low	0.95
Medium	1.00
High	1.05
Admission Source	
Community	0.89
Institutional	1.30
Timing	
Early	1.25
Late	0.87
Comorbidity Group	
No adjustment	0.97
Single Comorbidity	1.02
Comorbidity Interaction	1.22
Dual Status	
Not (Full) Dual Eligible	0.99
Yes (Full) Dual Eligible	1.03
Parenteral Nutrition	
No Parenteral Nutrition	1.00
Yes Parenteral Nutrition	1.18
Surgical Wounds	
No Known Surgical Wound	0.98
Yes Known Surgical Wound	1.11
Ulcers	
No Ulcers Recorded	0.99
Positive Number of Ulcers Recorded	1.16
Bathing	
Able to Bathe with some independence	0.97
Cannot bathe independently	1.08
Poorly-Controlled Cardiac Dysrhythmia	
No Poorly-Controlled Cardiac Dysrhythmia	1.00
Yes Poorly-Controlled Cardiac Dysrhythmia	1.04
Poorly-Controlled Diabetes	
No Poorly-Controlled Diabetes	0.99
Yes Poorly-Controlled Diabetes	1.06
Poorly-Controlled Peripheral Vascular Disease	
No Poorly-Controlled Peripheral Vascular Disease	1.00
Yes Poorly-Controlled Peripheral Vascular Disease	1.07
Poorly-Controlled Pulmonary Disorder	
No Poorly-Controlled Pulmonary Disorder	1.00

TABLE 61—IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS—Continued

	Ratio of average PDGM payment to average current (30-day equivalent) payment
Yes Poorly-Controlled Pulmonary Disorder	1.03
Open Wound/Lesion	
No Open Wound/Lesion	0.98
Yes Open Wound/Lesion	1.10
Temporary Health Risk	
No Temporary Health Risk	0.99
Yes Temporary Health Risk	1.02
Fragile/Serious Health Risk	
Yes Fragile/Serious Health Risk	0.98
No Fragile/Serious Health Risk	1.04

Note(s): **For this table only**, payments are for normal episodes and do not include outlier payments. For comparability with the 30-day PDGM, current payments have been halved from 60-day amounts to simulate 30-day payments. PDGM payments have been normalized so that national average 30-day payments equaled the 30-day current system equivalent payment to facilitate an understanding of reallocation of payments from the current system. For the ratio of PDGM to current payments in the right-hand column, a value greater than one signifies that characteristic would receive increased payment and a value less than one would signify that characteristic would receive lesser payment, all else equal, in the PDGM. To be classified as Poorly Controlled Cardiac Dysrhythmia, Diabetes, Peripheral Vascular Disease, or Pulmonary Disorder required one of the following respective primary or secondary diagnosis codes with an accompanying recorded “poorly-controlled” degree of symptom control: Cardiac Dysrhythmia: ICD-10 I-21-I22.9 & I47-I49; Diabetes: E08.0-E08.8, E09.0-E09.8, & E10-E14; Peripheral Vascular Disease: ICD-10 I73; and Pulmonary Disorder: (I40-47, J84.01, J84.02, J84.03, J84.10, J96.0-J96.92, & J98.01-J98.3).

2. HHVBP Model

Table 62 displays our analysis of the distribution for possible payment adjustments at the maximum 7-percent, and 8-percent rates that will be used in Years 4 and 5 of the Model. These analyses use performance year data from 2016, the first year of HHVBP, the most recent year for which complete performance year data are available. The estimated impacts are for the following proposed changes, each of which would take effect beginning with PY4 (2019):

- Remove two OASIS-based measures (Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received);
- Replace three OASIS-based measures (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation- Locomotion) with two composite measures (Total Change in Self Care, Total Change in Mobility). The two composite measures would have a maximum score of 15 points;
- Reduce the maximum possible improvement points from 10 to 9 (13.5 for the two composite measures); and,
- Change the weights given to the performance measures used in the Model so that the OASIS and claims-based measures each count for 35 percent and the HHCAPHS measures count for 30 percent of the 90 percent of the Total Performance Score (TPS) that is based on performance on the Clinical Quality of Care, Care

Coordination and Efficiency, and Person and Caregiver-Centered Experience measures. Data reporting for each New Measure would continue to have equal weight and account for the 10 percent of the TPS that is based on the New Measures collected as part of the Model. The weight of the unplanned hospitalization measure would also be increased so that it has three times the weight of the ED use without hospitalization measure.

We analyzed the payment adjustment percentage and the number of eligible HHAs under current policy to determine the impacts if the proposed changes in this rule were finalized. We used PY1 (CY2016) data to measure the impacts. The data sources for these analyses are data from the QIES system for the existing OASIS and claims-based measures, OASIS assessments for the two composite measures, HHCAPHS data received from the HHCAPHS contractor, and New Measure data submitted by Model participants. HHAs are classified as being in the smaller or larger volume cohort using the 2016 Quality Episode File, which is created using OASIS assessments. We note that this impact analysis is based on the aggregate value across all nine Model states.

Table 63 displays our analysis of the estimated impact of the proposals in this rule on the number of eligible HHAs and the distribution of percentage change in payment adjustment

percentage based on the same PY1 (CY2016) data used to calculate Table 62. We note that this impact analysis is based on the aggregate value across all nine Model states. Note that all Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. The analysis is calculated at the state and size cohort level. It is expected that a certain number of HHAs would not have a payment adjustment because they may be servicing too small of a population to report an adequate number of measures to calculate a TPS. Table 63 shows that there would be a reduction in the number of HHAs that would have a sufficient number of measures to receive a payment adjustment for performance year 4 of 31 HHAs (Change column), a decrease from 1,610 HHAs (Current column) to 1,579 HHAs (Simulated column) across the nine selected states.

This analysis reflects only HHAs that would have data for at least five measures that meet the requirements of § 484.305 and would be included in the LEF and would have a payment adjustment calculated. Value-based incentive payment adjustments for the estimated eligible 1,579 HHAs in the selected states that would compete in the HHVBP Model are stratified by size as described in section IV.B. of the CY 2017 HH PPS final rule. As finalized in

section IV.B. of the CY 2017 final rule, there must be a minimum of eight HHAs in any cohort.

Those HHAs that are in states that do not have at least eight smaller-volume HHAs will not have a separate smaller-volume cohort and thus there will only be one cohort that will include all the HHAs in that state. As indicated in Table 63, Maryland, North Carolina, Tennessee, Washington, and Arizona would have only one cohort while Florida, Iowa, Massachusetts, and Nebraska would have both a smaller-volume cohort and a larger-volume cohort. For example, Iowa would have 17 HHAs eligible to be exempt from being required to have their beneficiaries' complete HHCAHPS surveys because they provide HHA services to less than 60 beneficiaries. Therefore, those 17 HHAs would be competing in Iowa's smaller-volume cohort for CY 2019 (PY4) under the Model.

Table 63 shows the distribution of percentage change in payment adjustment percentage resulting from the proposals in this rule. Using 2016 data and the maximum payment adjustment for performance year 4 of 7 percent (as applied in CY 2021), based on the six proposed OASIS quality measures and two claims-based measures in QIES, the five HHCAHPS measures, and the three New Measures, we see that, across all nine states, 31 HHAs would no longer be eligible for a payment adjustment for PY4 because they would not have data on at least five measures that meet the requirements of § 484.305. The distribution of scores by percentile shows the distribution of the change in percent payment adjustment. For example, the distribution for HHAs in Florida in the smaller-volume cohort ranges from -2.5 percent at the 10th percentile to +2.9 percent at the 90th percentile. This means that, for 7 of the 77 HHAs in the smaller-volume cohort in Florida, the proposed changes would decrease their payment adjustment percentage by -2.5 percent or more

while, for another 7 HHAs these proposed changes would increase their payment adjustment percentage by 2.9 percent or more. For half of the HHAs in Florida's smaller volume cohort, the impact of these proposed changes on their payment adjustment percentage would be between -1.1 percent and +1.3 percent. These impact analyses suggest that, for most participating HHAs, the impacts of the proposed changes would be modest.

Table 64 provides the payment adjustment distribution based on agency size, proportion of dually-eligible beneficiaries, average case mix (using the average case-mix for non-LUPA episodes), the proportion of the HHA's beneficiaries that reside in rural areas and HHA organizational status. HHAs with a higher proportion of dually-eligible beneficiaries and HHAs whose beneficiaries have higher acuity tend to have a more negative impact associated with the proposals in this rule based on the 50th percentile of the impact of the changes on payment adjustment percentage.

Table 65 shows the current and proposed weights for individual performance measures by measure category and possible applicable measure category scenarios to demonstrate the weight of the individual measures when an HHA has scores on All Measures or if an HHA is missing all measures in a measure category. For example, for an HHA that has quality measure scores on All Measures in all the measure categories (OASIS-based, claims-based and HHCAHPS) under the current weighting method, the individual measures are weighted equally. The Proposed Weights columns show the proposed weights for the individual performance measures based on the changes to the weighting methodology proposed in this rule. For example, for HHAs with scores on All Measures, the OASIS-based measures account for 35 percent of the TPS, with equal weighting given to the Improvement in Oral Medications,

Improvement in Dyspnea, Improvement in Pain, and Discharge to Community measures. The proposed Composite Self-Care and Composite Mobility measures would be weighted 1.5 times more than the other OASIS-based measures so that the maximum score for the two composite measures is the same as for the three functional OASIS-based measures that they would replace (Improvement in Ambulation, Bathing and Bed Transferring). Under the proposed weights, the two claims-based measures, which would collectively account for 35 percent of an HHA's TPS, would not be weighted equally. We are proposing that the weight of the acute care hospitalization measure would be three times higher than that of the ED Use measure. Thus, its weight would be 26.25 percent while the weight of the ED Use measure would be 8.75 percent for an HHA that reported on all measures. The HHCAHPS measures would account for 30 percent of an HHA's TPS and each measure would be weighted equally.

Table 65 also shows the number of HHAs that would have enough measures to receive a payment adjustment under each possible scoring scenario under both the current and proposed weighting methodologies. Most of the HHAs that would no longer receive a payment adjustment with the proposed changes in this rule are those with no claims or HHCAHPS measures. With only OASIS measures, these HHAs are more impacted by the proposal to remove the two immunization measures and the proposal to replace three OASIS functional measures with the two composite measures. The number of HHAs without claims or HHCAHPS measures that do not have enough measures to receive a payment adjustment would drop from 99 to 73 (a decrease of 26 HHAs), and the majority of the HHAs that would no longer have a payment adjustment would be smaller HHAs (16 of the 26 HHAs).

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TABLE 62: ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES (PERCENTAGE)

Payment Adj. Distribution	Maximum Payment Adjustment Percentage	Percentile								
		10%	20%	30%	40%	Median	60%	70%	80%	90%
7% Payment Adj. For PY4 of the Model	7%	-3.3%	-2.4%	-1.7%	-0.9%	-0.2%	0.5%	1.2%	2.2%	3.7%
8% Payment Adj. For PY5 of the Model	8%	-3.8%	-2.8%	-1.9%	-1.0%	-0.3%	0.5%	1.4%	2.5%	4.2%

TABLE 63: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT
 [Based on a 7-percent payment adjustment]

State	Cohort	Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Proposed Changes				
		Current	Simulated	Change	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
	All	1610	1579	31	-2.1%	-1.0%	-0.1%	0.9%	1.9%
HHAs with no separate small HHA cohort									
AZ	All	113	112	1	-2.7%	-1.4%	-0.1%	0.7%	1.8%
MD	All	51	50	1	-1.7%	-0.6%	-0.3%	0.9%	1.6%
NC	All	163	163	0	-1.6%	-0.8%	0.0%	0.7%	1.9%
TN	All	122	122	0	-1.2%	-0.7%	0.2%	0.8%	1.7%
WA	All	57	57	0	-1.3%	-0.8%	0.0%	0.8%	2.0%
Large-volume HHA Cohort in states with small cohort									
FL	Large	706	703	3	-2.3%	-1.2%	-0.2%	1.0%	2.0%
IA	Large	99	97	2	-1.9%	-1.2%	-0.2%	0.8%	1.5%
MA	Large	123	119	4	-2.0%	-1.1%	-0.4%	0.5%	1.4%
NE	Large	45	45	0	-2.8%	-0.9%	-0.3%	0.6%	1.8%
Small-volume HHA Cohort in states with small cohort									
FL	Small	77	68	9	-2.5%	-1.1%	0.1%	1.3%	2.9%
IA	Small	25	17	8	0.1%	1.3%	2.9%	4.4%	6.4%
MA	Small	15	12	3	-1.4%	-0.5%	0.3%	1.5%	2.2%
NE	Small	14	14	0	-3.0%	-1.0%	0.0%	1.2%	2.2%

TABLE 64: PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS FOR THE HHVBP MODEL
 [Based on a 7-percent payment adjustment ^{1, 2}]

Cohort	Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Proposed Changes				
	Current	Simulated	Change	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Facility size (# of patients)								
Small HHA	136	117	19	-3.2%	-1.6%	-0.2%	1.1%	3.1%
Large HHA	1474	1462	12	-2.0%	-1.0%	-0.1%	0.9%	1.9%
Percentage of Medicaid patients								
No Medicaid	749	743	6	-2.2%	-1.1%	-0.1%	0.9%	2.0%
>0 and < 30% Medicaid	661	653	8	-1.7%	-0.9%	0.0%	0.9%	1.9%
30%+ Medicaid	200	183	17	-2.6%	-1.4%	-0.4%	0.6%	1.8%
Patient acuity								
Low Acuity	403	384	19	-2.2%	-1.0%	-0.1%	1.0%	2.0%
Medium Acuity	805	798	7	-1.8%	-0.9%	0.0%	0.9%	1.9%
High Acuity	402	397	5	-2.3%	-1.3%	-0.3%	0.9%	2.0%
Percentage of rural beneficiaries								
None	1482	1458	24	-2.1%	-1.1%	-0.1%	0.9%	1.9%
> 0 and < 90%	11	10	1	-4.1%	-1.1%	-0.4%	0.3%	1.7%
>=90%	117	111	6	-1.7%	-0.9%	0.2%	1.5%	2.7%
Facility type and control								
Non-profit	310	308	2	-1.4%	-0.8%	0.2%	1.0%	1.9%
For profit	1191	1169	22	-2.2%	-1.1%	-0.2%	0.8%	1.9%
Government	109	102	7	-1.9%	-0.9%	0.0%	1.2%	2.7%
Freestanding	1448	1419	29	-2.1%	-1.1%	-0.2%	0.9%	1.9%
Facility-based	162	160	2	-1.2%	-0.5%	0.2%	1.1%	2.0%

¹ Rural beneficiaries identified based on the CBSA code reported on the claim.

² Acuity is based on the average case-mx weight for non-LUPA episodes. Low acuity is defined as the bottom 25% (among HHVBP model participants); mid-acuity is the middle 50% and high acuity is the highest 25%.

TABLE 65: CURRENT AND PROPOSED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES FOR THE HHVBP MODEL¹²³⁴

	Current Weights				Proposed Weights: All Changes				Proposed Weights: Reweighting Changes Only			
	All Measures (n=1,026)	No HHCAPHS (n=465)	No claims (n=20)	No claims or HHCAPHS (n=99)	All Measures (n=1,026)	No HHCAPHS (n=460)	No claims (n=20)	No claims or HHCAPHS (n=73)	All Measures (n=1,026)	No HHCAPHS (n=460)	No claims (n=20)	No claims or HHCAPHS (n=73)
Large HHAs	1023	382	20	49	1023	380	20	39				
Small HHAs	3	83	0	50	3	80	0	34				
OASIS (35% weight)*												
Flu vaccine ever received**	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Pneumococcal vaccine**	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Bathing***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Bed Transfer***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Ambulation***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Oral Meds	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Improve Dyspnea	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Improve Pain	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Discharge to Community	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Composite self-care	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%	0.00%	0.00%	0.00%	0.00%
Composite mobility	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%	0.00%	0.00%	0.00%	0.00%
Total weight for OASIS measures	56.25%	81.82%	64.26%	100.00%	35.00%	49.98%	53.82%	99.96%	35.00%	50.00%	53.85%	100.00%
Claims (35% weight)												
Hospitalizations	6.25%	9.09%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%
Outpatient ED	6.25%	9.09%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%
Total weight for claims measures	12.50%	18.18%	0.00%	0.00%	35.00%	50.00%	0.00%	0.00%	35.00%	50.00%	0.00%	0.00%
HHCAPHS (30% weight)												
Care of patients	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Communication between provider and patient	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Discussion of specific care Issues	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Overall rating of care	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Willingness to recommend HHA to family or friends	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Total weight for HHCAPHS measures	31.25%	0.00%	35.70%	0.00%	30.00%	0.00%	46.15%	0.00%	30.00%	0.00%	46.15%	0.00%

¹ Under the proposal if individual OASIS items are missing, the weight of the non-missing OASIS items would be increased.

² Flu vaccine ever received and the pneumococcal polysaccharide vaccine measures are proposed to be removed from the applicable measure set beginning in CY 2019/PY4.

³ Improvement in Bathing, Bed Transfer and Ambulation measures are proposed to be removed if proposed composite measures are added to the applicable measure set beginning in CY 2019/PY4.

⁴ The proposed composite measures (Composite Self-Care and Composite Mobility) would replace three functional OASIS-based measures (Improvement in Bathing, Improvement in Bed Transfer, Improvement in Ambulation), thus they would be weighted 1.5 times more than the other OASIS-based measures so that the total weight for the functional-based OASIS measures is unchanged.

3. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a calendar year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to a HHA for that calendar year by 2 percentage points. For the CY 2018 annual payment update determination, 1,311 of the 11,776 active Medicare-certified HHAs, or approximately 11.1 percent, did not receive the full annual percentage increase. Information is not available to determine the precise number of HHAs that would not meet the requirements to receive the full annual percentage increase for the CY 2019 payment determination.

As discussed in section V.E. of this proposed rule, we are proposing to remove seven measures from the HH QRP: Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in the Status of Surgical Wounds, Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505),

Rehospitalization during the First 30 Days of HH (NQF #2380). All seven of these measures are proposed for removal starting with the CY 2021 HH QRP. As noted previously, section VII. of this proposed rule provides a detailed description of the net decrease in burden associated with these proposed changes in conjunction with the changes in burden that result from the proposed implementation of the PDGM for CY 2020. We estimate that the burden associated with OASIS item collection as a result of this proposed rule results in a net \$60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

4. Home Infusion Therapy Payment

The following analysis applies to the Temporary Transitional Payment for Home Infusion Therapy as set forth in section 1834(u)(7) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L 115–123), and accordingly, describes the impact for CY 2019 only. Table 66 represents the estimated increased costs of existing DME users currently using home infusion therapy services. We used CY 2017 data to identify beneficiaries with DME claims containing 1 of the 37 HCPCS codes identified in section 1834(u)(7)(C) of the

Act, which are shown in column 2. In column 3, 2017 claims were again used to determine the total weeks of care, which is the sum of weeks of care across all beneficiaries found in each category. Weeks of care for payment categories 1 and 3 are defined as the week of the last infusion drug or pump claim minus the week of the first infusion drug or pump claim plus one. For Category 2, we used the median number of weeks of care, 47, as many patients use immune globulin for the whole year. Column four assumes the initial week of care requires two nurse visits, and all subsequent weeks only require one visit, in order to estimate the total visits of care per category. In general, nursing visits for payment category 2, subcutaneous immune globulin (SCIG) administration, occur once per month; therefore, we assume the estimated number of visits for these patients is 12. The fifth column multiplies the volume of nurse visits across beneficiaries by the payment rate (using the 2018 Physician Fee Schedule amounts) in order to estimate the increased cost per each of the three infusion drug categories.¹¹² In the CY 2019 HH PPS final rule, we will update this impact analysis using more complete 2017 claims data (as of June 30, 2018 or later) and the CY 2019 Physician Fee Schedule amounts.

TABLE 66—ESTIMATED INCREASED COSTS OF EXISTING DME HOME INFUSION PATIENTS NOW RECEIVING COVERED HOME INFUSION THERAPY SERVICES, CY 2019

Payment category	Number of beneficiaries	Total weeks of care	Estimated total visits of care	2018 Payment rate	Estimated cost
1	5,885	130,896	136,781	\$141.12	\$19,302,535
2	6,315	236,470	75,780	224.28	16,995,938
3	5,774	87,260	93,034	239.76	22,305,832
Total	17,974				58,604,305

Table 67 displays the estimated regional impacts using the beneficiary enrollment address reported in the Medicare Master Beneficiary Summary File. Table 68 displays impacts based on rural or urban designations. All

beneficiaries identified had at least one applicable home infusion claim (claims with 1 of the 37 drug codes listed in section 1834(u)(7)(C) of the Act) in CY 2017. Unknown beneficiaries were those without valid state and county

information in the Master Beneficiary Summary File. Additionally, the tables provide the estimated impacts by drug category.

TABLE 67—ESTIMATED IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES BY REGION, CY 2019

Census Region	Number of home infusion patients	Category 1	Category 2	Category 3	Total
New England	719	\$1,030,740.48	\$866,617.92	\$263,496.24	\$2,160,854.64
Mid Atlantic	3,503	2,699,343.36	1,582,519.68	8,670,920.40	12,952,783.44
East North Central	2,493	3,204,976.32	1,733,235.84	3,346,330.32	8,284,542.48
West North Central	1,296	1,192,605.12	1,351,062.72	1,644,034.32	4,187,702.16
South Atlantic	4,396	4,367,805.12	4,849,830.72	4,516,359.12	13,733,994.96
East South Central	1,201	1,330,761.60	1,544,840.64	668,690.64	3,544,292.88

¹¹² Based on the 2018 Medicare PFS these rates are \$141.12 (\$74.16 + 3 * \$22.32) for Category 1,

\$224.28 (\$176.76 + 3 * \$15.84) for Category 2, and \$239.76 (\$144.72 + 3 * \$31.68) for Category 3.

TABLE 67—ESTIMATED IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES BY REGION, CY 2019—Continued

Census Region	Number of home infusion patients	Category 1	Category 2	Category 3	Total
West South Central	1,729	2,546,228.16	1,824,742.08	942,256.80	5,313,227.04
Mountain	847	978,949.44	1,404,889.92	281,957.76	2,665,797.12
Pacific	1,727	1,928,969.28	1,800,519.84	1,882,595.52	5,612,084.64
Other	63	22,155.84	37,679.04	89,190.72	149,025.60
Total	17,974	19,302,534.72	16,995,938.40	22,305,831.84	58,604,304.96

TABLE 68—ESTIMATED URBAN/RURAL IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES, CY 2019

CBSA Urban/rural	Number of home infusion patients	Category 1	Category 2	Category 3	Total
Urban	14,692	\$15,906,058.56	\$14,495,664.96	\$17,419,762.80	\$47,821,486.32
Rural	3,239	3,384,057.60	2,462,594.40	4,863,052.08	10,709,704.08
Unknown	43	12,418.56	37,679.04	23,016.96	73,114.56
Total	17,974	19,302,534.72	16,995,938.40	22,305,831.84	58,604,304.96

E. Alternatives Considered

1. HH PPS

a. HH PPS for CY 2019

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2019 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. For CY 2019, Section 1895(b)(3)(B)(vi) of the Act requires that the market basket update under the HHA prospective payment system be annually adjusted by changes in economy-wide productivity. The proposed 0.7 percentage point multifactor productivity adjustment to the proposed CY 2019 home health market basket update of 2.8 percent, is discussed in the preamble of this rule and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi)(I) of the Act.

We considered not rebasing the home health market basket. However, we believe that it is desirable to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. In addition, we considered not implementing the proposed revision to the labor-related share of 76.1 percent in a budget neutral manner. However, we believe it is more prudent to implement the revision to the labor-related share in a manner that does not increase or decrease budgetary expenditures.

With regards to payments made under the HH PPS for high-cost outlier episodes of care (that is, episodes of care

with unusual variations in the type or amount of medically necessary care), we did not consider maintaining the current FDL ratio of 0.55. As discussed in section III.E.3. of this proposed rule, we propose to revise the FDL ratio to 0.51. Simulations using CY 2017 claims data and the proposed CY 2019 HH PPS payment rates resulted in an estimated 2.32 percent of total HH PPS payments being paid as outlier payments using the existing methodology for calculating the cost of an episode of care. The FDL ratio and the loss-sharing ratio must be selected so that the estimated outlier payments do not exceed the 2.5 percent of total HH PPS payments (as required by section 1895(b)(5)(A) of the Act). We did not consider proposing a change to the loss sharing ratio (0.80) in order for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.)

b. HH PPS for CY 2020 (PDGM)

For CY 2020, we did not consider alternatives to changing the unit of payment from 60 days to 30 days, eliminating the use of therapy thresholds for the case-mix adjustment, and requiring the revised payments to be budget neutral. Section 51001 of the BBA of 2018 requires the change in the unit of payment from 60 days to 30 days to be made in a budget neutral manner and mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes. The BBA of 2018 also requires these measures to be implemented on January 1, 2020 and that we make assumptions about behavior changes that could occur as a

result of the implementation of the 30-day unit of payment and as a result of the case-mix adjustment factors that are implemented in CY 2020 in calculating a 30-day payment amount for CY 2020 in a budget neutral manner.

Alternatives to making 19 current OASIS items (48 data elements) optional at the FU time point as outlined in section VII. of this proposed rule, would be to either not implement the case-mix adjustment methodology changes proposed under the PDGM or to continue collecting the 19 current OASIS items at the FU time point, even though they would not be used to case-mix adjust payments under the PDGM. Similarly, an alternative to adding collection of two current OASIS items (10 data elements) at the FU time point as discussed in section VII. of this proposed rule would be to either not adopt the PDGM or not to include the two current OASIS items (M1800 and M1033) as part of the case-mix adjustment methodology under the proposed PDGM. As noted previously, we did not consider not implementing the case-mix methodology changes under the proposed PDGM as a new case-mix adjustment methodology is required to be implemented in accordance with section 51001 of the BBA of 2018, which mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes by January 1, 2020. We believe that continuing to require HHAs to report responses for the 19 current OASIS items at the FU time point that are no longer needed for case-mix adjustment purposes under the PDGM results in unnecessary burden for HHAs.

While requiring HHAs to report responses for two current OASIS items at the FU time point results in a small increase in burden if CMS were to not make 19 current OASIS items optional at the FU time point, those two OASIS items (M1800 and M1033) are correlated with increases in resource use and are used to determine the patient's functional impairment level under the HHGM, thus they are important for case-mix adjustment purposes in order to ensure accurate payments to HHAs under the proposed PDGM.

We considered whether to continue using the wage-weighted minutes of care (WWMC) approach to estimate resource use under the PDGM, as described in section III.F.2. of this proposed rule. Although the relationship in relative costs between the WWMC approach and the proposed cost-per-minute plus non-routine supplies (CPM + NRS) approach is very similar (correlation coefficient equal to 0.8512), the WWMC approach does not as evenly weight skilled nursing costs relative to therapy costs as evidenced in the cost report data and would require us to maintain a separate case-mix adjustment mechanism for NRS. If we were to maintain the current WWMC approach, skilled nursing and therapy costs would not be as evenly weighted and a certain level of complexity in calculating payments under the HH PPS would persist as we would need to continue with the current method of case-mix adjusting NRS payments separate from service costs (that is, skilled nursing, physical therapy, occupational therapy, speech-language pathology, home health aide, and medical social services) under the HH PPS.

In this proposed rule and to begin in CY 2020, we considered proposing a phase-out of the split percentage payment approach by reducing the percentage of the upfront payment over a period of time and requiring a notice of admission (NOA) to be submitted upon full elimination of the split-percentage payment. However, we wanted to take the opportunity in this year's rule to more clearly signal our intent to potentially eliminate the split percentage payment approach over time as a reduced timeframe for the unit of payment (30 days rather than 60 days) is now required in statute. Given that existing HHAs (certified with effective dates prior to January 1, 2019) would need to adapt to changes in cash flow with the elimination of the split percentage payment approach, we hope to receive additional feedback on the timeframes for a phase-out of the split percentage payment approach and

whether there is a need for an NOA upon completion of a phase-out of the split percentage payment approach that we can take into consideration for potential future rulemaking.

2. HHVBP Model

An alternative to our proposal to remove the two vaccination measures beginning with PY 4 would be to continue to include them in the applicable measure set.

An alternative to our proposal to replace three OASIS-based measures with two proposed composite measures would be to make no changes to the OASIS-based measures category.

Another alternative to this proposal would be to finalize one but not both composite measures. All three of the ADL measures that would be replaced (Improvement in Bathing, Improvement in Bed Transferring, Improvement in Ambulation-Locomotion) relate to the normalized change in self-care measure, so, if only the self-care measure were adopted it would replace the three individual ADL items and count for 30 points. If only the mobility composite measure were adopted, however, it would count for 15 points and the three individual measures (which would not be dropped) would count for 5 points each. That would keep the relative points for the ADL measures at 30 no matter which option were adopted.

An alternative to rescoring the maximum improvement points from 10 points to 9 points would be to keep the current scoring methodology.

An alternative to reweighting the OASIS-based, claims-based and HHCAHPS measure categories would be to keep the current equally weighted methodology.

3. HH QRP

An alternative to removing seven measures from the HH QRP (Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in the Status of Surgical Wounds, Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505), Rehospitalization during the First 30 Days of HH (NQF #2380)), as discussed in section V.E. of this proposed rule would be to retain these measures in the HH QRP.

4. Home Infusion Therapy

a. Health and Safety Standards

We considered establishing additional requirements related to patient assessment, infection control and quality improvement. However, according to the home infusion therapy supplier industry, and our research, we believe there are already AO standards that include requirements related to patient assessment, quality improvement, and infection control. While the exact content of the AO standards vary, we believe that the standards are adequate to ensure basic patient health and safety.

b. Payment

We did not consider alternatives to implementing the home infusion therapy benefit for CY 2019 and 2020 because section 1834(u)(7) of the Act requires the Secretary to provide a temporary transitional payment to eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs.

c. Accreditation of Qualified Home Infusion Therapy Suppliers

AOs that accredit home infusion therapy suppliers must become accredited by an AO designated by the Secretary. In these options, we have attempted to minimize the burden of accreditation on home infusion therapy suppliers, which include approving home infusion therapy AOs that consider the unique needs of small home infusion therapy suppliers. Also, it is likely that the surveys of home infusion therapy suppliers would be performed as a desk review instead of an onsite survey. Doing a desk audit survey would prevent the travel time and cost that is required when the AO has to send a survey team to the home infusion therapy supplier's location to perform an onsite survey.

F. Accounting Statement and Tables

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 69, we have prepared an accounting statement showing the classification of the transfers and costs associated with the CY 2019 HH PPS provisions of this rule. For CY 2020, due to the section 51001(a) of the BBA of 2018 requirement that the transition to the 30-day unit of payment be budget neutral, Table 70 displays a transfer of zero. Table 71 provides our best estimates of the changes to OASIS item collection as a result of the proposed implementation of the PDGM

and proposed changes to the HH QRP. Table 72 provides our best estimate of the increase in Medicare payments to home infusion therapy suppliers related to the temporary transitional payment for home infusion therapy in CY 2019. Table 73 provides our best estimate of cost of AO compliance with our proposed home infusion the Infusion Therapy requirements.

TABLE 69—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers.	\$400 million.
From Whom to Whom?	Federal Government to HHAs.

TABLE 70—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO THE PDGM PROPOSALS, FROM CY 2019 TO 2020 PDGM

Category	Transfers
Annualized Monetized Transfers.	\$0 million.
From Whom to Whom?	HHAs to Federal Government.

TABLE 71—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden for HHAs' Submission of the OASIS.	–\$60 million

TABLE 72—ACCOUNTING STATEMENT: TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers.	\$60 million.
From Whom to Whom?	Federal Government to Home Infusion Therapy Suppliers.

TABLE 73—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS FOR HOME INFUSION THERAPY ACCREDITATION ORGANIZATIONS, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden to Each Home Infusion Therapy AO for Compliance with the Proposed Regulations at §§ 488.1010 through 488.1050	\$23,258.

G. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” Details on the estimated costs of this proposed rule, including limitations on the ability thus far to quantify some categories of impacts, can be found in the rule’s economic analysis. The determination of this proposed rule’s status as a regulatory or deregulatory action for the purposes of Executive Order 13771 will be informed by comments received in response to this proposed rulemaking.

H. Conclusion

- 1. HH PPS
 - a. HH PPS for CY 2019

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is an increase of 2.1 percent, or \$400 million, in Medicare payments to HHAs for CY 2019. The \$400 million increase reflects the effects of the CY 2019 home health payment update of 2.1 percent (\$400 million increase), a 0.1 percent increase in payments due to decreasing the FDL ratio in order to target to pay no more than 2.5 percent of total payments as outlier payments (\$20 million increase), and a –0.1 percent decrease in CY 2019 payments due to the new rural add-on policy mandated by the BBA of 2018 (\$20 million decrease).

- b. HH PPS for CY 2020 (PDGM)

In conclusion, we estimate that Medicare payments to HHAs for CY 2020 will remain the same compared to CY 2019 as a result of the implementation of the PDGM. Section 51001(a) of the BBA of 2018 requires the

Secretary to implement the 30-day unit of payment in a budget-neutral manner.

- 2. OASIS Changes Related to the HH QRP and HH PPS (PDGM) for CY 2020

In conclusion, we estimate that the changes to OASIS item collection as a result of the proposed changes to the HH QRP and the proposed changes to the HH PPS (PDGM), both effective on and after January 1, 2020, would result in a net \$60 million in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

- 3. HHVBP Model

In conclusion, we estimate there would be no net impact (to include either a net increase or reduction in payments) in this proposed rule in Medicare payments to HHAs competing in the HHVBP Model for CY 2019. However, the overall economic impact of the HHVBP Model is an estimated \$378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model. We do not believe the changes proposed in this rule would affect the prior estimates.

- 4. Home Infusion Therapy

- a. Health and Safety Standards

In summary, the proposed health and safety standards would not have any economic impact on home infusion therapy suppliers or accreditation organizations.

- b. Payment

In conclusion, we estimate that the net impact of the temporary transitional payment to eligible home infusion suppliers for items and services associated with the furnishing of transitional home infusion drugs would result in approximately \$60 million in additional Medicare payments to home infusion suppliers in CY 2019.

- c. Accreditation of Qualified Home Infusion Therapy Suppliers

In summary, AOs that accredit HIT suppliers must become accredited by an AO designated by the Secretary. In these options, we have attempted to minimize the burden of accreditation on HIT suppliers, which include approving AOs that consider the unique needs of small HIT suppliers. Also, it is likely that the surveys of HIT suppliers will be performed as a desk review instead of an onsite survey. Doing a desk audit survey would prevent the travel time and cost that is required when the AO has to send a survey team to the HIT

supplier's location to perform an onsite survey.

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 409.43 [Amended]

- 2. Section 409.43 is amended—
- a. By removing paragraph (c)(2);
 - b. By resignating paragraphs (c)(3) and (4) as paragraphs (c)(2) and (3);
 - c. In newly redesignated paragraph (c)(2)(ii) by removing the phrase “for services is submitted for the final percentage prospective payment” and adding in its place the phrase “(for episodes beginning on or before December 31, 2019) or 30-day period (for periods beginning on or after January 1, 2020) is submitted”; and
 - d. In paragraph (e)(1)(iii) by removing the phrase “during the 60-day episode” and adding in its place the phrase “within 60 days”.
- 3. Section 409.46 is amended by adding paragraph (e) to read as follows:

§ 409.46 Allowable administrative costs.

* * * * *

(e) *Remote patient monitoring.* Remote patient monitoring is defined as the collection of physiologic data (for example, ECG, blood pressure, or glucose monitoring) digitally stored and transmitted by the patient or caregiver or both to the home health agency. If remote patient monitoring is used by the home health agency to augment the care planning process, the costs of the equipment and service related to this system are allowable administrative costs.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 4. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. Section 424.22 is amended by revising paragraphs (b)(2) and (c) to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(b) * * *

(2) *Content and basis of recertification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, if there is a continuing need for home health services, a physician must recertify the patient's continued eligibility for the home health benefit as outlined in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as set forth in paragraph (a)(1) of this section, and as specified in paragraphs (b)(2)(i) and (ii) of this section.

(i) Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy.

(ii) If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician must include a brief narrative describing the clinical justification of this need. If the narrative—

(A) Is part of the recertification form, then the narrative must be located immediately prior to the physician's signature.

(B) Exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must

sign immediately following the narrative in the addendum.

(c) *Determining patient eligibility for Medicare home health services.* (1) Documentation in the certifying physician's medical records or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) or both must be used as the basis for certification of the patient's eligibility for home health as described in paragraphs (a)(1) and (b) of this section. Documentation from the HHA may also be used to support the basis for certification of home health eligibility, but only if the following requirements are met:

(i) The documentation from the HHA can be corroborated by other medical record entries in the certifying physician's medical record for the patient or the acute/post-acute care facility's medical record for the patient or both, thereby creating a clinically consistent picture that the patient is eligible for Medicare home health services.

(ii)(A) The certifying physician signs and dates the HHA documentation demonstrating that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services.

(B) HHA documentation can include, but is not limited to, the patient's plan of care required under § 409.43 of this chapter and the initial or comprehensive assessment of the patient required under § 484.55 of this chapter.

(2) The documentation must be provided upon request to review entities or CMS or both. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment is not rendered for home health services provided.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 6. The authority citation for part 484 continues to read as follows:

Authority: Secs 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 7. Section 484.202 is amended by revising the definitions of “Rural area” and “Urban area” to read as follows:

§ 484.202 Definitions.

* * * * *

Rural area means an area defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means an area defined in § 412.64(b)(1)(ii)(A) and (B) of this chapter.

■ 8. Section 484.205 is revised to read as follows:

§ 484.205 Basis of payment.

(a) *Method of payment.* An HHA receives a national, standardized prospective payment amount for home health services previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national, standardized prospective payment is determined in accordance with § 484.215.

(b) *Unit of payment—(1) Episodes before December 31, 2019.* For episodes beginning on or before December 31, 2019, an HHA receives a unit of payment equal to a national, standardized prospective 60-day episode payment amount.

(2) *Periods on or after January 1, 2020.* For periods beginning on or after January 1, 2020, a HHA receives a unit of payment equal to a national, standardized prospective 30-day payment amount.

(c) *OASIS data.* A HHA must submit to CMS the OASIS data described at § 484.55(b) and (d) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240.

(d) *Payment adjustments.* The national, standardized prospective payment amount represents payment in full for all costs associated with furnishing home health services and is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in § 484.230.

(2) A partial payment adjustment as specified in § 484.235.

(3) An outlier payment as specified in § 484.240.

(e) *Medical review.* All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Medical necessity determinations.

(3) Case-mix group assignment.

(f) *Durable medical equipment (DME) and disposable devices.* DME provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount. Separate payment is made for “furnishing NPWT using a disposable device,” as that term is defined in § 484.202, and is not included in the national, standardized prospective payment.

(g) *Split percentage payments.* Normally, there are two payments

(initial and final) paid for an HH PPS unit of payment. The initial payment is made in response to a request for anticipated payment (RAP) as described in paragraph (h) of this section, and the residual final payment is made in response to the submission of a final claim. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(1) *Split percentage payments for episodes beginning on or before December 31, 2019—(i) Initial and residual final payments for initial episodes on or before December 31, 2019.* (A) The initial payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage-adjusted 60-day episode rate.

(ii) *Initial and residual final payments for subsequent episodes before December 31, 2019.* (A) The initial payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(2) *Split percentage payments for periods beginning on or after January 1, 2020—(i) Initial and residual final payments for initial periods beginning on or after January 1, 2020.* (A) The initial payment for initial 30-day periods is paid to an HHA at 60 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for initial 30-day periods is paid at 40 percent of the case-mix and wage-adjusted 30-day payment rate.

(ii) *Initial and residual final payments for subsequent periods beginning on or after January 1, 2020.* (A) The initial payment for subsequent 30-day periods is paid to an HHA at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for subsequent 30-day periods is paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

(iii) *Split percentage payments on or after January 1, 2019.* Split percentage payments are not made to HHAs that are certified for participation in Medicare effective on or after January 1, 2019. An HHA that is certified for participation in Medicare effective on or after January 1, 2019 receives a single payment for a 30-day period of care after the final claim is submitted.

(h) *Requests for anticipated payment (RAP).* (1) HHAs that are certified for

participation in Medicare effective by December 31, 2018 submit requests for anticipated payment (RAPs) to request the initial split percentage payment as specified in paragraph (g) of this section. HHAs that are certified for participation in Medicare effective on or after January 1, 2019 are still required to submit RAPs although no split percentage payments are made in response to these RAP submissions. The HHA can submit a RAP when all of the following conditions are met:

(i) After the OASIS assessment required at § 484.55(b)(1) and (d) is complete, locked or export ready, or there is an agency-wide internal policy establishing the OASIS data is finalized for transmission to the national assessment system.

(ii) Once a physician’s verbal orders for home care have been received and documented as required at §§ 484.60(b) and 409.43(d) of this chapter.

(iii) A plan of care has been established and sent to the physician as required at § 409.43(c) of this chapter.

(iv) The first service visit under that plan has been delivered.

(2) A RAP is based on the physician signature requirements in § 409.43(c) of this chapter and is not a Medicare claim for purposes of the Act (although it is a “claim” for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the following:

(i) Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a(i)(2)).

(ii) The Civil False Claims Act (as defined in 31 U.S.C. 3729(c)).

(iii) The Criminal False Claims Act (18 U.S.C. 287)).

(iv) The RAP is canceled and recovered unless the claim is submitted within the greater of 60 days from the end date of the appropriate unit of payment, as defined in paragraph (b) of this section, or 60 days from the issuance of the RAP.

(3) CMS has the authority to reduce, disprove, or cancel a RAP in situations when protecting Medicare program integrity warrants this action.

§ 484.210 [Removed and Reserved]

■ 9. Section 484.210 is removed and reserved.

■ 10. Section 484.215 is amended—

■ a. By revising the section heading;

■ b. In paragraph (d) introductory text by removing the phrase “CMS calculates the” and adding in its place the phrase “For episodes beginning on or before December 31, 2019, CMS calculates the”; and

■ c. By adding paragraph (f).

The revisions and addition reads as follows:

§ 484.215 Initial establishment of the calculation of the national, standardized prospective payment rates.

* * * * *

(f) For periods beginning on or after January 1, 2020, a national, standardized prospective 30-day payment rate applies. The national, standardized prospective 30-day payment rate is an amount determined by the Secretary, as subsequently adjusted in accordance with § 484.225.

■ 11. Section 484.220 is amended—

- a. By revising the section heading and introductory text; and
- b. In paragraph (a) introductory text by removing the phrase “national prospective 60-day episode” and adding in its place the phrase “national, standardized prospective”.

The revisions read as follows:

§ 484.220 Calculation of the case-mix and wage area adjusted prospective payment rates.

CMS adjusts the national, standardized prospective payment rates as referenced in § 484.215 to account for the following:

* * * * *

■ 12. Section 484.225 is amended—

- a. By revising the section heading and paragraph (a);
- b. In paragraphs (b) and (c) by removing the phrase “national prospective 60-day episode” and adding in its place the phrase “national, standardized prospective”; and
- c. By adding paragraph (d).

The revisions and addition reads as follows:

§ 484.225 Annual update of the unadjusted national, standardized prospective payment rates.

(a) CMS annually updates the unadjusted national, standardized prospective payment rate on a calendar year basis (in accordance with section 1895(b)(1)(B) of the Act).

* * * * *

(d) For CY 2020, the national, standardized prospective 30-day payment amount is an amount determined by the Secretary. CMS annually updates this amount on a calendar year basis in accordance with paragraphs (a) through (c) of this section.

■ 13. Section 484.230 is revised to read as follows:

§ 484.230 Low-utilization payment adjustments.

(a) For episodes beginning on or before December 31, 2019, an episode with four or fewer visits is paid the national per-visit amount by discipline determined in accordance with

§ 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(1) The national per-visit amount is adjusted by the appropriate wage index based on the site of service of the beneficiary.

(2) An amount is added to the low-utilization payment adjustments for low-utilization episodes that occur as the beneficiary’s only episode or initial episode in a sequence of adjacent episodes.

(3) For purposes of the home health PPS, a sequence of adjacent episodes for a beneficiary is a series of claims with no more than 60 days without home care between the end of one episode, which is the 60th day (except for episodes that have been PEP-adjusted), and the beginning of the next episode.

(b) For periods beginning on or after January 1, 2020, an HHA receives a national 30-day payment of a predetermined rate for home health services, unless CMS determines at the end of the 30-day period that the HHA furnished minimal services to a patient during the 30-day period.

(1) For each payment group used to case-mix adjust the 30-day payment rate, the 10th percentile value of total visits during a 30-day period of care is used to create payment group specific thresholds with a minimum threshold of at least 2 visits for each case-mix group.

(2) A 30-day period with a total number of visits less than the threshold is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(3) The national per-visit amount is adjusted by the appropriate wage index based on the site of service for the beneficiary.

(c) An amount is added to low-utilization payment adjustments for low-utilization periods that occur as the beneficiary’s only 30-day period or initial 30-day period in a sequence of adjacent periods of care. For purposes of the home health PPS, a sequence of adjacent periods of care for a beneficiary is a series of claims with no more than 60 days without home care between the end of one period, which is the 30th day (except for episodes that have been partial payment adjusted), and the beginning of the next episode.

■ 14. Section 484.235 is revised to read as follows:

§ 484.235 Partial payment adjustments.

(a) *Partial episode payments (PEPs) for episodes beginning on or before December 31, 2019.* (1) An HHA receives a national, standardized 60-day

payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 60-day episode, warrants a new 60-day episode for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required.

(2) The PEP adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode.

(ii) The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 60-day payment and a new physician certification and a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The PEP is calculated by determining the actual days served as a proportion of 60 multiplied by the initial 60-day payment amount.

(b) *Partial payment adjustments for periods beginning on or after January 1, 2020.* (1) An HHA receives a national, standardized 30-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 30-day period, warrants a new 30-day period for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required.

(2) The partial payment adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on

behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 30-day period.

(ii) The common ownership exception to the transfer partial payment adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 30-day period before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 30-day payment and a new physician certification and a new plan of care, the initial HHA receives a partial payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The partial payment is calculated by determining the actual days served as a proportion of 30 multiplied by the initial 30-day payment amount.

■ 15. Section 484.240 is revised to read as follows:

§ 484.240 Outlier payments.

(a) For episodes beginning on or before December 31, 2019, an HHA receives an outlier payment for an episode whose estimated costs exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the episode payment amount for that group, or the PEP adjustment amount for the episode, plus a fixed dollar loss amount that is the same for all case-mix groups.

(b) For periods beginning on or after January 1, 2020, an HHA receives an outlier payment for a 30-day period whose estimated cost exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the 30-day payment amount for that group, or the partial payment adjustment amount for the 30-day period, plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of imputed cost beyond the threshold.

(d) CMS imputes the cost for each claim by multiplying the national per-15 minute unit amount of each discipline by the number of 15 minute units in the discipline and computing the total imputed cost for all disciplines.

■ 16. Section 484.250 is amended by revising paragraph (a)(1) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) Such OASIS data described at § 484.55(b) and (d) as is necessary for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240; and such OASIS data described at § 484.55(b) and (d) as is necessary to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

■ 17. Section 484.320 is amended by revising paragraph (c) to read as follows:

§ 484.320 Calculation of the Total Performance Score.

* * * * *

(c)(1) For performance years 1 through 3, CMS will sum all points awarded for each applicable measure excluding the New Measures, weighted equally at the individual measure level to calculate a value worth 90 percent of the Total Performance Score.

(2) For performance years 4 and 5, CMS will sum all points awarded for each applicable measure within each category of measures (OASIS-based, claims-based and HHCAHPs) excluding the New Measures, weighted at 35 percent for the OASIS-based measure category, 35 percent for the claims-based measure category, and 30 percent for the HHCAHPs measure category when all three measure categories are reported, to calculate a value worth 90 percent of the Total Performance Score.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 18. The authority citation for part 486 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

■ 19. Add reserved subpart H and subpart I to read as follows:

Subpart H—[Reserved]

Subpart I—Requirements for Home Infusion Therapy Suppliers

General Provisions

Sec.

486.500 Basis and Scope.

486.505 Definitions.

Standards for Home Infusion Therapy

486.520 Plan of care.

486.525 Required services.

Subpart I—Requirements for Home Infusion Therapy Suppliers

General Provisions

§ 486.500 Basis and scope.

Section 1861(s)(2)(iii) of the Act requires the Secretary to establish the conditions that home infusion therapy suppliers must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients.

§ 486.505 Definitions.

Applicable provider means a physician, a nurse provider, and a physician assistant.

Home means a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, CAH, or SNF as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Home infusion drug means a parental drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

Infusion drug administration calendar day means the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets the all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Meets such other requirements as the Secretary determines appropriate.

Standards for Home Infusion Therapy**§ 486.520 Plan of care.**

The qualified home infusion therapy supplier ensures the following:

(a) All patients must be under the care of an applicable provider.

(b) All patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.

(c) The plan of care for each patient must be periodically reviewed by the physician.

§ 486.525 Required services.

The qualified home infusion therapy supplier must provide the following services on a 7-day-a-week, 24-hour-a-day basis in accordance with the plan of care:

(a) Professional services, including nursing services.

(b) Patient training and education not otherwise paid for as durable medical equipment as described in § 424.57(c)(12) of this chapter.

(c) Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 20. The authority citation for part 488 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

■ 21. Section 488.5 is amended—

■ a. By redesignating paragraphs (a)(7) through (21) as paragraphs (a)(8) through (22);

■ b. By adding a new paragraph (a)(7);

■ c. In newly redesignated paragraph (a)(18)(i) by removing the word “and” at the end of the paragraph;

■ d. In newly redesignated paragraph (a)(18)(ii) by removing the period and adding in its place “; and”; and

■ e. By adding paragraph (a)(18)(iii).

The additions read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(7) A statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter.

* * * * *

(18) * * *

(iii) Include a written statement that if a fully accredited and deemed facility in good standing provides written notification that they wish to

voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

* * * * *

■ 22. Add reserved subpart K and subpart L to read as follows:

Subpart K—[Reserved]**Subpart L—Accreditation of Home Infusion Therapy Suppliers****General Provisions**

Sec.

488.1000 Basis and scope.

488.1005 Definitions.

Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations

488.1010 Application and reapplication procedures for national home infusion therapy accrediting organizations.

488.1015 Resubmitting a request for reapproval.

488.1020 Public notice and comment.

488.1025 Release and use of home infusion therapy accreditation surveys.

488.1030 Ongoing review of home infusion therapy accrediting organizations.

488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accreditation organization.

488.1040 Onsite observations of home infusion therapy accrediting organization operations.

488.1045 Voluntary and involuntary termination.

488.1050 Reconsideration.

Subpart L—Accreditation of Home Infusion Therapy Suppliers**General Provisions****§ 488.1000 Basis and scope.**

(a) Regulatory basis for home infusion therapy services. The home infusion therapy health and safety regulations are codified at part 486, subpart L, of this chapter.

(b) *Statutory basis for the accreditation of home infusion therapy suppliers.* (1) Sections 1102 and 1871 of the Act require that the Secretary prescribe such regulations as may be necessary to carry out the administration of the Medicare program.

(2) Section 1834(u)(5) of the Act require the Secretary to designate and approve independent organizations for the purposes of accrediting qualified home infusion therapy suppliers.

(c) *Scope.* This subpart sets forth the following:

(1) Application and reapplication procedures for national accrediting organizations seeking approval or re-

approval of authority to accredit qualified home infusion therapy suppliers.

(2) Ongoing CMS oversight processes for approved accrediting organizations that accredit qualified home infusion therapy suppliers.

(3) Appeal procedures for accrediting organizations that accredit qualified home infusion therapy suppliers.

§ 488.1005 Definitions.

As used in this subpart—

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare accreditation requirements has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient.

National accrediting organization means an organization that accredits provider or supplier entities under a specific program and whose accredited provider or supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is active, fully implemented, and operational.

National in scope means a program is fully implemented, operational, and widely dispersed geographically throughout the country.

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets the all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Meets such other requirements as the Secretary determines appropriate.

Reasonable assurance means an accrediting organization has demonstrated to CMS' satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

Rural area as defined at section 1886(d)(2)(D) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in the newspaper, magazine articles or other media, that

would, if found to be present, adversely affect the health and safety of patients and raises doubts as to a qualified home infusion therapy supplier's compliance with the applicable Medicare accreditation requirements.

Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations

§ 488.1010 Application and reapplication procedures for national accrediting organizations.

(a) *Information submitted with application.* A national home infusion therapy accrediting organization applying to CMS for approval or re-approval of a designated home infusion therapy accreditation program must furnish CMS with information and materials that demonstrate that its home infusion therapy accreditation program requirements meet or exceed the applicable Medicare requirements for accrediting organizations, including the following:

(1) Documentation that demonstrates the organization meets the definition of a national accrediting organization under § 488.1005 as it relates to the accreditation program.

(2) The Medicare provider or supplier type for which the organization is requesting approval or re-approval.

(3) Documentation that demonstrates the home infusion therapy accrediting organization's ability to take into account the capacities of rural home infusion therapy suppliers (as required by section 1834(u)(5)(A)(ii) of the Act).

(4) Information that demonstrates the home infusion therapy accrediting organization's knowledge, expertise, and experience in home infusion therapy.

(5) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare requirements, the exact language of the organization's comparable accreditation requirements and standards.

(6) A detailed description of the home infusion therapy accrediting organization's survey processes to confirm that a home infusion therapy supplier's processes are comparable to those of Medicare. This description must include all of the following:

(i) The types and frequency of surveys performed, and a rationale for which accreditation requirements will be evaluated via onsite surveys and which will be evaluated via offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including an explanation

of how the accrediting organization will maintain the schedule it proposes.

(ii) Copies of the home infusion therapy accrediting organizations survey and audit forms, guidelines, and instructions to surveyors.

(iii) Documentation demonstrating that the home infusion therapy accrediting organization's onsite survey or offsite audit reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare home infusion therapy accreditation requirements, as applicable.

(iv) A description of the home infusion therapy accrediting organization's accreditation survey review process.

(v) A description of the home infusion therapy accrediting organization's procedures and timelines for notifying a surveyed or audited home infusion therapy supplier of non-compliance with the home infusion therapy accreditation program's standards.

(vi) A description of the home infusion therapy accrediting organization's procedures and timelines for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.

(vii) The ability of the home infusion therapy accrediting organization to conduct timely reviews of accreditation applications.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the home infusion therapy accrediting organization agrees to provide CMS with information extracted from each home infusion therapy accreditation onsite survey, offsite audit or other evaluation strategies as part of its data submissions required under paragraph (a)(19) of this section, and, upon request from CMS, a copy of the most recent accreditation onsite survey, offsite audit, or other evaluation strategy together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the home infusion therapy accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 488.1005. Using the format specified by CMS, the home infusion therapy accrediting organization must notify CMS within 2 business days from the date the accrediting organization identifies the immediate jeopardy.

(7) Procedures to ensure that—

(i) Unannounced onsite surveys, as appropriate, will be conducted periodically, including procedures that protect against unannounced surveys becoming known to the provider or supplier in advance of the visit; or

(ii) Offsite survey audits are performed to evaluate the quality of services provided which may be followed up with periodic onsite visits.

(8) The criteria for determining the size and composition of the home infusion therapy accrediting organization's survey, audit and other evaluation strategy teams for individual supplier onsite surveys. The home infusion therapy accrediting organization's criteria should include, but not be limited to the following information:

(i) The expected number of individual home infusion therapy supplier locations to be surveyed using an onsite survey.

(ii) The number of home infusion therapy suppliers to be surveyed using off-site audits.

(iii) A description of other types of home infusion therapy accreditation review activities to be used.

(iv) The reasons for each type of survey (that is, initial accreditation survey, reaccreditation survey, and complaint survey).

(9) The overall adequacy of the number of the home infusion therapy accrediting organization's surveyors, auditors, and other staff available to perform survey related activities, including how the organization will increase the size of the survey, audit, and other evaluation staff to match growth in the number of accredited facilities or programs while maintaining re-accreditation intervals for existing accredited facilities or programs.

(10) Detailed information about the individuals who perform onsite surveys, offsite audits or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including all of the following information:

(i) The number and types of professional and technical staff available for conducting onsite surveys, offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements.

(ii) The education, employment, and experience requirements surveyors and auditors must meet.

(iii) The content and length of the orientation program.

(11) The content, frequency and types of in-service training provided to survey and audit personnel.

(12) The evaluation systems used to monitor the performance of individual surveyors, auditors and survey teams.

(13) The home infusion therapy accrediting organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

(14) The policies and procedures used when a home infusion therapy supplier has a dispute regarding survey or audit findings, or an adverse decision.

(15) Procedures for the home infusion therapy supplier to use to notify the home infusion therapy accrediting organization when the accredited home infusion therapy supplier does the either of the following:

(i) Removes or ceases furnishing services for which they are accredited.

(ii) Adds services for which they are not accredited.

(16) The home infusion therapy accrediting organization's procedures for responding to, and investigating complaints against accredited facilities, including policies and procedures regarding referrals, when applicable, to appropriate licensing bodies, ombudsmen offices, and CMS.

(17) A description of the home infusion therapy accrediting organization's accreditation status decision-making process. The home infusion therapy accrediting organization must furnish the following:

(i) Its process for addressing deficiencies identified with accreditation program requirements, and the procedures used to monitor the correction of deficiencies identified during an accreditation survey and audit process.

(ii) A description of all types and categories of accreditation decisions associated with the program, including the duration of each of the organization's accreditation decisions.

(iii) Its policies and procedures for the granting, withholding or removal of accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements.

(iv) A statement acknowledging that the home infusion therapy accrediting organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, terminate, or revise the accreditation status of a home infusion therapy supplier, within 3 business days

from the date the organization takes an action.

(18) A list of all currently accredited home infusion therapy suppliers, the type and category of accreditation, currently held by each, and the expiration date for each home infusion therapy supplier's current accreditation.

(19) A schedule of all survey activity (such as onsite surveys, offsite audits and other types of survey strategies) expected to be conducted by the organization during the 6-month period following submission of an initial or renewal application.

(20) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data.

(21) A description of the home infusion therapy accrediting organization's data management and analysis system with respect to its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the home infusion therapy accrediting organization uses its data to assure the compliance of its home infusion therapy accreditation program with the Medicare home infusion therapy accreditation program requirements.

(ii) A written statement acknowledging that the home infusion therapy accrediting organization agrees to submit timely, accurate, and complete data that CMS has determined is both necessary to evaluate the accrediting organization's performance and is not unduly burdensome for the accrediting organization to submit.

(A) The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(B) Data to be submitted includes the following:

(1) Accredited home infusion therapy supplier identifying information.

(2) Survey findings.

(3) Quality measures.

(4) Notices of accreditation decisions.

(22) The three most recent annual audited financial statements of the home infusion therapy accrediting organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys, audits, and related activities to maintain the accreditation program.

(23) A written statement acknowledging that, as a condition for approval, the home infusion therapy accrediting organization agrees to the following:

(i) *Voluntary termination.* Provide written notification to CMS and all home infusion therapy suppliers accredited under its CMS-approved

home infusion therapy accreditation program at least 90 calendar days in advance of the effective date of a decision by the home infusion therapy accrediting organization to voluntarily terminate its CMS-approved home infusion therapy accreditation program and the implications for the suppliers' payment status once their current term of accreditation expires in accordance with the requirements at § 488.1045(a).

(ii) *Involuntary termination.* Provide written notification to all accredited home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of its accreditation program and the implications for the home infusion therapy supplier's payment status in accordance with the requirements at § 488.1045(b) once their current term of accreditation expires.

(A) For both voluntary and involuntary terminations, provide a second written notification to all accredited home infusion therapy suppliers 10 calendar days prior to the organization's accreditation program effective date of termination.

(B) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accredited home infusion therapy supplier from any source where the deficiency poses an immediate jeopardy to the home infusion therapy supplier's beneficiaries or a hazard to the general public.

(iii) Provide, on an annual basis, summary accreditation activity data and trends including the following:

(A) Deficiencies.

(B) Complaints.

(C) Terminations.

(D) Withdrawals.

(E) Denials.

(F) Accreditation decisions.

(G) Other survey-related activities as specified by CMS.

(iv) If CMS terminates a home infusion therapy accrediting organization's approved status, the home infusion therapy accrediting organization must work collaboratively with CMS to direct its accredited home infusion therapy suppliers to the remaining CMS-approved accrediting organizations within a reasonable period of time.

(v) Notify CMS at least 60 days in advance of the implementation date of any significant proposed changes in its CMS-approved home infusion therapy accreditation program and that it agrees not to implement the proposed changes

without prior written notice of continued program approval from CMS, except as provided for at § 488.1040(b)(2).

(vi) A statement acknowledging that, in response to a written notice from CMS to the home infusion therapy accrediting organization of a change in the applicable home infusion therapy accreditation requirements or survey process, the organization will provide CMS with proposed corresponding changes in the accrediting organization's home infusion therapy accreditation requirements for its CMS-approved home infusion therapy accreditation program to ensure that its accreditation standards continue to meet or exceed those of Medicare, or survey process remains comparable with that of Medicare. The home infusion therapy accrediting organization must comply with the following requirements:

(A) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the home infusion therapy accrediting organization or by a date specified in the notice, whichever is later. CMS gives due consideration to a home infusion therapy accrediting organization's request for an extension of the deadline as long as it is submitted prior to the due date.

(B) The proposed changes are not to be implemented without prior written notice of continued program approval from CMS, except as provided for at § 488.1040(b)(2)(ii).

(24) The organization's proposed fees for accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.

(b) *Additional information needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the home infusion therapy accrediting organization's initial application or re-application for CMS-approval of an accreditation program, CMS requires that the home infusion therapy accrediting organization submit any specific documentation requirements and attestations as a condition of approval of accreditation status. CMS notifies the home infusion therapy accrediting organization and afford it an opportunity to provide the additional information.

(c) *Withdrawing an application.* A home infusion therapy accrediting organization may withdraw its initial application for CMS' approval of its home infusion therapy accreditation program at any time before CMS

publishes the final notice described in § 488.1025(b).

(d) *Notice of approval or disapproval of application.* CMS sends a notice of its decision to approve or disapprove the home infusion therapy accrediting organization's application within 210 calendar days from the date CMS determines the home infusion therapy accrediting organization's application is complete. The final notice specifies the following:

(1) The basis for the decision.

(2) The effective date.

(3) The term of the approval (not exceed 6 years).

§ 488.1015 Resubmitting a request for reapproval.

(a) Except as provided in paragraph (b) of this section, a home infusion therapy accrediting organization whose request for CMS's approval or re-approval of an accreditation program has been denied, or a home infusion therapy accrediting organization that has voluntarily withdrawn an initial application, may resubmit its application if the home infusion therapy accrediting organization satisfies all of the following requirements:

(1) Revises its home infusion therapy accreditation program to address the issues related to the denial of its previous request or its voluntary withdrawal.

(2) Resubmits the application in its entirety.

(b) If a home infusion therapy accrediting organization has requested, in accordance with § 488.1050, a reconsideration of CMS's disapproval, it may not submit a new application for approval of a home infusion therapy accreditation program until such reconsideration is administratively final.

§ 488.1020 Public notice and comment.

CMS publishes a notice in the **Federal Register** when the following conditions are met:

(a) *Proposed notice.* CMS publishes a notice after the receipt of a completed application from a national home infusion therapy accrediting organization seeking CMS's approval of a home infusion therapy accreditation program. The notice identifies the home infusion therapy accrediting organization, the type of suppliers covered by the home infusion therapy accreditation program, and provides at least a 30 day public comment period (beginning on the date of publication).

(b) *Final notice.* The final notice announces CMS decision to approve or deny a national accrediting organization application. The notice specifies the basis for the CMS decision.

(1) *Approval or re-approval.* If CMS approves or re-approves the home infusion therapy accrediting organization's home infusion therapy accreditation program, the final notice at a minimum includes the following information:

(i) A description of how the home infusion therapy accreditation program meets or exceeds Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of approval (no later than the publication date of the notice).

(iii) The term of the approval (6 years or less).

(2) *Denial.* If CMS does not approve the home infusion therapy accrediting organization's accreditation program, the final notice describes the following:

(i) How the home infusion therapy accrediting organization fails to meet Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of the decision.

§ 488.1025 Release and use of home infusion therapy accreditation surveys.

The home infusion therapy accrediting organization must include, in its accreditation agreement with each supplier, an acknowledgement that the supplier agrees to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require, corrective action plans.

(a) CMS may determine that a home infusion therapy supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

§ 488.1030 Ongoing review of home infusion therapy accrediting organizations.

(a) *Performance review.* CMS evaluates the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis. This review includes the review of the following:

(1) The home infusion therapy accrediting organization's survey activity.

(2) The home infusion therapy accrediting organization's continued

fulfillment of the requirements at §§ 488.1010 and 488.1035.

(b) *Comparability review.* CMS assesses the equivalency of a home infusion therapy accrediting organization's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements. When this occurs, the following takes place:

(1) CMS provides the home infusion therapy accrediting organizations with written notice of the changes to the Medicare home infusion therapy accreditation requirements.

(2) The home infusion therapy accrediting organization must make revisions to its home infusion therapy accreditation standards or survey processes which incorporate the new or revised Medicare accreditation requirements.

(3) In the written notice, CMS specifies the deadline (no less than 30 calendar days) by which the home infusion therapy accrediting organization must submit its proposed revised home infusion therapy accreditation standard or survey process revisions, and the timeframe(s) for implementation of these revised home infusion therapy accreditation standards.

(4) CMS may extend the submission deadline by which the accrediting organization must submit its proposed revised home infusion therapy accreditation standards and survey processes, if both of the following occur:

(i) The accrediting organization submits a written request for an extension of the submission deadline.

(ii) The request for extension is submitted prior to the original submission deadline.

(5) After completing the comparability review of the home infusion therapy accrediting organizations revised home infusion therapy accreditation standards and survey processes, CMS shall provide written notification to the home infusion therapy accrediting organization regarding whether or not its home infusion therapy accreditation program, including the proposed revised home infusion therapy accreditation standards and implementation timeframe(s), continues to meet or exceed all applicable Medicare requirements.

(6) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide the written notice to the home infusion therapy accrediting organization required, then the revised

home infusion therapy accreditation standards and program is deemed to meet or exceed all applicable Medicare requirements and to have continued CMS-approval.

(7) If a home infusion therapy accrediting organization is required to submit a new application because CMS imposes new home infusion therapy regulations or makes significant substantive revisions to the existing home infusion therapy regulations, CMS provides notice of the decision to approve or disapprove the new application submitted by the home infusion therapy accrediting organization within the time period specified in § 488.1010(d).

(8) If a home infusion therapy accrediting organization fails to submit its proposed changes to its home infusion therapy accreditation standards and survey processes within the required timeframe, or fails to implement the proposed changes that have been determined or deemed by CMS to be comparable, CMS may open an accreditation program review in accordance with paragraph (d) of this section.

(c) *Review of revised home infusion therapy accreditation standards submitted to CMS by an accrediting organization.* When a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy accrediting organization must do the following:

(1) Provide CMS with written notice of any proposed changes in home infusion therapy accreditation standards, requirements or survey process at least 60 days prior to the proposed implementation date of the proposed changes.

(2) Not implement any of the proposed changes before receiving CMS's approval, except as provided in paragraph (c)(4) of this section.

(3) Provide written notice to CMS that includes all of the following:

(i) A detailed description of the changes that are to be made to the organization's home infusion therapy accreditation standards, requirements and survey processes.

(ii) A detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each.

(4) CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does

not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. If CMS has made a finding that the home infusion therapy accrediting organization's home infusion therapy accreditation program, accreditation requirements and survey processes, including the proposed revisions does not continue to meet or exceed all applicable Medicare home infusion therapy requirements, CMS must state the reasons for these findings.

(5) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide written notice to the home infusion therapy accrediting organization that the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements, then the revised home infusion therapy accreditation program is deemed to meet or exceed all applicable Medicare home infusion therapy requirements and to have continued CMS approval.

(6) If a home infusion therapy accrediting organization implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with paragraph (d) of this section.

(d) *CMS-approved home infusion therapy accreditation program review.* If a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program with the requirements of this subpart, CMS may initiate a home infusion therapy accreditation program review.

(1) If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy accrediting organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice will provide all of the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy accrediting organization to offer factual information related to CMS' findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the home infusion therapy accreditation program review.

(iv) The actions the home infusion therapy accrediting organization must take to address the identified deficiencies

(v) The length of the accreditation program review probation period, which will include monitoring of the home infusion therapy accrediting organization's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date that CMS approves the AOs corrective action plan.

(2) CMS will review and approve the home infusion therapy accrediting organization's plan of correction for acceptability within 30 days after receipt.

(3) CMS will monitor the AO's performance and implementation of the plan of correction during the probation period which is not to exceed 180 days from the date of approval of the plan of correction.

(4) If CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the 180-day probation period described in paragraph (d)(1)(v) of this section to implement additional corrective actions or demonstrate sustained compliance, not to exceed the home infusion therapy accrediting organization's current term of approval. In the case of a renewal application where CMS has already placed the home infusion therapy accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the home infusion therapy accrediting

organization as to whether or not its CMS-approved home infusion therapy accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS determines that the home infusion therapy accrediting organization does not meet the requirements, CMS may withdraw approval of the CMS-approved home infusion therapy accreditation program. The notice of determination provided to the home infusion therapy accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (d)(4)(iii) of this section.

(iii) CMS publishes in the **Federal Register** a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days after the date of publication of the notice.

(e) *Immediate jeopardy.* If at any time CMS determines that the continued approval of a CMS-approved home infusion therapy accreditation program of any home infusion therapy accrediting organization poses an immediate jeopardy to the patients of the suppliers accredited under the program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved home infusion therapy accreditation program of that home infusion therapy accrediting organization and publish a notice of the removal, including the reasons for it, in the **Federal Register**.

(f) *Notification to home infusion therapy suppliers of withdrawal of CMS approval status.* A home infusion therapy accrediting organization whose CMS approval of its home infusion therapy accreditation program has been withdrawn must notify each of its accredited home infusion therapy suppliers, in writing, of the withdrawal of CMS approval status no later than 30 calendar days after the notice is published in the **Federal Register**. The notification to the accredited home infusion therapy suppliers must inform them of the implications for their payment status once their current term of accreditation expires.

§ 488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization.

A home infusion therapy accreditation organization approved by CMS must carry out the following activities on an ongoing basis:

(a) Provide CMS with all of the following in written format (either electronic or hard copy):

(1) Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(2) Notice of all accreditation decisions.

(3) Notice of all complaints related to providers or suppliers.

(4) Information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation.

(5) The home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(6) Notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process. If the home infusion therapy accrediting organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accrediting organization.

(b) Within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(c) The home infusion therapy accrediting organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(d) Within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy accrediting organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accrediting organization.

(e) Within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy accrediting organization that CMS intends to withdraw approval of the home infusion therapy accrediting organization, the home infusion therapy accrediting organization must provide written notice of the withdrawal to all of the home infusion therapy accrediting organization's accredited suppliers.

§ 488.1040 Onsite observations of home infusion therapy accrediting organization operations.

(a) As part of the application review process, the ongoing review process, or the continuing oversight of a home infusion therapy accrediting organization's performance, CMS may conduct onsite inspections of the home infusion therapy accrediting organization's operations and offices at any time to verify the home infusion therapy accrediting organization's representations and to assess the home infusion therapy accrediting organization's compliance with its own policies and procedures.

(b) Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following:

- (1) Interviews with various accrediting organization staff.
- (2) Review of documents, survey files, audit tools, and related records.
- (3) Observation of meetings concerning the home infusion therapy accreditation process.
- (4) Auditing meetings concerning the accreditation process.
- (5) Observation of in-progress surveys and audits.
- (6) Evaluation of the accrediting organization's survey results and accreditation decision-making process.

§ 488.1045 Voluntary and involuntary termination.

(a) *Voluntary termination by a CMS-approved accrediting program.* In accordance with § 488.1010(a)(23), a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 90 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

(b) *Involuntary termination of an accrediting organization's approval by CMS.* Once CMS publishes the notice in the **Federal Register** announcing its decision terminate the home infusion therapy accrediting organization's home infusion therapy accreditation program, the home infusion therapy accrediting organization must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of its home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in

accordance with the requirements at § 488.1010(f) once their current term of accreditation expires.

(c) *Voluntary and involuntary terminations.* For both voluntary and involuntary terminations—

(1) The accreditation status of affected home infusion therapy suppliers is considered to remain in effect until their current term of accreditation expires;

(2) If the home infusion therapy supplier wishes to avoid a suspension of payment, it must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date that it has submitted an application for home infusion therapy accreditation under another CMS-approved home infusion therapy accreditation program. Failure to comply with this 60-calendar day requirement prior to expiration of their current home infusion therapy accreditation stations within could result in a suspension of payment; and

(3) The home infusion therapy accrediting organization provides a second written notification to all accredited home infusion therapy suppliers ten calendar days prior to the organization's accreditation program effective date of termination.

(d) *Voluntary withdrawal from accreditation requested by a home infusion therapy supplier.* If a voluntary withdrawal from accreditation is requested by the home infusion therapy supplier, the withdrawal may not become effective until the accrediting organization completes all of the following steps:

(1) The accrediting organization must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program.

(2) The home infusion therapy accrediting organization must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status.

(3) The home infusion therapy accrediting organization must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

§ 488.1050 Reconsideration.

(a) *General rule.* A home infusion therapy accrediting organization dissatisfied with a determination that its home infusion therapy accreditation

requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy accrediting organization meet the applicable quality standards is entitled to reconsideration.

(b) *Filing requirements.* (1) A written request for reconsideration must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(2) The written request for reconsideration must specify the findings or issues with which the home infusion therapy accrediting organization disagrees and the reasons for the disagreement.

(3) A requestor may withdraw its written request for reconsideration at any time before the issuance of a reconsideration determination.

(c) *CMS response to a request for reconsideration.* In response to a request for reconsideration, CMS provides the accrediting organization with—

(1) The opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accrediting organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(2) Written notice of the time and place of the hearing at least 10 business days before the scheduled date.

(d) *Hearing requirements and rules.*

(1) The reconsideration hearing is a public hearing open to all of the following:

(i) Authorized representatives and staff from CMS, including, but not limited to, the following:

(A) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(B) Legal counsel.

(C) Non-technical witnesses with personal knowledge of the facts of the case.

(ii) Representatives from the accrediting organization requesting the reconsideration including, but not limited to, the following:

(A) Authorized representatives and staff from the accrediting organization.

(B) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(C) Legal counsel.

(D) Non-technical witnesses, such as patients and family members that have personal knowledge of the facts of the case.

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(3) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(4) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(5) Within 45 calendar days after the close of the hearing, the hearing officer

will present the findings and recommendations to the accrediting organization that requested the reconsideration.

(6) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(7) The hearing officer's decision is final.

Dated: June 25, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018-14443 Filed 7-2-18; 4:15 pm]

BILLING CODE 4120-01-P



FEDERAL REGISTER

Vol. 83

Thursday,

No. 134

July 12, 2018

Part III

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Inversions and Related Transactions; Rule

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[TD 9834]

RIN 1545–BO20; 1545–BO22

Inversions and Related Transactions**AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Final regulations, temporary regulations, and removal of temporary regulations.

SUMMARY: This document contains final regulations that address transactions that are structured to avoid the purposes of sections 7874 and 367 of the Internal Revenue Code (the Code) and certain post-inversion tax avoidance transactions. These regulations affect certain domestic corporations and domestic partnerships whose assets are directly or indirectly acquired by a foreign corporation and certain persons related to such domestic corporations and domestic partnerships. This document finalizes proposed regulations, and removes temporary regulations, published on April 8, 2016.

DATES:

Effective date: These regulations are effective on July 12, 2018.

Applicability dates: For dates of applicability, see §§ 1.304–7(e), 1.367(a)–3(c)(11)(ii), 1.367(b)–4(h), 1.956–2(i), 1.7701(l)–4(h), 1.7874–1(i)(2), 1.7874–2(l)(2), 1.7874–3(f)(2), 1.7874–6(h), 1.7874–7(g), 1.7874–8(i), 1.7874–9(g), 1.7874–10(l), 1.7874–11(f), and 1.7874–12(b).

FOR FURTHER INFORMATION CONTACT:

Regarding the regulations under sections 304, 367, and 7874, Shane M. McCarrick, (202) 317–6937; regarding the regulations under sections 956 and 7701(l), Rose E. Jenkins, (202) 317–6934 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:**Background****I. Overview**

On April 8, 2016, the Department of the Treasury (the Treasury Department) and the IRS published final and temporary regulations under sections 304, 367, 956, 7701(l), and 7874 (TD 9761) in the **Federal Register** (81 FR 20858, as corrected at 81 FR 40810 and 81 FR 46832). On the same date, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–135734–14) in the **Federal Register** (81 FR 20588, as corrected at 81 FR 35275) by cross-

reference to the temporary regulations (the 2016 proposed regulations) (together with the final and temporary regulations described in the preceding sentence, the 2016 regulations). No public hearing was requested or held. Numerous written comments were received with respect to the proposed regulations and are available at www.regulations.gov or upon request. A comment was also received with respect to a notice that preceded the 2016 regulations (Notice 2015–79, 2015–49 I.R.B. 775) and, as explained in the preamble to those regulations, the comment has been included in the administrative record for the proposed regulations. The majority of the comments supported the 2016 regulations.

On January 18, 2017, the Treasury Department and the IRS published final and temporary regulations under section 7874 (TD 9812) in the **Federal Register** (82 FR 5388, as corrected at 82 FR 42233), which adopted as final regulations the proposed regulations in § 1.7874–4 (including the portions included in the 2016 regulations) and modified certain portions of the 2016 regulations (see 82 FR 5476–01). This Treasury decision adopts the remaining 2016 proposed regulations, with the changes generally described in the Summary of Comments and Explanation of Revisions section of this preamble, as final regulations and removes the corresponding temporary regulations.

II. Section 7874 Background

A foreign corporation (foreign acquiring corporation) generally is treated as a surrogate foreign corporation under section 7874(a)(2)(B) if, pursuant to a plan (or a series of related transactions), three conditions are satisfied. First, the foreign acquiring corporation completes, after March 4, 2003, the direct or indirect acquisition of substantially all of the properties held directly or indirectly by a domestic corporation (domestic entity acquisition). Second, after the domestic entity acquisition, at least 60 percent of the stock (by vote or value) of the foreign acquiring corporation is held by former shareholders of the domestic corporation (former domestic entity shareholders) by reason of holding stock in the domestic corporation (such percentage, the ownership percentage, and the fraction used to calculate the ownership percentage, the ownership fraction). And third, after the domestic entity acquisition, the expanded affiliated group (as defined in section 7874(c)(1)) that includes the foreign acquiring corporation (EAG) does not have substantial business activities in

the foreign country in which, or under the law of which, the foreign acquiring corporation is created or organized when compared to the total business activities of the EAG. Similar provisions apply if a foreign acquiring corporation acquires substantially all of the properties constituting a trade or business of a domestic partnership. The domestic corporation or the domestic partnership described in this paragraph is referred to at times in this preamble as the “domestic entity.” For other definitions used throughout this preamble but not defined in this preamble, see § 1.7874–12 (providing common definitions for purposes of certain regulations under sections 367(b), 956, 7701(l), and 7874).

The tax treatment of a domestic entity acquisition in which the EAG does not have substantial business activities in the relevant foreign country varies depending on the level of owner continuity. If the ownership percentage is at least 80, the foreign acquiring corporation is treated as a domestic corporation for all purposes of the Code pursuant to section 7874(b).

If, instead, the ownership percentage is at least 60 but less than 80 (in which case the domestic entity acquisition is referred to in this preamble as an “inversion transaction”), the foreign acquiring corporation is respected as a foreign corporation but the domestic entity and certain other persons are subject to special rules that reduce the tax benefits of the inversion transaction. For example, section 7874(a)(1) prevents the use of certain tax attributes to reduce the U.S. federal income tax owed on certain income or gain (inversion gain) recognized in transactions intended to remove foreign operations from the U.S. taxing jurisdiction. “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018” (the Act), Public Law 115–97, amended certain sections of the Code to further reduce the tax benefits of inversion transactions. See section 1(h)(11)(C)(iii) (shareholders of surrogate foreign corporations not eligible for reduced rate on dividends); section 59A (for inverted groups, generally treating costs of goods sold as a base erosion payment for purposes of the base erosion and anti-abuse tax); section 965 (upon certain inversions, recapturing the benefit of a deduction related to a transition tax); and section 4985 (increasing the rate of the excise tax imposed on certain holders of stock options and other stock-based compensation).

Section 7874(c)(6) grants the Secretary authority to prescribe regulations as

may be appropriate to determine whether a corporation is a surrogate foreign corporation, including regulations to treat stock as not stock. In addition, section 7874(g) grants the Secretary authority to provide regulations necessary to carry out section 7874, including regulations providing for such adjustments to the application of section 7874 as are necessary to prevent the avoidance of the purposes of section 7874.

Summary of Comments and Explanation of Revisions

I. Rules Addressing Certain Transactions That Are Structured To Avoid the Purposes of Section 7874

To address certain transactions that are structured to avoid the purposes of section 7874, the 2016 regulations provided rules for (i) identifying domestic entity acquisitions and foreign acquiring corporations in certain multiple-step transactions; (ii) calculating the ownership percentage and, more specifically, disregarding certain stock of the foreign acquiring corporation for purposes of computing the denominator of the ownership fraction and, in addition, taking into account certain non-ordinary course distributions (NOCDs) made by a domestic entity for purposes of computing the numerator of the ownership fraction; (iii) determining when certain stock of a foreign acquiring corporation is treated as held by a member of the EAG; and (iv) determining when an EAG has substantial business activities in a relevant foreign country. The comments and modifications with respect to these rules are discussed in this Part I.

A. Calculation of the Ownership Percentage

1. Passive Assets Rule

Section 1.7874-7T of the 2016 regulations provides a rule (the passive assets rule) that excludes from the denominator of the ownership fraction stock of the foreign acquiring corporation attributable to certain passive assets. In general, the rule applies with respect to a domestic entity acquisition if, on the completion date, more than 50 percent of the gross value of all foreign group property constitutes foreign group nonqualified property. The amount of stock that is excluded is equal to the product of (i) the value of the stock of the foreign acquiring corporation, other than stock that is described in section 7874(a)(2)(B)(ii) and stock that is excluded from the denominator of the ownership fraction under either § 1.7874-1(b) or § 1.7874-

4(b) (the multiplicand), and (ii) the proportion of foreign group property that is foreign group nonqualified property, determined based on gross value (the foreign group nonqualified property fraction). For purposes of determining the foreign group nonqualified property fraction, property received by the EAG that gives rise to stock excluded from the ownership fraction under § 1.7874-4(b) is not taken into account.

Under the 2016 regulations, the passive assets rule applies for purposes of determining the ownership percentage by vote and value. The Treasury Department and the IRS have determined that applying the rule for purposes of determining the ownership percentage by vote could give rise to administrative complexities, because the rule does not exclude particular shares of stock but instead excludes an amount of stock. In particular, when classes of stock of the foreign acquiring corporation have different voting power, a special rule would be needed to allocate the excluded amount among the shares. Consistent with other rules under section 7874, the Treasury Department and the IRS have concluded that the rule should apply only for purposes of determining the ownership percentage by value. See § 1.7874-8 (excluding an amount of stock for purposes of determining the ownership percentage by value); § 1.7874-10 (treating an amount as additional stock described in section 7874(a)(2)(B)(ii) for purposes of determining the ownership percentage by value). The final regulations therefore contain this modification. See § 1.7874-7(b).

The Treasury Department and the IRS have also determined that the passive assets rule should be modified to take into account the other stock exclusion rules. For example, stock excluded under § 1.7874-8(b) (disregard of certain stock attributable to serial acquisitions) or § 1.7874-9(b) (disregard of certain stock in third-country transactions) should not be taken into account when determining the multiplicand. In addition, property of an entity the acquisition of which gives rise to stock excluded under § 1.7874-8(b) or § 1.7874-9(b) generally should not be taken into account when determining the foreign group nonqualified property fraction. The final regulations thus modify the multiplicand so that stock excluded under any of the stock exclusion rules is not taken into account. See § 1.7874-7(b)(1). Further, the final regulations modify the foreign group nonqualified property fraction so that, in general, property that gives rise to stock excluded under any of the stock

exclusion rules is not taken into account. See § 1.7874-7(e)(3). The final regulations also include an example illustrating these rules. See § 1.7874-7(f) *Example 4*.

Further, in response to a comment, the final regulations clarify that the passive assets rule is subject to section 7874(c)(4). See § 1.7874-7(a) (penultimate sentence). For example, section 7874(c)(4) can apply to the transfer of properties or liabilities as part of a plan a principal purpose of which is to prevent the more-than-50-percent threshold of the passive assets rule from being satisfied with respect to a domestic entity acquisition. In these cases, section 7874(c)(4) would disregard the transaction and, as a result, the passive assets rule (including the more-than-50-percent threshold) would be applied as if the transfer did not occur.

Lastly, and also in response to a comment, the Treasury Department and the IRS clarify § 1.7874-7(e)(1)(i)(C), which excludes property that gives rise to income described in section 1297(b)(2)(A) or (B) from the definition of foreign group nonqualified property. Under section 1297(b)(2)(A) and (B), for certain purposes of the passive foreign investment company rules, passive income does not include certain income derived in the active conduct of a banking or insurance business. The final regulations clarify that for purposes of determining whether property qualifies for the exclusion under § 1.7874-7(e)(1)(i)(C), other passive foreign investment company rules do not apply. See § 1.7874-7(e)(1)(i)(C) (parenthetical language). Thus, for example, the rules in section 1298(b)(2) or (3) that except certain corporations from being treated as passive foreign investment companies during a start-up year or following a change in business do not apply for this purpose.

2. Serial Acquisitions of Domestic Entities

Section 1.7874-8T of the 2016 regulations provides a rule (the serial acquisition rule) that, with respect to a domestic entity acquisition (a relevant domestic entity acquisition), excludes from the denominator of the ownership fraction stock of the foreign acquiring corporation attributable to certain domestic entity acquisitions previously completed by the foreign acquiring corporation (or a predecessor). Consistent with the explanation in the preamble to the 2016 regulations, this rule addresses a concern that domestic entity acquisitions previously completed by the foreign acquiring corporation serve as a platform for

additional and even larger domestic entity acquisitions.

For administrability purposes, the serial acquisition rule under the 2016 regulations looks only to whether the foreign acquiring corporation completed a domestic entity acquisition within the 36-month period ending on the signing date of the relevant domestic entity acquisition (such acquisition, in general, a “prior domestic entity acquisition”). Absent this 36-month look-back period, the rule could be difficult to administer, as all domestic entity acquisitions previously completed by the foreign acquiring corporation would need to be identified. In addition, as the period between a relevant domestic entity acquisition and a previous domestic entity acquisition increases, it may become more difficult to determine which stock of the foreign acquiring corporation is attributable to the previous domestic entity acquisition (for example, due to changes in the capital structure of the foreign acquiring corporation resulting from divisive or acquisitive transactions). The use of a 36-month look-back period provides an administrable standard and is consistent with other look-back periods under the Code and regulations. See, e.g., section 865(f) (sourcing rule for sales of stock in a foreign affiliate); section 2035 (transfers before death); section 7701(b)(3) (substantial presence test for residency); and § 1.7874–10 (NOCD rule). The final regulations therefore retain the 36-month look-back period.

The majority of the comments received on the 2016 regulations involved the serial acquisition rule. Of those comments, nearly every one supported the rule.

One comment, however, while generally supporting the prevention of inversions, asserted that the serial acquisition rule targets a specific transaction that was pending when the 2016 regulations were issued. The comment suggested that this would cause mistrust of federal agencies and could ultimately harm U.S. businesses. The Treasury Department and the IRS disagree with the comment. The serial acquisition rule does not target a specific transaction. Instead, and as explained in the preamble to the 2016 regulations, it addresses a particular practice occurring in the marketplace in which a foreign acquiring corporation completes multiple domestic entity acquisitions over a span of just a few years, with the corporation’s increased value serving as a platform to complete still larger domestic entity acquisitions that avoid the application of section 7874. The Treasury Department and the IRS have concluded that such serial

acquisitions, which in effect permit a single foreign acquiring corporation to facilitate the inversion of multiple domestic entities over time, are inconsistent with the policies underlying section 7874. As also explained in the preamble to the 2016 regulations, the Treasury Department and the IRS have determined that the rule appropriately addresses this practice. See Part I.B.3.a of the Explanation of Provisions of the preamble to the 2016 regulations; see also S. Rep. No. 192, at 142 (2003) (expressing concern that certain inversions “permit corporations and other entities to continue to conduct business in the same manner as they did prior to the inversion, but with the result that the inverted entity avoids U.S. tax on foreign operations and may engage in earnings-stripping techniques to avoid U.S. tax on domestic operations.”).

One other comment asserted that the serial acquisition rule exceeds statutory authority and lacks a reasoned explanation. Those same claims were subsequently asserted in *Chamber of Commerce of the United States v. Internal Revenue Serv.*, No. 1:16–CV–944–LY (W.D. Tex. Sept. 29, 2017), *appeal docketed*, No. 17–51063 (5th Cir. Dec. 1, 2017), in which the serial acquisition rule in the temporary regulations was challenged. While the district court invalidated the temporary regulation on procedural grounds because it was not subjected to prior notice and comment, the court found that the serial acquisition rule was substantively valid under sections 7874(c)(6) and (g) (the Code sections under which the Treasury Department and the IRS promulgated the rule). The court concluded that the rule did not exceed the statutory authority of the Treasury Department and the IRS because it was within their broad authority under section 7874 to “treat stock as not stock”—the exercise of which, the court noted, could in certain cases “substantially alter a calculation under the statute”—and to prevent the avoidance of the purposes of section 7874. The court also “reviewed the full analysis by which the Agencies determined the Rule is necessary” and concluded that the Treasury Department and the IRS provided a sufficient explanation in issuing the serial acquisition rule in the temporary regulation, and did not engage in arbitrary and capricious rulemaking.

The final regulations adopt the rule with three technical clarifications or modifications, in response to comments.

First, the final regulations clarify that the determination of stock of the foreign

acquiring corporation attributable to a prior domestic entity acquisition does not take into account stock of the foreign acquiring corporation deemed under § 1.7874–10(b) (the NOCD rule) or section 7874(c)(4) more broadly to have been received in the prior domestic entity acquisition. See § 1.7874–8(g)(3) (excluding such stock from the definition of total number of prior acquisition shares).

Second, the final regulations provide an exception to the definition of the term prior domestic entity acquisition in addition to the one under the 2016 regulations (relating to certain de minimis acquisitions). Under this additional exception, the term does not include a domestic entity acquisition that occurs within a foreign-parented group and qualifies for the internal group restructuring exception of § 1.7874–1(c)(2). See § 1.7874–8(g)(4)(ii)(B). In these cases, the Treasury Department and the IRS have determined that because the domestic entity remains (or is considered to remain) within the same foreign-parented group, the acquisition should not be viewed as creating a platform to complete larger domestic entity acquisitions. As a result, the Treasury Department and the IRS have concluded that these acquisitions do not give rise to the policy concerns underlying the serial acquisition rule. Accordingly, like under the 2016 regulations, the term prior domestic entity acquisition under the final regulations means any domestic entity acquisition completed by the foreign acquiring corporation (or a predecessor) within a 36-month look-back period, except for those acquisitions that, for administrative or policy reasons, qualify for an exception.

Third, the final regulations define a predecessor of a foreign acquiring corporation for purposes of the serial acquisition rule. See § 1.7874–8(b) (defining predecessor by cross-reference to the definition in the NOCD rule under § 1.7874–10(f)(1)).

3. Third-Country Rule

Section 1.7874–9T of the 2016 regulations provides a rule (the third-country rule) that excludes stock of the foreign acquiring corporation from the denominator of the ownership fraction when a domestic entity acquisition is a “third-country transaction,” which occurs when three requirements are satisfied. First, the foreign acquiring corporation must complete a “covered foreign acquisition” in a transaction related to the domestic entity acquisition. In general, a covered foreign acquisition is an acquisition by the foreign acquiring corporation of another

foreign corporation (such acquisition, a “foreign acquisition,” and such corporation, an “acquired foreign corporation”), provided that an ownership continuity requirement is satisfied. Second, after all related transactions are complete, the foreign acquiring corporation must be a tax resident in a “third country”—that is, a foreign country other than the foreign country in which, before the foreign acquisition and any related transaction, the acquired foreign corporation was a tax resident. (The 2016 regulations refer to the country in which a corporation is “subject to tax as a resident,” rather than the country in which a corporation is “tax resident.” However, similar to the reasons discussed in Part I.C. of this Summary of Comments and Explanation of Revisions section (concerning the substantial business activities test), the final regulations refer to “tax resident.”) And third, the ownership percentage, determined without regard to the third country rule, must be at least 60 (by vote or value).

As explained in Notice 2015–79, the Treasury Department and the IRS have determined that when a domestic entity acquisition is a third-country transaction, the decision to locate the tax residence of the foreign acquiring corporation in the third country generally is driven by tax planning, including the facilitation of U.S. tax avoidance following the acquisition, and, as a result, generally is contrary to the policies underlying section 7874. Accordingly, the third country rule provides that stock of the foreign acquiring corporation held by former shareholders of the acquired foreign corporation by reason of holding stock in the acquired foreign corporation is excluded from the denominator of the ownership fraction.

a. Exceptions to Rule’s Application

A comment suggested that the Treasury Department and the IRS consider adding one or more exceptions to the third-country rule, so as to better tailor the rule’s application to domestic entity acquisitions in which the use of a third country is likely driven by tax planning. The comment recommended against an exception based on the subjective criterion of whether a non-tax business purpose exists for the foreign acquiring corporation’s use of the third country. Instead, the comment suggested that any exception should be based on objective criteria. In particular, the comment proposed exceptions based on (i) the foreign group’s business activities in the third country, and (ii) a comparison of the treaty benefits (specifically, the withholding tax rate

with respect to dividends, interest, and royalties) available to the foreign acquiring corporation in the third country as compared to the benefits that would be available in the country in which the acquired foreign corporation is a tax resident.

In response to the comment, the final regulations provide that the third-country rule generally does not apply if the EAG has substantial business activities in the third country compared to the total business activities of the EAG. See § 1.7874–9(d)(4)(ii) (providing an exception to the definition of a covered foreign acquisition). For this purpose, the principles of § 1.7874–3 apply, and the determination of whether there are substantial business activities is made without regard to the domestic entity acquisition.

The final regulations also generally provide that the third-country rule does not apply if (i) both the foreign acquiring corporation and the acquired foreign corporation are created or organized in, or under the law of, a foreign country that does not impose corporate income tax, and (ii) neither the foreign acquiring corporation nor the acquired foreign corporation is a tax resident of any other foreign country. See § 1.7874–9(d)(4)(iii) (providing an exception to the definition of a covered foreign acquisition). In these cases, the Treasury Department and the IRS have determined that the migration from one no-income-tax jurisdiction to another such jurisdiction is unlikely to be driven by tax planning, as the countries would generally be equally favorable from a tax perspective.

The Treasury Department and the IRS decline, however, to provide an additional exception based on a comparison of treaty benefits. Even if the withholding rates with respect to certain categories of income are at least as high under the U.S. tax treaty with the third country as compared to the U.S. tax treaty with the country in which the acquired foreign corporation is a tax resident, the use of the third country may nevertheless be motivated by tax planning. For example, there could be tax-related features other than withholding rates that make the third country more advantageous; and, significant administrative difficulties could arise if the comparison were to include those features. Moreover, the third country might have a less restrictive regime for controlled foreign corporations, which could facilitate the use of low- or no-taxed entities to erode the U.S. tax base following the domestic entity acquisition. Consistent with the explanation in Notice 2015–79, the Treasury Department and the IRS have

concluded that it is appropriate for the third-country rule to address this concern.

b. Other Issues

A comment observed that, in a transaction related to a domestic entity acquisition, the foreign acquiring corporation could change its tax residency by simply changing the country in which it is considered managed and controlled. The comment noted that, in such a case, the foreign acquiring corporation might not be viewed as having completed a foreign acquisition and, as a result, the third-country rule could inappropriately be circumvented. The Treasury Department and the IRS agree with this comment and the final regulations are modified accordingly. See § 1.7874–9(e)(5).

Finally, a comment recommended clarifying that the third-country rule compares only the tax residency of the foreign acquiring corporation and acquired foreign corporation, and thus does not consider the countries in which the corporations are created or organized. The Treasury Department and the IRS have determined that this is clear under the 2016 regulations; therefore the text of § 1.7874–9(c)(2) is unchanged from the corresponding provision in the 2016 regulations.

4. NOCD Rule

Section 1.7874–10T of the 2016 regulations provides a rule (the NOCD rule) that, for purposes of determining the ownership percentage by value, deems former domestic entity shareholders or former domestic entity partners to receive, by reason of holding stock or an interest in the domestic entity, an amount of stock of the foreign acquiring corporation with a fair market value equal to the aggregate value of NOCDs made by the domestic entity (such stock, “NOCD stock”). The rule provides mechanics for determining NOCDs.

The final regulations include seven clarifications or modifications to the NOCD rule, in response to comments. First, the regulations clarify and refine the definition of distribution. The 2016 regulations define the term broadly but provide several exclusions, including, in general, an exclusion for a distribution that occurs pursuant to an asset reorganization. The final regulations clarify that the exclusion does not apply to a distribution to which section 355 applies, regardless of whether in connection with a reorganization described in section 368(a)(1)(D). See § 1.7874–10(k)(1)(i)(C). That is, a distribution of stock of a controlled corporation pursuant to a

divisive reorganization is a distribution for purposes of the NOCD rule, but a distribution of an acquiring corporation's stock pursuant to an acquisitive reorganization (such as a merger described in section 368(a)(1)(A)) is not a distribution for this purpose. In addition, the final regulations refine the definition of distribution such that, in the case of a partnership, a distribution does not include a deemed distribution pursuant to section 752(b) to the extent that the transaction giving rise to the deemed distribution does not reduce the partnership's value.

Second, the final regulations modify a special rule that applies when a domestic corporation (distributing corporation) distributes stock of another domestic corporation (controlled corporation) pursuant to a transaction described in section 355 and, immediately before the distribution, the fair market value of the controlled corporation represents more than 50 percent of the fair market value of the stock of the distributing corporation. When the special rule applies, the controlled corporation is deemed for purposes of the NOCD rule to have distributed the stock of the distributing corporation. The final regulations modify the condition for the rule to apply: As modified, the rule considers the fair market value of the stock of the controlled corporation owned by the distributing corporation and any related person. See § 1.7874-10(g). Accordingly, the special rule would not apply, for example, if the fair market value of the stock of the distributing corporation were \$100x (not taking into account the fair market value of the stock of the controlled corporation), the fair market value of the stock of the controlled corporation were \$110x, and \$100x or less of the stock of the controlled corporation were owned by the distributing corporation (with the balance owned by a person unrelated to the distributing corporation).

Third, the final regulations clarify how the NOCD rule relates to the expanded affiliated group rules of section 7874(c)(2)(A) and § 1.7874-1 (the EAG rules). The preamble to the 2016 regulations indicates that the NOCD rule applies only for purposes of determining the ownership percentage by value and that it does not apply for any other purpose, including the loss of control exception of § 1.7874-1(c)(3) (one of the EAG rules). The final regulations clarify that NOCD stock is not taken into account for purposes of the EAG rules. See § 1.7874-1(d)(2) (providing that NOCD stock is not taken into account for purposes of

determining the members of an EAG or whether a domestic entity acquisition qualifies for the internal group restructuring or loss of control exception). As a result, the determination of the EAG and whether a domestic entity acquisition qualifies for the internal group restructuring or loss of control exception is based on the stock of the foreign acquiring corporation that actually exists. See also Part I.B of this Summary of Comments and Explanation of Revisions section (discussing the interaction of the stock exclusion rules and the EAG rules).

Fourth, the final regulations provide guidance regarding how to allocate NOCD stock among the former domestic entity shareholders. Because the NOCD rule provides that NOCD stock is treated as stock described in section 7874(a)(2)(B)(ii), in most cases the NOCD stock will simply be included in both the numerator and denominator of the ownership fraction and, as a result, it will be irrelevant which former domestic entity shareholders or former domestic entity partners are considered to hold such stock. However, in certain cases involving the application of the EAG rules, the allocation of the NOCD stock among the former domestic entity shareholders or former domestic entity partners may affect whether the stock is included in the numerator and denominator of the ownership fraction.

For example, assume two foreign corporations, F1 and F2, each own 50% of the stock of a domestic corporation, DT. During year y, DT makes a \$10x distribution to each of F1 and F2 and, thereafter, distributes \$40x to F2 in redemption of all of F2's stock of DT. Then, on December 31 of year y, and in a transaction related to the redemption, F1 contributes all of the stock of DT to a newly-formed foreign corporation, FA, in exchange for all the stock of FA (DT acquisition). Assume that there are \$36x of NOCDs with respect to the look-back year ending on December 31 of year y and that there are no NOCDs with respect to the other look-back years. An EAG exists (for this purpose, NOCD stock is not taken into account), composed of F1, FA, and DT, but the DT acquisition does not qualify for the internal group restructuring exception because F1 did not own 80 percent or more of the stock of DT before the DT acquisition and any related transaction. See § 1.7874-1(c)(2)(i) and (g). Moreover, the acquisition does not qualify for the loss of control exception because after the acquisition F1 (a former domestic entity shareholder) holds more than 50 percent of the stock of a member of the EAG. See § 1.7874-1(c)(3). Thus, all FA stock held by F1,

including any NOCD stock considered held by F1, is excluded from the numerator and denominator of the ownership fraction. See § 1.7874-1(b). Any NOCD stock considered held by F2, however, is included in both the numerator and the denominator of the ownership fraction.

To address this allocation issue, the final regulations provide that NOCD stock is allocated among the former domestic entity shareholders or former domestic entity partners based on the amount of NOCDs that the persons are treated as receiving. See § 1.7874-10(h). For this purpose, and for ease of administration, the regulations provide that a pro rata portion of each distribution during a look-back year is treated as comprising a NOCD with respect to the look-back year, based on the amount of NOCDs during the year relative to the total amount of distributions during the year. Thus, in the example above, because 60 percent of the distributions during year y constituted NOCDs (\$36x/\$60x), 60 percent of each of the \$10x dividend distributions to F1 and F2, as well as 60 percent of the \$40x distribution to F2 as part of the redemption, are treated as comprising the NOCD. Accordingly, under § 1.7874-10(h), F1 and F2 are treated as having received \$6x and \$30x of distributions comprising the NOCD, respectively. F1 and F2 are therefore treated as holding \$6x and \$30x of NOCD stock, respectively. As a result, the ownership percentage (by value) with respect to the DT acquisition is 100 (\$30x/\$30x).

Fifth, the final regulations provide guidance when multiple foreign acquiring corporations complete a domestic entity acquisition, as to which corporation's or corporations' stock the NOCD stock is considered comprised. In general, the final regulations provide that the NOCD stock is considered comprised, on a pro rata basis, of stock of each foreign acquiring corporation that directly or indirectly provided consideration in the domestic entity acquisition. For this purpose, consideration is not considered directly provided by a foreign acquiring corporation if it was indirectly provided by another foreign acquiring corporation. See § 1.7874-10(i). For example, assume FP, a foreign corporation, owns all the stock of FS, also a foreign corporation, and FS acquires all the stock of DT, a domestic corporation, solely in exchange for FP stock. Pursuant to § 1.7874-2(c)(1)(i) and (iii), both FS and FP are treated as having completed a domestic entity acquisition. Under § 1.7874-10(i), because FP indirectly provided 100

percent of the consideration in the domestic entity acquisition, stock of FP is considered to comprise 100 percent of any NOCD stock.

Sixth, the final regulations address how the NOCD rule applies when, pursuant to § 1.7874-2(e), two or more domestic entities are treated as a single domestic entity. Specifically, the regulations provide that the NOCD rule is initially applied to each domestic entity on a separate basis, and then the amount of NOCDs treated as made by the single domestic entity is the sum of the separately computed NOCDs made by each domestic entity. See § 1.7874-10(j).

Finally, the final regulations confirm that NOCD stock is included in both the numerator and the denominator of the ownership fraction, except to the extent that the stock is treated as held by a member of the EAG and excluded from the numerator or both the numerator and denominator, as applicable, under the EAG rules. See § 1.7874-1(d)(2).

5. De Minimis Exceptions

Certain stock exclusion rules under section 7874 contain a de minimis exception. See § 1.7874-4(b) (disqualified stock rule); § 1.7874-7T(b) (passive assets rule); and 1.7874-10T(b) (NOCD rule). As explained in the preamble to TD 9812 (final regulations regarding the disqualified stock rule), together the de minimis exceptions generally prevent one or more of the disqualified stock rule, the passive assets rule, and NOCD rule from causing section 7874 to apply to a domestic entity acquisition that, given minimal actual ownership continuity, largely resembles a cash purchase by the foreign acquiring corporation of the stock of (or interests in) the domestic entity.

Each of the de minimis exceptions is satisfied when two requirements are met. First, the ownership percentage—determined without regard to the application of the disqualified stock rule, the passive assets rule, and the NOCD rule—must be less than five (by vote and value). Second, after the domestic entity acquisition and all related transactions, each former domestic entity shareholder or former domestic entity partner, as applicable, must own (applying the attribution rules of section 318(a) with the modifications described in section 304(c)(3)(B)) less than five percent (by vote and value) of the stock of (or a partnership interest in) each member of the EAG. Originally, this second requirement considered the ownership by the former domestic entity shareholders or former domestic entity partners collectively. However, in

response to a comment, TD 9812 modified the requirement so that it considers only the ownership by the former domestic entity shareholders or former domestic entity partners individually.

Similar to a comment submitted with respect to the disqualified stock rule and addressed in TD 9812, a comment recommended additional modifications to the second requirement. The comment stated that, particularly in cases involving a publicly-traded domestic entity or a complex ownership structure, it could be difficult or burdensome to identify each former domestic entity shareholder or former domestic entity partner (including a de minimis former domestic entity shareholder or former domestic entity partner), as applicable, and then determine (taking into account the applicable attribution rules) the person's ownership of the foreign acquiring corporation and each member of the EAG.

The Treasury Department and the IRS agree that it is appropriate to modify the second requirement in order to make the de minimis exceptions easier for taxpayers to comply with and for the IRS to administer. Accordingly, under the final regulations, only former domestic entity shareholders or former domestic entity partners, as applicable, that own (taking into account the applicable attribution rules) at least five percent of the stock of (or a partnership interest in) the domestic entity need be identified. If none of those former domestic entity shareholders or former domestic entity partners owns (taking into account the applicable attribution rules) at least five percent of the foreign acquiring corporation or a member of the EAG, then the second requirement is satisfied.

B. Coordination of Rules Affecting the Ownership Fraction With the EAG Rules

Existing regulations under section 7874 coordinate the application of (i) rules that disregard certain stock of the foreign acquiring corporation for purposes of determining the ownership fraction, with (ii) the EAG rules. See § 1.7874-4(h) (regarding the interaction of the EAG rules with the rule that disregards disqualified stock) and § 1.7874-7T(e) (regarding the interaction of the EAG rules with the rule that disregards certain stock attributable to passive assets). The final regulations broaden this coordination to other rules that similarly disregard certain stock of the foreign acquiring corporation for purposes of determining the ownership fraction—namely, the serial acquisition rule and the third-country rule, as well

as section 7874(c)(4) generally, the application of which in certain cases would similarly disregard stock of the foreign acquiring corporation. The final regulations provide a general coordination rule in § 1.7874-1(d)(1) to coordinate the stock exclusion rules and the EAG rules, and remove provisions of the existing regulations that are duplicative of this rule. See § 1.7874-4(i), *Example 8* and *Example 9* for illustrations involving the general coordination rule.

C. The Substantial Business Activities Test

Section 1.7874-3T(b)(4) of the 2016 regulations provides that, for an EAG to be considered to have substantial business activities in the relevant foreign country, the foreign acquiring corporation must be subject to tax as a resident of the “relevant foreign country” (the tax residence requirement). The relevant foreign country means the foreign country in which, or under the law of which, the foreign acquiring corporation was created or organized (country of organization). The tax residence requirement is in addition to the three qualitative requirements relating to the percentage of employees, assets, and income in the relevant foreign country. See § 1.7874-3(b)(1) through (3).

One comment made several recommendations with respect to the substantial business activities test. First, the comment recommended providing standards for determining when the tax residence requirement is considered satisfied, including in cases in which the relevant foreign country is a no-income-tax jurisdiction. The comment suggested that the standards be based on the definition of residence under the United States' income tax treaties with foreign countries. It further suggested providing guidance on when a foreign acquiring corporation is considered to be fiscally-transparent in, and thus not a tax resident of, the relevant foreign country.

The Treasury Department and the IRS generally agree with these recommendations. The final regulations thus define a tax resident of a country as a body corporate liable to tax under the laws of the country as a resident. See § 1.7874-3(d)(11). The Treasury Department and the IRS have concluded that defining tax resident in this manner obviates the need to provide specific guidance on when a foreign acquiring corporation is treated as fiscally-transparent under the laws of the relevant foreign country. In addition, the Treasury Department and the IRS have determined that when the relevant

foreign country is a country that does not impose corporate income tax, the tax residency requirement should not apply. See § 1.7874-3(b)(4) (second sentence).

The comment also suggested that the Treasury Department and the IRS consider changing the definition of relevant foreign country from the country of organization to the country in which the foreign acquiring corporation is a tax resident. Under this approach, the substantial business activities test would look to the percentage of the EAG's employees, assets, and income in the foreign country where the foreign acquiring corporation is a tax resident, without regard to the corporation's country of organization. The Treasury Department and the IRS have concluded that section 7874(a)(2)(B)(iii) requires substantial business activities in the country of organization, with tax residency in that country serving as a necessary component for establishing substantial business activities. Accordingly, the final regulations do not adopt this comment.

II. Rules Addressing Certain Post-Inversion Tax Avoidance Transactions

As described in the preamble to the 2016 regulations, as well as in Notice 2015-79 and Notice 2014-52 (2014-42 I.R.B. 712), certain inversion transactions are motivated in substantial part by the ability to engage in tax avoidance transactions after the inversion transaction that would not be possible in the absence of the inversion transaction. To reduce the tax benefits of certain post-inversion tax avoidance transactions, the 2016 regulations provided rules under sections 304(b)(5)(B), 367, 956(e), 7701(l), and 7874. The comments and modifications with respect to these rules are discussed in this Part II.

A. United States Property Rule

Section 1.956-2T(a)(4)(i) of the 2016 regulations provides that, generally, for purposes of section 956 and § 1.956-2(a), United States property includes an obligation of a foreign person and stock of a foreign corporation if (i) the obligation or stock is held by a CFC that is an expatriated foreign subsidiary (EFS), (ii) the foreign person or foreign corporation is a non-CFC foreign related person, and (iii) the obligation or stock was acquired either during the applicable period or in a transaction related to the inversion transaction. Similarly, § 1.956-2T(c)(5) extends the pledge and guarantee rule in § 1.956-2(c) to apply to obligations of non-CFC foreign related persons.

Comments requested that the rules in § 1.956-2T of the 2016 regulations (the United States property rule) be extended to apply to all foreign-parented groups, and not only those that are foreign-parented as a result of an inversion transaction. The Treasury Department and the IRS continue to study those comments, but do not adopt them in these final regulations.

B. Nomenclature and Other Changes

For clarity, the final regulations use the term “non-EFS foreign related person” instead of the term “non-CFC foreign related person.”

In addition, the final regulations modify various examples involving foreign corporations that were not controlled foreign corporations before the effective date of section 14214 of the Act (amending section 958(b) so as to provide “downward attribution” of stock from foreign persons to United States persons). In general, the final regulations now refer to those foreign corporations as CFCs, as appropriate, and otherwise retain the regulations under sections 367(b), 956, and 7701(l). Although the recent amendment to section 958(b)(4) makes it more difficult for post-inversion planning to cause an EFS to cease to be a CFC, such planning could still substantially dilute a United States shareholder's interest in the EFS. Accordingly, the recharacterization rules under § 1.7701(l)-4T concerning post-inversion dilution are finalized. The Treasury Department and the IRS decline at this time to extend the application of § 1.7701(l)-4 to all foreign-parented groups, in part, because other provisions may address such planning, including the fast-pay arrangement rules under § 1.7701(l)-3.

Further, for purposes of determining whether an entity is an EFS, the final regulations provide that downward attribution from a non-United States person to a United States person does not apply. Absent this modification, in certain cases the term EFS would be over-inclusive and, as a result, the term non-EFS foreign related person would be under-inclusive; this could result in the regulations under sections 367(b), 956, and 7701(l) inappropriately not applying in certain cases. Similarly, the final regulations provide that, when determining if an entity is a CFC for purposes of § 1.304-7, downward attribution from a non-United States person to a United States person does not apply. The Treasury Department and the IRS have determined that these modifications—the effect of which is that the determination of whether an entity is an EFS, as well as whether an entity is a CFC for purposes of § 1.304-

7, is the same under pre- and post-Act law—are necessary to carry out the purposes of the provisions.

III. Miscellaneous Rules

A. New Definitions Section in Section 7874 Regulations

Section 1.7874-12T of the 2016 regulations provides definitions for certain terms commonly used in §§ 1.367(b)-4, 1.956-2, 1.7701(l)-4, and certain of the section 7874 regulations. These final regulations adopt this definitions section. They also update other portions of the section 7874 regulations to conform those sections with the nomenclature used in § 1.7874-12.

B. Rules Under Section 956 Relating to the Definition of Obligation

Section 1.956-2T(d)(2)(iv) of the 2016 regulations provides the short-term obligation exception described in Notice 88-108, 1988-2 C.B. 446, and § 1.956-2T(d)(2)(v) provides the alternative short-term obligation exception described in Notice 2008-91, 2008-43 I.R.B. 1001, as modified by Notice 2009-10, 2009-5 I.R.B. 419, and Notice 2010-12, 2010-4 I.R.B. 326. No comments were received on these rules; accordingly, § 1.956-2(d)(2)(iv) is adopted as proposed. However, these final regulations do not contain the rule contained in proposed § 1.956-2(d)(2)(v), which applied only for certain taxable years beginning before 2011.

C. Applicability Dates

Section 7805(b)(1)(B) and (C) provide that a final regulation may apply to a taxable period ending on or after the date on which a proposed or temporary regulation to which the final regulation relates was filed with the **Federal Register** or the date on which a notice substantially describing the expected contents of the regulation was issued to the public. The applicability dates of the rules in the final regulations are generally the same as the applicability dates of the rules as set forth in the 2016 regulations, which were issued as temporary regulations to address transactions that are structured to avoid the purposes of sections 7874 and 367 and certain post-inversion tax avoidance transactions. Accordingly, the applicability date of some provisions in the final regulations corresponds to the date the 2016 regulations were filed with the **Federal Register**, and the applicability dates of other provisions in the final regulations predate the filing of the 2016 regulations and correspond to the issuance of Notice 2014-52, 2014-

42 I.R.B. 712, which was issued on September 22, 2014, or Notice 2015–79, 2015–49 I.R.B. 775, which was issued on November 19, 2015.

However, differences between the final regulations and the 2016 regulations generally apply on a prospective basis, with an option for taxpayers to apply the differences retroactively. Moreover, because taxpayers may have relied on the 2016 regulations, the modifications to the final regulations generally apply prospectively. However, domestic entity acquisitions completed before July 12, 2018 continue to be subject to those rules as set forth in the 2016 regulations (but generally with an option for taxpayers to apply the differences retroactively).

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings, notices, and other guidance cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at <http://www.irs.gov>.

Special Analyses

Regulatory Planning and Review—Economic Analysis

Executive Orders 13563 and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. This final rule is considered an E.O. 13771 deregulatory action. For more detail on the economic analysis, please refer to the analysis below.

Need for the Final Regulations

These final regulations refine and clarify certain aspects of the proposed and temporary regulations published in 2016 (collectively referred to as the 2016 regulations, as explained in the preamble). The changes finalized in this

set of regulations help to ensure that the regulations do not impact mergers that provide market benefits independent of tax avoidance; for example, those that increase efficiencies within the corporation or provide other growth opportunities or that contribute to social welfare. These regulations still maintain the thresholds and substantiation requirements of the 2016 regulations aimed at discouraging tax-motivated inversions.

Background

Cross-border mergers can make the U.S. economy stronger by enabling U.S. companies to invest overseas and encouraging foreign investment to flow into the United States. In order for these benefits to be realized, these transactions should be driven by underlying economic considerations rather than by a desire to avoid U.S. taxes. One way for a U.S.-based multinational to avoid or reduce U.S. tax is for the company to expatriate by changing its tax residence from the U.S. to another country through an inversion transaction. Though there are some limitations, the transaction allows the inverted company to reduce future taxes on U.S.-source earnings, for example, by deducting interest paid on loans from the new foreign parent. In addition to potentially eroding the U.S. tax base, inversions may impose other costs on the U.S. economy. For instance, as a result of the inversion, a company's headquarters may move overseas. This loss of a U.S. corporate identity or location of headquarters for the company may reduce employment in the United States.

To limit inversions that are tax-motivated, section 7874 (enacted in 2004), in general, targets transactions in which a foreign corporation acquires a domestic corporation and, immediately after the transaction, the former shareholders of the domestic corporation make up a significant portion of the shareholders of the acquiring foreign corporation. If the former shareholders of the domestic corporation hold 80 percent or more of the stock of the foreign corporation after the transaction, the foreign corporation is treated as a domestic corporation for U.S. tax purposes. If the former shareholders hold at least 60 percent but less than 80 percent of the stock of the foreign acquiring corporation after the transaction, then the transaction is respected but use of tax attributes such as net operating losses and foreign tax credits is limited. Transactions where the former shareholders of the domestic corporation hold less than 60 percent of

the stock of the foreign acquiring corporation are generally not limited.

Since the enactment of section 7874, multiple sets of regulations have been issued interpreting the statute and restricting the ability of domestic corporations to undertake an inversion transaction.

The Tax Cuts and Jobs Act of 2017 (TCJA) reduced, but did not completely eliminate, the tax-motivated incentives to invert. Particular TCJA provisions that reduced those incentives include the reduction in the maximum U.S. statutory corporate tax rate from 35 percent to 21 percent, the exemption from U.S. tax of dividends received from certain foreign corporations, the strengthening of Internal Revenue Code Section 163(j) on interest stripping, and the adoption of four punitive disincentives for new inversions in the 60 percent to 80 percent range. While the TCJA also included provisions that may increase incentives to invert, including the tax imposed on Global Intangible Low Tax Income (GILTI) of foreign subsidiaries, overall tax-motivated incentives to invert were reduced.

The following qualitative analysis provides further detail regarding the anticipated impacts of this rulemaking.

Baseline

The 2016 regulations serve as the no-action baseline for our tax regulatory review. The 2016 regulations, which were issued pursuant to authority under sections 7874 and 7805 (as well as other sections), restrict the ability of U.S. companies to invert and reduce the incentives to invert.

Alternatives

As an alternative to these final regulations, Treasury considered retaining the 2016 regulations without amendment. Given public comment and the agency's desire to provide transparency and clarity to the public, Treasury decided against this approach and moved forward with the final regulations as drafted.

Anticipated Impacts

These final regulations maintain the thresholds and substantiation requirements of the 2016 regulations aimed at discouraging tax-motivated inversions. In response to public comments, the final regulations make certain limited changes to the 2016 regulations that are designed to improve clarity, provide additional exceptions to their application, and reduce unnecessary burdens on taxpayers, including by providing guidance on how to apply particular mechanical

rules. Specifically, clarifying changes were made to certain of the stock exclusion rules, and in particular, the passive assets rule, the serial acquisition rule, and the third country rule, as well as to the substantial business activities rule. Additional exceptions were added to the serial acquisition rule and the third country rule that narrowed their scope on the margins. Finally, changes to the passive assets rule, the NOCD rule, and the rules coordinating the application of the stock exclusion rules with the expanded affiliated group (EAG) rules were made to reduce complexity and ambiguity associated with these provisions.

Given the limited nature of the changes made by these final regulations relative to the no-action baseline, Treasury estimates that collectively, these final regulations are not economically significant under Executive Order 12866.

Revenue Impacts

Due to the narrow scope of clarifications and refinements in the final regulations and the small number of taxpayers subject to these regulations, Treasury does not anticipate any meaningful change to revenues.

Anticipated Benefits

At the margin, the final regulations may increase the incentive for cross-border mergers that are economically beneficial and not tax-motivated. The regulations are designed to help ensure that the regulations do not impact mergers that provide market benefits. Economically beneficial mergers make the U.S. economy stronger by enabling U.S. companies to invest overseas and encouraging foreign investment to flow into the U.S.

Anticipated Costs

The changes made by the final regulations are designed generally to reduce unnecessary burdens on taxpayers, an action that may lead to increased merger activity, and some of these additional mergers may potentially be tax-motivated at least in part. Due to the narrow scope of these changes, however, Treasury anticipates that any increase in tax-motivated cross-border merger activity will be relatively small relative to the no-action baseline and will not result in any meaningful adverse effects on economic activity relative to the no-action baseline. In particular, additional exceptions added to the serial acquisition rule and the third country rule are designed to narrow their role in defining cross-border mergers that are subject to targeted tax treatment.

Effects on Compliance Costs

The final regulations narrow the scope of regulated activities and reduce compliance costs relative to the 2016 regulations. The regulations also aim to reduce required paperwork burden, complexity, and ambiguities that may unintentionally discourage legitimate merger activity. In particular, changes that reduce complexity and ambiguity were made to the passive assets rule, the NOCD rule, and the rules coordinating the application of the stock exclusion rules with the expanded affiliated group (EAG) rules. Clarifying changes were made to the passive assets rule, the serial acquisition rule, the third country rule, and the substantial business activities rule.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply because the regulations do not impose a collection of information on small entities. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business. No comments were received.

Drafting Information

The principal authors of these regulations are Rose E. Jenkins and Shane M. McCarrick of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of the Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the entries for §§ 1.304–7T, 1.367(b)–4T, 1.956–2T, 1.7701(l)–4T, 1.7874–2T, 1.7874–3T, 1.7874–6T, 1.7874–7T, 1.7874–8T, 1.7874–9T, 1.7874–10T, 1.7874–11T, 1.7874–12T and adding entries for §§ 1.304–7, 1.7701(l)–4, 1.7874–2, 1.7874–6, 1.7874–7, 1.7874–8, 1.7874–9, 1.7874–10, 1.7874–11, and 1.7874–12 in numerical order and revising the entry for § 1.367(b)–4 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.304–7 also issued under 26 U.S.C. 304(b)(5)(C).

* * * * *

Section 1.367(b)–4 also issued under 26 U.S.C. 367(a) and (b) and 954(c)(6)(A).

* * * * *

Section 1.7701(l)–4 also issued under 26 U.S.C. 7701(l) and 954(c)(6)(A).

* * * * *

Section 1.7874–2 also issued under 26 U.S.C. 7874(c)(6) and (g).

* * * * *

Section 1.7874–6 also issued under 26 U.S.C. 7874(c)(6) and (g).

Section 1.7874–7 also issued under 26 U.S.C. 7874(c)(6) and (g).

Section 1.7874–8 also issued under 26 U.S.C. 7874(c)(6) and (g).

Section 1.7874–9 also issued under 26 U.S.C. 7874(c)(6) and (g).

Section 1.7874–10 also issued under 26 U.S.C. 7874(c)(4) and (g).

Section 1.7874–11 also issued under 26 U.S.C. 7874(g).

Section 1.7874–12 also issued under 26 U.S.C. 7874(g).

* * * * *

■ **Par. 2.** Section 1.304–7 is added to read as follows:

§ 1.304–7 Certain acquisitions by foreign acquiring corporations.

(a) *Scope.* This section provides rules regarding the application of section 304(b)(5)(B) to an acquisition of stock described in section 304 by an acquiring corporation that is foreign (foreign acquiring corporation). Paragraph (b) of this section provides the rule for determining which earnings and profits are taken into account for purposes of applying section 304(b)(5)(B). Paragraph (c) of this section provides rules addressing the use of a partnership, option (or similar interest), or other arrangement. Paragraph (d) of this section provides examples that illustrate the rules of this section. Paragraph (e) of this section provides the applicability date.

(b) *Earnings and profits taken into account.* For purposes of applying section 304(b)(5)(B), only the earnings and profits of the foreign acquiring corporation are taken into account in determining whether more than 50 percent of the dividends arising from the acquisition (determined without regard to section 304(b)(5)(B)) would neither be subject to tax under chapter 1 of subtitle A of the Internal Revenue Code for the taxable year in which the dividends arise (subject to tax) nor be includible in the earnings and profits of a controlled foreign corporation (includible by a controlled foreign corporation). For purposes of this section, a controlled foreign corporation has the meaning provided in section 957 and without regard to section 953(c),

determined without applying subparagraphs (A), (B), and (C) of section 318(a)(3) so as to consider a United States person as owning stock which is owned by a person who is not a United States person.

(c) *Use of a partnership, option (or similar interest), or other arrangement.* If a partnership, option (or similar interest), or other arrangement, is used with a principal purpose of avoiding the application of this section (for example, to treat a transferor as a controlled foreign corporation), then the partnership, option (or similar interest), or other arrangement will be disregarded for purposes of applying this section.

(d) *Examples.* The following examples illustrate the rules of this section. For purposes of the examples, assume the following facts in addition to the facts stated in the examples:

- (1) FA is a foreign corporation that is not a controlled foreign corporation;
- (2) FA wholly owns DT, a domestic corporation;
- (3) DT wholly owns FS1, a controlled foreign corporation; and
- (4) No portion of a dividend from FS1 would be treated as from sources within the United States under section 861.

Example 1—(i) Facts. DT has earnings and profits of \$51x, and FS1 has earnings and profits of \$49x. FA transfers DT stock with a fair market value of \$100x to FS1 in exchange for \$100x of cash.

(ii) *Analysis.* Under section 304(a)(2), the \$100x of cash is treated as a distribution in redemption of the stock of DT. The redemption of the DT stock is treated as a distribution to which section 301 applies pursuant to section 302(d), which ordinarily would be sourced first from FS1 under section 304(b)(2)(A). Without regard to the application of section 304(b)(5)(B), more than 50 percent of the dividend arising from the acquisition, taking into account only the earnings and profits of FS1 pursuant to paragraph (b) of this section, would neither be subject to tax nor includible by a controlled foreign corporation. In particular, no portion of a dividend from FS1 would be subject to tax or includible by a controlled foreign corporation. Accordingly, section 304(b)(5)(B) and paragraph (b) of this section apply to the transaction, and no portion of the distribution of \$100x is treated under section 301(c)(1) as a dividend out of the earnings and profits of FS1. Furthermore, the \$100x of cash is treated as a dividend to the extent of the earnings and profits of DT (\$51x).

Example 2—(i) Facts. FA and DT own 40 percent and 60 percent, respectively, of the capital and profits interests of PRS, a foreign partnership. PRS wholly owns FS2, a controlled foreign corporation. The FS2 stock has a fair market value of \$100x. FS1 has earnings and profits of \$150x. PRS transfers all of its FS2 stock to FS1 in exchange for \$100x of cash. DT enters into a gain

recognition agreement that complies with the requirements set forth in section 4.01 of Notice 2012–15, 2012–9 I.R.B 424, with respect to the portion (60 percent) of the FS2 stock that DT is deemed to transfer to FS1 in an exchange described in section 367(a)(1). See § 1.367(a)–1T(c)(3)(i)(A).

(ii) *Analysis.* Under section 304(a)(1), PRS and FS1 are treated as if PRS transferred its FS2 stock to FS1 in an exchange described in section 351(a) solely for FS1 stock, and, in turn, FS1 redeemed such FS1 stock in exchange for \$100x of cash. The redemption of the FS1 stock is treated as a distribution to which section 301 applies pursuant to section 302(d). Without regard to the application of section 304(b)(5)(B), more than 50 percent of a dividend arising from the acquisition, taking into account only the earnings and profits of FS1 pursuant to paragraph (b) of this section, would be subject to tax. In particular, 60 percent of a dividend from FS1 would be included in DT's distributive share of PRS's partnership income and therefore would be subject to tax. Accordingly, section 304(b)(5)(B) does not apply, and the entire distribution of \$100x is treated under section 301(c)(1) as a dividend out of the earnings and profits of FS1.

(e) *Applicability date.* This section applies to acquisitions that are completed on or after September 22, 2014.

§ 1.304–7T [Removed]

- **Par. 3.** Section 1.304–7T is removed.
- **Par. 4.** Section 1.367(a)–3 is amended by revising paragraphs (c)(3)(iii)(C) and (c)(11)(ii) to read as follows:

§ 1.367(a)–3 Treatment of transfers of stock or securities to foreign corporations.

* * * * *

- (c) * * *
- (3) * * *
- (iii) * * *

(C) *Special rule for U.S. target company value.* For purposes of § 1.367(a)–3(c)(3)(iii)(A), the fair market value of the U.S. target company includes the aggregate amount of non-ordinary course distributions (NOCDs) made by the U.S. target company. To calculate the aggregate value of NOCDs, the principles of § 1.7874–10, including the rule regarding predecessors in § 1.7874–10(e) and the rule regarding a deemed distribution of stock in certain cases in § 1.7874–10(g), apply. However, this paragraph (c)(3)(iii)(C) does not apply if the principles of the de minimis exception in § 1.7874–10(d) are satisfied.

* * * * *

- (11) * * *

(ii) *Applicability date of certain provisions of this paragraph (c).* The first and second sentence of paragraph (c)(3)(iii)(C) of this section apply to transfers completed on or after September 22, 2014. The third sentence

of paragraph (c)(3)(iii)(C) of this section applies to transfers completed on or after November 19, 2015. Taxpayers may, however, elect to apply the third sentence of paragraph (c)(3)(iii)(C) of this section to transfers completed on or after September 22, 2014, and before November 19, 2015.

* * * * *

§ 1.367(a)–3T [Removed]

- **Par. 5.** Section 1.367(a)–3T is removed.
- **Par. 6.** Section 1.367(b)–4 is amended by revising paragraph (a), paragraph (b) introductory text, and paragraphs (b)(1)(i)(C), (d)(1), (e), (f), (g), and (h) to read as follows:

§ 1.367(b)–4 Acquisition of foreign corporate stock or assets by a foreign corporation in certain nonrecognition transactions.

(a) *Scope.* This section applies to certain acquisitions by a foreign corporation of the stock or assets of a foreign corporation in an exchange described in section 351 or in a reorganization described in section 368(a)(1). Paragraph (b) of this section provides a rule regarding when an exchanging shareholder is required to include in income as a deemed dividend the section 1248 amount attributable to the stock that it exchanges. Paragraph (c) of this section provides a rule excluding deemed dividends from foreign personal holding company income. Paragraph (d) of this section provides rules for subsequent sales or exchanges. Paragraphs (e) and (f) of this section provide rules regarding certain exchanges following inversion transactions. Paragraph (g) of this section provides definitions and special rules, including special rules regarding triangular reorganizations and recapitalizations. Paragraph (h) of this section provides the applicability dates for certain paragraphs of this section. See also § 1.367(a)–3(b)(2) for transactions subject to the concurrent application of sections 367(a) and (b) and § 1.367(b)–2 for additional definitions that apply.

(b) *Income inclusion.* If a foreign corporation (the transferee foreign corporation) acquires the stock of a foreign corporation in an exchange described in section 351 or the stock or assets of a foreign corporation in a reorganization described in section 368(a)(1) (in either case, the foreign acquired corporation), then an exchanging shareholder must, if its exchange is described in paragraph (b)(1)(i), (b)(2)(i), or (b)(3) of this section, include in income as a deemed dividend the section 1248 amount

attributable to the stock that it exchanges.

(1) * * *

(i) * * *

(C) The exchange is not a specified exchange to which paragraph (e)(1) of this section applies.

* * * * *

(d) * * *

(1) *Rule.* If an exchanging shareholder (as defined in § 1.1248–8(b)(1)(iv)) is not required to include in income as a deemed dividend the section 1248 amount under paragraph (b) or paragraph (e)(1) of this section (non-inclusion exchange), then, for purposes of applying section 367(b) or 1248 to subsequent sales or exchanges, and subject to the limitation of § 1.367(b)–2(d)(3)(ii) (in the case of a transaction described in § 1.367(b)–3), the determination of the earnings and profits attributable to the stock an exchanging shareholder receives in the non-inclusion exchange is determined pursuant to the rules of section 1248 and the regulations under that section.

* * * * *

(e) *Income inclusion and gain recognition in certain exchanges following an inversion transaction—(1) General rule.* If a foreign corporation (the transferee foreign corporation) acquires stock of a foreign corporation in an exchange described in section 351 or stock or assets of a foreign corporation in a reorganization described in section 368(a)(1) (in either case, the foreign acquired corporation), then an exchanging shareholder must, if its exchange is a specified exchange and the exception in paragraph (e)(3) of this section does not apply—

(i) Include in income as a deemed dividend the section 1248 amount attributable to the stock that it exchanges; and

(ii) After taking into account the increase in basis provided in § 1.367(b)–2(e)(3)(ii) resulting from the deemed dividend (if any), recognize all realized gain with respect to the stock that would not otherwise be recognized.

(2) *Specified exchanges.* An exchange is a specified exchange if—

(i) Immediately before the exchange, the foreign acquired corporation is an expatriated foreign subsidiary and the exchanging shareholder is either an expatriated entity described in paragraph (b)(1)(i)(A)(1) of this section or an expatriated foreign subsidiary described in paragraph (b)(1)(i)(A)(2) of this section;

(ii) The stock received in the exchange is stock of a foreign corporation; and

(iii) The exchange occurs during the applicable period.

(3) *De minimis exception.* The exception in this paragraph (e)(3) applies if—

(i) Immediately after the exchange, the foreign acquired corporation (in the case of an acquisition of stock of the foreign acquired corporation) or the transferee foreign corporation (in the case of an acquisition of assets of the foreign acquired corporation) is a controlled foreign corporation;

(ii) The post-exchange ownership percentage with respect to the foreign acquired corporation (in the case of an acquisition of stock of the foreign acquired corporation) or the transferee foreign corporation (in the case of an acquisition of assets of the foreign acquired corporation) is at least 90 percent of the pre-exchange ownership percentage with respect to the foreign acquired corporation; and

(iii) The post-exchange ownership percentage with respect to each lower-tier expatriated foreign subsidiary of the foreign acquired corporation is at least 90 percent of the pre-exchange ownership percentage with respect to the lower-tier expatriated foreign subsidiary.

(4) *Certain exceptions from foreign personal holding company not available.* An income inclusion of a foreign corporation under paragraph (e)(1) of this section does not qualify for the exceptions from foreign personal holding company income provided by sections 954(c)(3)(A)(i) and 954(c)(6) (to the extent in effect).

(5) *Examples.* The following examples illustrate the application of this paragraph (e). For purposes of all of the examples, unless otherwise indicated: FP, a foreign corporation, owns all of the stock of USP, a domestic corporation, and all 40 shares of stock of FS, a controlled foreign corporation for its taxable year beginning January 1, 2017, but not for prior taxable years, except as a result of a transaction described in the facts of an example. USP owns all 50 shares of stock of FT1, a controlled foreign corporation, which, in turn, owns all 50 shares of FT2, a controlled foreign corporation. FP acquired all of the stock of USP in an inversion transaction that was completed on July 1, 2016. Therefore, with respect to that inversion transaction, USP is an expatriated entity; FT1 and FT2 are expatriated foreign subsidiaries; and FP and FS are each a non-EFS foreign related person. All entities have a calendar year tax year for U.S. tax purposes. All shares of stock have a fair market value of \$1x, and each corporation has a single class of stock outstanding.

Example 1. Specified exchange to which general rule applies—(i) Facts. During the applicable period, and pursuant to a reorganization described in section 368(a)(1)(B), FT1 transfers all 50 shares of FT2 stock to FS in exchange solely for 50 newly issued voting shares of FS. Immediately before the exchange, USP is a section 1248 shareholder with respect to FT1 and FT2. At the time of the exchange, the FT2 stock owned by FT1 has a fair market value of \$50x and an adjusted basis of \$5x, such that the FT2 stock has a built-in gain of \$45x. In addition, the earnings and profits of FT2 attributable to FT1's stock in FT2 for purposes of section 1248 is \$30x, taking into account the rules of § 1.367(b)–2(c)(1)(i) and (ii), and therefore the section 1248 amount with respect to the FT2 stock is \$30x (the lesser of the \$45x of built-in gain and the \$30x of earnings and profits attributable to the stock).

(ii) *Analysis.* FT1's exchange is a specified exchange because the requirements set forth in paragraphs (e)(2)(i) through (iii) of this section are satisfied. The requirement set forth in paragraph (e)(2)(i) of this section is satisfied because, immediately before the exchange, FT2 (the foreign acquired corporation) is an expatriated foreign subsidiary and FT1 (the exchanging shareholder) is an expatriated foreign subsidiary that is described in paragraph (b)(1)(i)(A)(2) of this section. The requirement set forth in paragraph (e)(2)(ii) of this section is also satisfied because the stock received in the exchange (FS stock) is stock of a foreign corporation. The requirement set forth in paragraph (e)(2)(iii) of this section is satisfied because the exchange occurs during the applicable period. Accordingly, under paragraph (e)(1)(i) of this section, FT1 must include in income as a deemed dividend \$30x, the section 1248 amount with respect to its FT2 stock. In addition, under paragraph (e)(1)(ii) of this section, FT1 must, after taking into account the increase in basis provided in § 1.367(b)–2(e)(3)(ii) resulting from the deemed dividend (which increases FT1's basis in its FT2 stock from \$5x to \$35x), recognize \$15x (\$50x amount realized less \$35x basis), the realized gain with respect to the FT2 stock that would not otherwise be recognized.

Example 2. De minimis shift to non-EFS foreign related persons—(i) Facts. The facts are the same as in the introductory sentences of this paragraph (e)(5), except as follows. FT1 does not own any shares of FT2, and all 40 shares of FS are owned by DX, a domestic corporation wholly owned by individual A, and thus FS is not a non-EFS foreign related person. During the applicable period and pursuant to a reorganization described in section 368(a)(1)(D), FT1 transfers all of its assets to FS in exchange for 50 newly issued FS shares, FT1 distributes the 50 FS shares to USP in liquidation under section 361(c)(1), and USP exchanges its 50 shares of FT1 stock for the 50 FS shares under section 354. Further, immediately after the exchange, FS is a controlled foreign corporation.

(ii) *Analysis.* Although USP's exchange is a specified exchange, paragraph (e)(1) of this section does not apply to the exchange because, as described in paragraphs (ii)(A)

through (C) of this *Example 2*, the requirements of paragraph (e)(3) of this section are satisfied.

(A) Because the assets, rather than the stock, of FT1 (the foreign acquired corporation) are acquired, the requirement set forth in paragraph (e)(3)(i) of this section is satisfied if FS (the transferee foreign corporation) is a controlled foreign corporation immediately after the exchange. As stated in the facts, FS is a controlled foreign corporation immediately after the exchange.

(B) The requirement set forth in paragraph (e)(3)(ii) of this section is satisfied if the post-exchange ownership percentage with respect to FS is at least 90% of the pre-exchange ownership percentage with respect to FT1. Because USP, a domestic corporation that is an expatriated entity, directly owns 50 shares of FT1 stock immediately before the exchange, none of those shares are treated as indirectly owned by FP (a non-EFS foreign related person) for purposes of calculating the pre-exchange ownership percentage with respect to FT1. See paragraph (g)(1) of this section. Thus, for purposes of calculating the pre-exchange ownership percentage with respect to FT1, FP is treated as directly or indirectly owning 0%, or 0 of 50 shares, of the stock of FT1. Accordingly, the pre-exchange ownership percentage with respect to FT1 is 100 (calculated as 100% less 0%, the percentage of FT1 stock that non-EFS foreign related persons are treated as directly or indirectly owning immediately before the exchange). Consequently, for the requirement set forth in paragraph (e)(3)(ii) of this section to be satisfied, the post-exchange ownership percentage with respect to FS must be at least 90. Because USP, a domestic corporation that is an expatriated entity, directly owns 50 shares of FS stock immediately after the exchange, none of those shares are treated as indirectly owned by FP (a non-EFS foreign related person) for purposes of calculating the post-exchange ownership percentage with respect to FS. See paragraph (g)(1) of this section. Thus, for purposes of calculating the post-exchange ownership percentage with respect to FS, FP is treated as directly or indirectly owning 0%, or 0 of 90 shares, of the stock of FS. As a result, the post-exchange ownership percentage with respect to FS is 100 (calculated as 100% less 0%, the percentage of FS stock that non-EFS foreign related persons are treated as directly or indirectly owning immediately after the exchange). Therefore, because the post-exchange ownership percentage with respect to FS (100) is at least 90, the requirement set forth in paragraph (e)(3)(ii) of this section is satisfied.

(C) Because there is not a lower-tier expatriated foreign subsidiary of FT1, the requirement set forth in paragraph (e)(3)(iii) of this section does not apply.

(f) *Gain recognition upon certain transfers of property described in section 351 following an inversion transaction*—(1) *General rule.* If, during the applicable period, an expatriated foreign subsidiary transfers specified property to a foreign corporation (the transferee foreign corporation) in an

exchange described in section 351, then the expatriated foreign subsidiary must recognize all realized gain with respect to the specified property transferred that would not otherwise be recognized, unless the exception in paragraph (f)(2) of this section applies.

(2) *De minimis exception.* The exception in this paragraph (f)(2) applies if—

(i) Immediately after the transfer, the transferee foreign corporation is a controlled foreign corporation; and

(ii) The post-exchange ownership percentage with respect to the transferee foreign corporation is at least 90 percent of the pre-exchange ownership percentage with respect to the expatriated foreign subsidiary.

(3) *Examples.* The following examples illustrate the application of this paragraph (f). For purposes of all of the examples, unless otherwise indicated: FP, a foreign corporation, owns all of the stock of USP, a domestic corporation, and all 10 shares of stock of FS, a controlled foreign corporation for its taxable year beginning January 1, 2017, but not for prior taxable years, except as a result of a transaction described in the facts of an example. USP owns all 50 shares of stock of FT, a controlled foreign corporation. FT owns Asset A, which is specified property with a fair market value of \$50x and an adjusted basis of \$10x. FP acquired all of the stock of USP in an inversion transaction that was completed on or after September 22, 2014. Accordingly, with respect to that inversion transaction, USP is an expatriated entity, FT is an expatriated foreign subsidiary, and FP and FS are each a non-EFS foreign related person. All entities have a calendar year tax year for U.S. tax purposes. All shares of stock have a fair market value of \$1x, and each corporation has a single class of stock outstanding.

Example 1. Transfer to which general rule applies—(i) *Facts.* In addition to the stock of USP and FS, FP owns Asset B, which has a fair market value of \$40x. During the applicable period, and pursuant to an exchange described in section 351, FT transfers Asset A to FS in exchange for 50 newly issued shares of FS stock, and FP transfers Asset B to FS in exchange for 40 newly issued shares of FS stock.

(ii) *Analysis.* Paragraph (f)(1) of this section applies to the transfer by FT (an expatriated foreign subsidiary) of Asset A, which is specified property, to FS (the transferee foreign corporation). Thus, FT must recognize gain of \$40x under paragraph (f)(1) of this section, which is the realized gain with respect to Asset A that would not otherwise be recognized (\$50x amount realized less \$10x basis). For rules regarding whether the FS stock held by FT is treated

as United States property for purposes of section 956, see § 1.956-2(a)(4)(i).

Example 2. De minimis shift to non-EFS foreign related persons—(i) *Facts.* Individual, a United States person, owns Asset B, which has a fair market value of \$40x. During the applicable period, and pursuant to an exchange described in section 351, FT transfers Asset A to FS in exchange for 50 newly issued shares of FS stock, and Individual transfers Asset B to FS in exchange for 40 newly issued shares of FS stock.

(ii) *Analysis.* Paragraph (f)(1) of this section does not apply to the transfer by FT (an expatriated foreign subsidiary) of Asset A, which is specified property, to FS (the transferee foreign corporation) because the requirements set forth in paragraph (f)(2) of this section are satisfied. The requirement set forth in paragraph (f)(2)(i) of this section is satisfied because FS is a controlled foreign corporation immediately after the transfer.

The requirement set forth in paragraph (f)(2)(ii) of this section is satisfied if the post-exchange ownership percentage with respect to FS is at least 90 percent of the pre-exchange ownership percentage with respect to FT. Because USP, a domestic corporation that is an expatriated entity, directly owns 50 shares of FT stock immediately before the transfer, none of those shares are treated as indirectly owned by FP (a non-EFS foreign related person) for purposes of calculating the pre-exchange ownership percentage with respect to FT. See paragraph (g)(1) of this section. Thus, for purposes of calculating the pre-exchange ownership percentage with respect to FT, FP is treated as directly or indirectly owning 0 percent, or 0 of 50 shares, of the stock of FT. Accordingly, the pre-exchange ownership percentage with respect to FT is 100 (calculated as 100 percent less 0 percent, the percentage of FT stock that non-EFS foreign related persons are treated as directly or indirectly owning immediately before the transfer).

Consequently, for the requirement set forth in paragraph (f)(2)(ii) of this section to be satisfied, the post-exchange ownership percentage with respect to FS must be at least 90. Although FP directly owns 10 FS shares, none of the 50 FS shares that FP owns through USP (a domestic corporation that is an expatriated entity) are treated as indirectly owned by FP for purposes of calculating the post-exchange ownership percentage with respect to FS because USP directly owns them. See paragraph (g)(1) of this section. Thus, for purposes of calculating the post-exchange ownership percentage with respect to FS, FP is treated as directly or indirectly owning 10 percent, or 10 of 100 shares, of the stock of FS. As a result, the post-exchange ownership percentage with respect to FS is 90 (calculated as 100 percent less 10 percent, the percentage of FS stock that non-EFS foreign related persons are treated as directly or indirectly owning immediately after the transfer). Therefore, because the post-exchange ownership percentage with respect to FS (90) is at least 90, the requirement set forth in paragraph (f)(2)(ii) of this section is satisfied.

(g) *Definitions and special rules.* In addition to the definitions and special

rules in §§ 1.367(b)–2 and 1.7874–12, the following definitions and special rules apply for purposes of this section.

(1) *Indirect ownership.* To determine indirect ownership of the stock of a corporation for purposes of calculating a pre-exchange ownership percentage or post-exchange ownership percentage with respect to that corporation, the principles of section 958(a) apply without regard to whether an intermediate entity is foreign or domestic. For this purpose, stock of the corporation that is directly or indirectly (applying the principles of section 958(a) without regard to whether an intermediate entity is foreign or domestic) owned by a domestic corporation that is an expatriated entity is not treated as indirectly owned by a non-EFS foreign related person.

(2) A *lower-tier expatriated foreign subsidiary* means an expatriated foreign subsidiary whose stock is directly or indirectly owned (under the principles of section 958(a)) by an expatriated foreign subsidiary.

(3) *Pre-exchange ownership percentage* means, with respect to a corporation, 100 percent less the percentage of stock (by value) in the corporation that, immediately before an exchange, is owned, in the aggregate, directly or indirectly by non-EFS foreign related persons.

(4) *Post-exchange ownership percentage* means, with respect to a corporation, 100 percent less the percentage of stock (by value) in the corporation that, immediately after the exchange, is owned, in the aggregate, directly or indirectly by non-EFS foreign related persons.

(5) *Specified property* means any property other than stock of a lower-tier expatriated foreign subsidiary.

(6) *Recapitalizations.* A foreign corporation that undergoes a reorganization described in section 368(a)(1)(E) is treated as both the foreign acquired corporation and the transferee foreign corporation.

(7) *Triangular reorganizations—(i) Definition.* A triangular reorganization means a reorganization described in § 1.358–6(b)(2)(i) (forward triangular merger), (ii) (triangular C reorganization), (iii) (reverse triangular merger), (iv) (triangular B reorganization), and (v) (triangular G reorganization).

(ii) *Special rules—(A) Triangular reorganizations other than a reverse triangular merger.* In the case of a triangular reorganization other than a reverse triangular merger, the surviving corporation is the transferee foreign corporation that acquires the assets or stock of the foreign acquired

corporation, and the reference to controlling corporation (foreign or domestic) is to the corporation that controls the surviving corporation.

(B) *Reverse triangular merger.* In the case of a reverse triangular merger, the surviving corporation is the entity that survives the merger, and the controlling corporation (foreign or domestic) is the corporation that before the merger controls the merged corporation. In the case of a reverse triangular merger, this section applies only if stock of the foreign surviving corporation is exchanged for stock of a foreign corporation in control of the merging corporation; in such a case, the foreign surviving corporation is treated as a foreign acquired corporation.

(h) *Applicability date of certain paragraphs in this section.* Except as otherwise provided in this paragraph (h), paragraphs (a), (b) introductory text, (b)(1)(i)(C), (d)(1), (e), (f), and (g) of this section apply to exchanges completed on or after September 22, 2014, but only if the inversion transaction was completed on or after September 22, 2014. Paragraph (e)(1)(ii) of this section applies to exchanges completed on or after November 19, 2015, but only if the inversion transaction was completed on or after September 22, 2014. The portion of paragraph (e)(2)(i) of this section that requires the exchanging shareholder to be an expatriated entity or an expatriated foreign subsidiary apply to exchanges completed on or after April 4, 2016, but only if the inversion transaction was completed on or after September 22, 2014. For inversion transactions completed on or after September 22, 2014, however, taxpayers may elect to apply the portion of paragraph (e)(2)(i) of this section that requires the exchanging shareholder to be an expatriated entity or an expatriated foreign subsidiary to exchanges completed on or after September 22, 2014, and before April 4, 2016. Paragraphs (f) and (g)(5) of this section apply to transfers completed on or after April 4, 2016, but only if the inversion transaction was completed or after September 22, 2014. See § 1.367(b)–4, as contained in 26 CFR part 1 revised as of April 1, 2016, for exchanges completed before September 22, 2014.

§ 1.367(b)–4T [Removed]

■ **Par. 7.** Section 1.367(b)–4T is removed.

§ 1.367(b)–6 [Amended]

■ **Par. 8.** Section 1.367(b)–6 is amended by:

- 1. Removing paragraph (a)(1)(iii).

■ 2. Redesignating paragraphs (a)(1)(iv) and (v) as (a)(1)(iii) and (iv), respectively.

■ 3. In newly redesignated paragraph (a)(1)(iv), removing the language “1.367(b)–4(a), §” in the first sentence and removing the language “§ 1.367(b)–4(a)” in the second sentence.

■ **Par. 9.** Section 1.956–2 is amended by:

■ 1. Revising paragraphs (a)(4), (c)(5), and (d)(2).

■ 2. Adding paragraphs (f) and (h)(3) through (6).

■ 3. Removing paragraph (i).

The revisions and additions read as follows:

§ 1.956–2 Definition of United States property.

(a) * * *

(4) *Certain foreign stock and obligations held by expatriated foreign subsidiaries following an inversion transaction—(i) General rule.* Except as provided in paragraph (a)(4)(ii) of this section, for purposes of section 956 and paragraph (a) of this section, United States property includes an obligation of a foreign person and stock of a foreign corporation when the following conditions are satisfied—

(A) The obligation or stock is held by a controlled foreign corporation that is an expatriated foreign subsidiary, regardless of whether, when the obligation or stock was acquired, the acquirer was a controlled foreign corporation or an expatriated foreign subsidiary;

(B) The foreign person or foreign corporation is a non-EFS foreign related person, regardless of whether, when the obligation or stock was acquired, the foreign person or foreign corporation was a non-EFS foreign related person; and

(C) The obligation or stock was acquired—

(1) During the applicable period; or

(2) In a transaction related to the inversion transaction.

(ii) *Exceptions.* For purposes of section 956 and paragraph (a) of this section, United States property does not include—

(A) Any obligation of a non-EFS foreign related person arising in connection with the sale or processing of property if the amount of the obligation at no time during the taxable year exceeds the amount that would be ordinary and necessary to carry on the trade or business of both the other party to the sale or processing transaction and the non-EFS foreign related person had the sale or processing transaction been made between unrelated persons; and

(B) Any obligation of a non-EFS foreign related person to the extent the

principal amount of the obligation does not exceed the fair market value of readily marketable securities sold or purchased pursuant to a sale and repurchase agreement or otherwise posted or received as collateral for the obligation in the ordinary course of its business by a United States or foreign person which is a dealer in securities or commodities.

(iii) *Definitions.* The definitions in § 1.7874–12 apply for the purposes of the application of paragraphs (a)(4), (c)(5), and (d)(2) of this section.

(iv) *Examples.* The following examples illustrate the rules of this paragraph (a)(4). For purposes of the examples, FA, a foreign corporation, wholly owns DT, a domestic corporation, which, in turn, wholly owns FT, a foreign corporation that is a controlled foreign corporation. FA also wholly owns FS, a foreign corporation that is a controlled foreign corporation for its taxable year beginning January 1, 2017, but not for prior taxable years except as a result of a transaction described in the facts of an example. All entities have a calendar year tax year for U.S. tax purposes. FA acquired DT in an inversion transaction that was completed on January 1, 2015.

Example 1. (A) Facts. FT acquired an obligation of FS on January 31, 2015.

(B) *Analysis.* Pursuant to § 1.7874–12, DT is a domestic entity, FT is an expatriated foreign subsidiary, and FS is a non-EFS foreign related person. In addition, FT acquired the FS obligation during the applicable period. Thus, as of January 31, 2015, the obligation of FS is United States property with respect to FT for purposes of section 956(a) and this paragraph (a).

Example 2. (A) Facts. The facts are the same as in *Example 1* of this paragraph (a)(4)(iv), except that on February 15, 2015, FT contributed assets to FS in exchange for 60% of the stock of FS, by vote and value.

(B) *Analysis.* As a result of the transaction on February 15, 2015, FS became a controlled foreign corporation with respect to which an expatriated entity, DT, is a United States shareholder. Accordingly, under § 1.7874–12(a)(9), FS is an expatriated foreign subsidiary, and is therefore not a non-EFS foreign related person. Thus, as of February 15, 2015, the stock and obligation of FS are not United States property with respect to FT for purposes of section 956(a) and this paragraph (a). FS is not excluded from the definition of expatriated foreign subsidiary pursuant to § 1.7874–12(a)(9)(ii) because FS was not a CFC on the completion date.

Example 3. (A) Facts. Before the inversion transaction, FA also wholly owns USP, a domestic corporation, which, in turn, wholly owns, LFS, a foreign corporation that is a controlled foreign corporation. DT was not a United States shareholder of LFS on or before the completion date. On January 31, 2015, FT contributed assets to LFS in exchange for 60% of the stock of LFS, by vote and value.

FT acquired an obligation of LFS on February 15, 2015.

(B) *Analysis.* LFS is a foreign related person. Because LFS was a controlled foreign corporation and a member of the EAG with respect to the inversion transaction on the completion date, and DT was not a United States shareholder with respect to LFS on or before the completion date, LFS is excluded from the definition of expatriated foreign subsidiary pursuant to § 1.7874–12(a)(9)(ii). Thus, pursuant to § 1.7874–12(a)(16), LFS is a non-EFS foreign related person, and the stock and obligation of LFS are United States property with respect to FT for purposes of section 956(a) and this paragraph (a). The fact that FT contributed assets to LFS in exchange for 60% of the stock of LFS does not change this result.

Example 4. (A) Facts. The facts are the same as in *Example 3* of this paragraph (a)(4)(iv), except that on February 10, 2015, LFS organized a new foreign corporation (LFSS), transferred all of its assets to LFSS, and liquidated, in a transaction treated as a reorganization described in section 368(a)(1)(F), and FT acquired an obligation of LFSS, instead of LFS, on February 15, 2015. On March 1, 2015, LFSS acquired an obligation of FS.

(B) *Analysis.* LFS is a controlled foreign corporation with respect to which USP, an expatriated entity, is a United States shareholder. USP is an expatriated entity because on the completion date, USP and DT became related to each other within the meaning of section 267(b). Because LFSS was not a member of the EAG with respect to the inversion transaction on the completion date, LFSS is not excluded from the definition of expatriated foreign subsidiary pursuant to § 1.7874–12(a)(9)(ii). Accordingly, under § 1.7874–12(a)(9)(i), LFSS is an expatriated foreign subsidiary and is therefore not a non-EFS foreign related person. Thus, the stock and obligation of LFSS are not United States property with respect to FT for purposes of section 956(a) and paragraph (a) of this section. However, because LFSS is an expatriated foreign subsidiary, pursuant to § 1.7874–12(a)(9), the obligation of FS, a non-EFS foreign related person, is United States property with respect to LFSS for purposes of section 956(a) and this paragraph (a).

* * * * *

(c) * * *

(5) *Special guarantee and pledge rule for expatriated foreign subsidiaries—*(i)

General rule. In applying paragraphs (c)(1) and (2) of this section to a controlled foreign corporation that is an expatriated foreign subsidiary, the phrase “of a United States person or a non-EFS foreign related person” is substituted for the phrase “of a United States person” each place it appears.

(ii) *Additional rules.* The rule in paragraph (c)(5)(i) of this section—

(A) Applies regardless of whether, when the pledge or guarantee was entered into or treated as entered into, the controlled foreign corporation was a controlled foreign corporation or an expatriated foreign subsidiary, or a

foreign person whose obligation is subject to the pledge or guarantee, or deemed pledge or guarantee, was a non-EFS foreign related person; and

(B) Applies to pledges or guarantees entered into, or treated pursuant to paragraph (c)(2) of this section as entered into—

(1) During the applicable period; or

(2) In a transaction related to the inversion transaction.

(d) * * *

(2) *Obligation defined.* For purposes of section 956 and this section, the term “obligation” includes any bond, note, debenture, certificate, bill receivable, account receivable, note receivable, open account, or other indebtedness, whether or not issued at a discount and whether or not bearing interest, except that the term does not include—

(i) Any indebtedness arising out of the involuntary conversion of property which is not United States property within the meaning of paragraph (a) of this section;

(ii) Any obligation of a United States person (as defined in section 957(c)) arising in connection with the provision of services by a controlled foreign corporation to the United States person if the amount of the obligation outstanding at any time during the taxable year of the controlled foreign corporation does not exceed an amount which would be ordinary and necessary to carry on the trade or business of the controlled foreign corporation and the United States person if they were unrelated. The amount of the obligations shall be considered to be ordinary and necessary to the extent of such receivables that are paid within 60 days;

(iii) Any obligation of a non-EFS foreign related person arising in connection with the provision of services by an expatriated foreign subsidiary to the non-EFS foreign related person if the amount of the obligation outstanding at any time during the taxable year of the expatriated foreign subsidiary does not exceed an amount which would be ordinary and necessary to carry on the trade or business of the expatriated foreign subsidiary and the non-EFS foreign related person if they were unrelated. The amount of the obligations shall be considered to be ordinary and necessary to the extent of such receivables that are paid within 60 days; or

(iv) Any obligation of a United States person (as defined in section 957(c)) that is collected within 30 days from the time it is incurred (a *30-day obligation*), unless the controlled foreign corporation that holds the 30-day

obligation holds for 60 or more calendar days during the taxable year in which it holds the 30-day obligation any obligations which, without regard to the exclusion described in this paragraph (d)(2)(iv), would constitute United States property within the meaning of section 956 and paragraph (a) of this section.

* * * * *

(f) [Reserved]. For further guidance, see § 1.956-2T(f).

* * * * *

(h) * * *

(3) Except as otherwise provided in this paragraph (h)(3), paragraphs (a)(4) and (c)(5) of this section apply to obligations or stock acquired or to pledges or guarantees entered into, or treated as entered into, on or after September 22, 2014, but only if the inversion transaction was completed on or after September 22, 2014. The phrase “, regardless of whether, when the obligation or stock was acquired, the acquirer was a controlled foreign corporation or an expatriated foreign subsidiary” in paragraph (a)(4)(i)(A) of this section, the phrase “regardless of whether, when the obligation or stock was acquired, the foreign person or foreign corporation was a non-EFS foreign related person” in paragraph (a)(4)(i)(B) of this section, and paragraphs (a)(4)(i)(C)(2), (c)(5)(ii)(A), and (c)(5)(ii)(B)(2) of this section apply to obligations or stock acquired or pledges or guarantees entered into or treated as entered into on or after April 4, 2016, but only if the inversion transaction was completed on or after September 22, 2014. Paragraph (a)(4)(ii) of this section applies to obligations acquired on or after April 4, 2016. For inversion transactions completed on or after September 22, 2014, however, taxpayers may elect to apply paragraph (a)(4)(ii) of this section to an obligation acquired before April 4, 2016. For purposes of paragraph (a)(4)(i) of this section and this paragraph (h)(3), a deemed exchange of an obligation or stock pursuant to section 1001 constitutes an acquisition of the obligation or stock. For purposes of paragraph (c)(5) of this section and this paragraph (h)(3), a pledgor or guarantor or deemed pledgor or guarantor is treated as entering into a pledge or guarantee when there is a significant modification, within the meaning of § 1.1001-3(e), of an obligation with respect to which it is a pledgor or guarantor or is treated as a pledgor or guarantor.

(4) Paragraphs (d)(2)(i) and (ii) of this section are effective June 14, 1988, with

respect to investments made on or after June 14, 1988.

(5) Paragraph (d)(2)(iii) of this section applies to obligations acquired on or after April 4, 2016, but only if the inversion transaction was completed on or after September 22, 2014. For inversion transactions completed on or after September 22, 2014, however, taxpayers may elect to apply paragraph (d)(2)(iii) of this section to an obligation acquired on or after September 22, 2014, and before April 4, 2016. For purposes of paragraph (d)(2)(iii) of this section and this paragraph (h)(5), a significant modification, within the meaning of § 1.1001-3(e), of an obligation on or after April 4, 2016, constitutes an acquisition of an obligation on or after April 4, 2016.

(6) Paragraph (d)(2)(iv) of this section applies to obligations held on or after September 16, 1988. See § 1.956-2T(d)(2)(v), as contained in 26 CFR part 1 revised as of April 1, 2017, for additional rules applicable to certain taxable years of a foreign corporation beginning before January 1, 2011.

■ **Par. 10.** Section 1.956-2T is amended by:

■ 1. Removing and reserving paragraph (a)(4).

■ 2. Revising paragraphs (b)(2) through (c)(4).

■ 3. Removing and reserving paragraphs (c)(5) and (d)(2).

■ 4. Removing paragraphs (i) and (j).

The revisions read as follows:

§ 1.956-2T Definition of United States property (temporary).

* * * * *

(b)(2) through (c)(4). [Reserved] For further guidance, see § 1.956-2(b)(2) through (c)(4).

* * * * *

■ **Par. 11.** Section 1.7701(l)-4 is added to read as follows:

§ 1.7701(l)-4 Rules regarding inversion transactions.

(a) *Overview.* This section provides rules applicable to United States shareholders of controlled foreign corporations after certain inversion transactions. Paragraph (b) of this section defines specified transactions and provides the scope of the rules in this section. Paragraph (c) of this section provides rules recharacterizing certain specified transactions. Paragraph (d) of this section sets forth rules governing transactions that affect the stock of an expatriated foreign subsidiary following a recharacterized specified transaction. Paragraph (e) of this section sets forth a rule concerning the treatment of amounts included in income as a result of a specified transaction as foreign

personal holding company income. Paragraph (f) of this section sets forth definitions that apply for purposes of this section. Paragraph (g) of this section sets forth examples illustrating these rules. Paragraph (h) of this section provides applicability dates. See § 1.367(b)-4(e) and (f) for rules concerning certain other exchanges after an inversion transaction. See also § 1.956-2(a)(4), (c)(5), and (d)(2) for additional rules applicable to United States property held by controlled foreign corporations after an inversion transaction.

(b) *Specified transaction*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, paragraph (c) of this section applies to specified transactions. For purposes of this section, a *specified transaction* is, with respect to an expatriated foreign subsidiary, a transaction in which stock of the expatriated foreign subsidiary is issued or transferred to a person that immediately before the issuance or transfer is a specified related person, provided the transaction occurs during the applicable period. However, a specified transaction does not include a transaction in which stock of the expatriated foreign subsidiary is deemed issued pursuant to section 304.

(2) *Exceptions.* Paragraph (c) of this section does not apply to a specified transaction—

(i) That is a fast-pay arrangement that is recharacterized under § 1.7701(l)-3(c)(2);

(ii) In which the specified stock was transferred by a shareholder of the expatriated foreign subsidiary, and the shareholder either—

(A) Pursuant to § 1.367(b)-4(e)(1), both—

(1) Included in gross income as a deemed dividend the section 1248 amount attributable to the specified stock; and

(2) After taking into account the increase in basis provided in § 1.367(b)-2(e)(3)(ii) resulting from the deemed dividend (if any), recognized all realized gain with respect to the stock that otherwise would not have been recognized; or

(B) Included in gross income all of the gain recognized on the transfer of the specified stock (including gain included in gross income as a dividend pursuant to section 964(e), section 1248(a), or section 356(a)(2)); or

(iii) In which—

(A) Immediately after the specified transaction and any related transaction, the expatriated foreign subsidiary is a controlled foreign corporation;

(B) The post-transaction ownership percentage with respect to the

expatriated foreign subsidiary is at least 90 percent of the pre-transaction ownership percentage with respect to the expatriated foreign subsidiary; and

(C) The post-transaction ownership percentage with respect to any lower-tier expatriated foreign subsidiary is at least 90 percent of the pre-transaction ownership percentage with respect to the lower-tier expatriated foreign subsidiary. See *Example 3* and *Example 4* of paragraph (g) of this section.

(c) *Recharacterization of specified transactions*—(1) *In general.* Except as otherwise provided, a specified transaction that is recharacterized under this paragraph (c) is recharacterized for all purposes of the Internal Revenue Code as of the date on which the specified transaction occurs, unless and until the rules of paragraph (d) of this section apply to alter or terminate the recharacterization. For purposes of paragraphs (c)(2) and (3) and (d) of this section, stock is considered owned by a section 958(a) U.S. shareholder if it is owned within the meaning of section 958(a) by the section 958(a) U.S. shareholder.

(2) *Specified transactions through stock issuance.* A specified transaction in which the specified stock is issued by an expatriated foreign subsidiary to a specified related person is recharacterized as follows—

(i) The transferred property is treated as having been transferred by the specified related person to the persons that were section 958(a) U.S. shareholders of the expatriated foreign subsidiary immediately before the specified transaction, in proportion to the stock of the expatriated foreign subsidiary owned by each section 958(a) U.S. shareholder, in exchange for deemed instruments in the section 958(a) U.S. shareholders; and

(ii) The transferred property treated as transferred to the section 958(a) U.S. shareholders pursuant to paragraph (c)(2)(i) of this section is treated as having been contributed by the section 958(a) U.S. shareholders (through intermediate entities, if any, in exchange for equity in the intermediate entities) to the expatriated foreign subsidiary in exchange for deemed issued stock in the expatriated foreign subsidiary. See *Example 1*, *Example 2*, and *Example 6* of paragraph (g) of this section.

(3) *Specified transactions through shareholder transfer.* A specified transaction in which specified stock is transferred by shareholders of the expatriated foreign subsidiary to a specified related person is recharacterized as follows—

(i) The transferred property is treated as having been transferred by the specified related person to the persons that were section 958(a) U.S. shareholders of the expatriated foreign subsidiary immediately before the specified transaction, in proportion to the specified stock owned by each section 958(a) U.S. shareholder, in exchange for deemed instruments in the section 958(a) U.S. shareholders; and

(ii) To the extent the section 958(a) U.S. shareholders are not the transferring shareholders, the transferred property treated as transferred to the section 958(a) U.S. shareholders pursuant to paragraph (c)(3)(i) of this section is treated as having been contributed by the section 958(a) U.S. shareholders (through intermediate entities, if any, in exchange for equity in the intermediate entities) to the transferring shareholder in exchange for equity in the transferring shareholder. See *Example 5* of paragraph (g) of this section.

(4) *Treatment of deemed instruments following a recharacterized specified transaction*—(i) *Deemed instruments.* The deemed instruments described in paragraphs (c)(2) and (3) of this section have the same terms as the specified stock issued or transferred pursuant to the specified transaction (that is, the disregarded specified stock), other than the issuer. When a distribution is made with respect to the disregarded specified stock, matching seriatim distributions with respect to the deemed issued stock are treated as made by the expatriated foreign subsidiary, through intermediate entities, if any, to the section 958(a) U.S. shareholders, which, in turn, are treated as making corresponding payments with respect to the deemed instruments to the specified related person.

(ii) *Paying agent.* The expatriated foreign subsidiary is treated as the paying agent of the section 958(a) U.S. shareholder with respect to the deemed instruments treated as issued by the section 958(a) U.S. shareholder to the specified related person.

(d) *Transactions affecting ownership of stock of an expatriated foreign subsidiary following a recharacterized specified transaction*—(1) *Transfers of stock other than specified stock.* When, after a specified transaction with respect to an expatriated foreign subsidiary that is recharacterized under paragraph (c)(2) or (3) of this section, stock of the expatriated foreign subsidiary, other than disregarded specified stock, that is owned by a section 958(a) U.S. shareholder is transferred, the deemed issued stock treated as owned by the section 958(a) U.S. shareholder as a

result of the specified transaction continues to be treated as directly owned by the holder, as are the deemed instruments treated as issued to the specified related person as a result of the specified transaction.

(2) *Transactions in which the expatriated foreign subsidiary ceases to be a foreign related person.* When, after a specified transaction with respect to an expatriated foreign subsidiary that is recharacterized under paragraph (c)(2) or (3) of this section, there is a transaction that affects the ownership of the stock (including disregarded specified stock) of the expatriated foreign subsidiary, and, immediately after the transaction, the expatriated foreign subsidiary is not a foreign related person (determined without taking into account the recharacterization under paragraph (c)(2) or (3) of this section), then, immediately before the transaction—

(i) Each section 958(a) U.S. shareholder that is treated as owning deemed issued stock in the expatriated foreign subsidiary under paragraph (c)(2) or (3) of this section is treated as transferring the deemed issued stock (after the deemed issued stock is deemed to be transferred to the section 958(a) U.S. shareholder through intermediate entities, if any, in redemption of equity deemed issued by the intermediate entities pursuant to paragraph (c)(2) or (3) of this section) to the specified related person that is treated as holding the deemed instruments issued by the section 958(a) U.S. shareholder under paragraph (c)(2) or (3) of this section, in redemption of the deemed instruments; and

(ii) The deemed issued stock that is treated as transferred pursuant to paragraph (d)(2)(i) of this section is treated as recapitalized into the disregarded specified stock actually held by the specified related person, which immediately thereafter is treated as specified stock owned by the specified related person for all purposes of the Internal Revenue Code. See *Example 8*, *Example 9*, and *Example 12* of paragraph (g) of this section.

(3) *Transfers in which disregarded specified stock ceases to be held by a foreign related person, specified related person, or expatriated entity.* When, after a specified transaction with respect to an expatriated foreign subsidiary that is recharacterized under paragraph (c)(2) or (3) of this section, there is a direct or indirect transfer of the disregarded specified stock in the expatriated foreign subsidiary, and immediately after the transfer, the expatriated foreign subsidiary is a foreign related person, then, to the extent that, as a result of the

transfer, the disregarded specified stock is actually held (determined without taking into account the recharacterization under paragraph (c)(2) or (3) of this section) by a person that is not a foreign related person, a specified related person, or an expatriated entity, immediately before the transfer—

(i) Each section 958(a) U.S. shareholder that is treated as owning all or a portion of the deemed issued stock in the expatriated foreign subsidiary is treated as transferring the deemed issued stock that is allocable to the transferred disregarded specified stock that is out-of-group transferred disregarded specified stock (after the deemed issued stock is deemed to be transferred to the section 958(a) U.S. shareholder through intermediate entities, if any, in redemption of equity deemed issued by the intermediate entities pursuant to paragraph (c)(2) or (3) of this section) to the specified related person that is treated as holding the deemed instruments allocable to the out-of-group transferred disregarded specified stock, in redemption of the deemed instruments that are allocable to the out-of-group transferred disregarded specified stock; and

(ii) The deemed issued stock that is treated as transferred pursuant to paragraph (d)(3)(i) of this section is treated as recapitalized into the disregarded specified stock actually held by the specified related person, which immediately thereafter is treated as specified stock owned by the specified related person for all purposes of the Internal Revenue Code. See *Example 7* and *Example 11* of paragraph (g) of this section.

(4) *Certain direct transfers of disregarded specified stock to which unwind rules do not apply.* When a specified related person directly transfers the disregarded specified stock of the expatriated foreign subsidiary and paragraphs (d)(2) and (3) of this section do not apply with respect to the transfer, the specified related person is deemed to transfer the deemed instruments allocable to the transferred disregarded specified stock, whether it is in-group transferred disregarded specified stock or out-of-group transferred disregarded specified stock, to the transferee of the specified stock, in lieu of the disregarded specified stock, in exchange for the consideration provided by the transferee for the disregarded specified stock. See *Example 10* of paragraph (g) of this section.

(5) *Determination of deemed issued stock and deemed instruments allocable to transferred disregarded specified*

stock—(i) *Out-of-group transfers of disregarded specified stock.* For purposes of paragraphs (d)(3) and (4) of this section, the portion of the deemed issued stock treated as owned, and of the deemed instruments treated as issued, by each section 958(a) U.S. shareholder as a result of the specified transaction that is allocable to out-of-group transferred disregarded specified stock is the amount that is proportionate to the ratio of the amount of the out-of-group transferred disregarded specified stock to the amount of disregarded specified stock of the expatriated foreign subsidiary that is actually held by the specified related person immediately before the transfer referred to in paragraph (d)(3) or (4) of this section as a result of the specified transaction.

(ii) *In-group direct transfers of disregarded specified stock.* For purposes of paragraph (d)(4) of this section, the portion of the deemed issued stock treated as owned by each section 958(a) U.S. shareholder as a result of the specified transaction that is allocable to in-group transferred disregarded specified stock is the amount that is proportionate to the ratio of the amount of the in-group transferred disregarded specified stock to the amount of disregarded specified stock of the expatriated foreign subsidiary that is actually held by the specified related person immediately before the transfer described in paragraph (d)(4) of this section as a result of the specified transaction.

(e) *Certain exception from foreign personal holding company income not available.* An amount included in the gross income of a controlled foreign corporation as a dividend with respect to stock transferred in a specified transaction does not qualify for the exception from foreign personal holding company income provided by section 954(c)(6) (to the extent in effect).

(f) *Definitions.* In addition to the definitions in § 1.7874–12, the following definitions and special rules apply for purposes of this section:

(1) *Deemed instruments* mean, with respect to a specified transaction, instruments deemed issued by a section 958(a) U.S. shareholder in exchange for transferred property in the specified transaction.

(2) *Deemed issued stock* means, with respect to a specified transaction, stock of an expatriated foreign subsidiary deemed issued to a section 958(a) U.S. shareholder (or an intermediate entity) in the specified transaction.

(3) *Disregarded specified stock* means, with respect to a specified transaction, specified stock that is actually held by a specified related person but that is

disregarded for all purposes of the Internal Revenue Code pursuant to paragraph (c)(2) or (3) of this section.

(4) *Indirect ownership.* To determine indirect ownership of the stock of a corporation for purposes of calculating a pre-transaction ownership percentage or post-transaction ownership percentage with respect to that corporation, the principles of section 958(a) apply without regard to whether an intermediate entity is foreign or domestic. For this purpose, stock of the corporation that is directly or indirectly (applying the principles of section 958(a) without regard to whether an intermediate entity is foreign or domestic) owned by a domestic corporation that is an expatriated entity is not treated as indirectly owned by a non-EFS foreign related person.

(5) *In-group transferred disregarded specified stock* means disregarded specified stock that is directly transferred to a foreign related person, a specified related person, or an expatriated entity.

(6) A *lower-tier expatriated foreign subsidiary* means an expatriated foreign subsidiary, stock of which is directly or indirectly owned by an expatriated foreign subsidiary.

(7) *Out-of-group transferred disregarded specified stock* means disregarded specified stock that, as a result of a transfer of disregarded specified stock, is actually held by a person that is not a foreign related person, a specified related person, or an expatriated entity.

(8) *Pre-transaction ownership percentage* means, with respect to a corporation, 100 percent less the percentage of stock (by value) in the corporation that, immediately before a specified transaction and any related transaction, is owned, in the aggregate, directly or indirectly by non-EFS foreign related persons.

(9) *Post-transaction ownership percentage* means, with respect to a corporation, 100 percent less the percentage of stock (by value) in the corporation that, immediately after the specified transaction and any related transaction, is owned, in the aggregate, directly or indirectly by non-EFS foreign related persons.

(10) A *section 958(a) U.S. shareholder* means, with respect to an expatriated foreign subsidiary, a United States shareholder with respect to the expatriated foreign subsidiary that owns (within the meaning of section 958(a)) stock of the expatriated foreign subsidiary and that is an expatriated entity.

(11) *Specified stock* means the stock of the expatriated foreign subsidiary that

is issued or transferred to a specified related person in a specified transaction.

(12) *Transferred property* means the property transferred by the specified related person in exchange for specified stock in a specified transaction.

(g) *Examples.* The following examples illustrate the regulations described in this section. Except as otherwise provided, FA, a foreign corporation, wholly owns DT, a domestic corporation, which, in turn, wholly owns FT, a foreign corporation that is a controlled foreign corporation. FA also wholly owns FS, a foreign corporation that is a controlled foreign corporation for its taxable year beginning January 1, 2017, but not for prior taxable years. FA acquired DT in an inversion transaction that was completed on January 1, 2015. Accordingly, DT is the domestic entity and a section 958(a) U.S. shareholder with respect to FT, FT is an expatriated foreign subsidiary, and FA and FS are non-EFS foreign related persons and specified related persons. All entities have a calendar year tax year for U.S. tax purposes.

Example 1. (i) Facts. On February 1, 2015, FA acquires \$6x of FT stock, representing 60% of the total voting power and value of the stock of FT, from FT in a stock issuance, in exchange for \$6x of cash.

(ii) *Analysis.* (A) Under paragraph (b) of this section, FA's acquisition of the FT specified stock from FT is a specified transaction because stock of an expatriated foreign subsidiary was issued to a specified related person (FA) during the applicable period. Furthermore, the exceptions to recharacterization in paragraph (b)(2) of this section do not apply to the transaction.

(B) FA's acquisition of the FT specified stock is recharacterized under paragraphs (c)(1) and (2) of this section as follows, with the result that FT continues to be a CFC even before its taxable year beginning January 1, 2017:

(1) DT is treated as having issued deemed instruments to FA in exchange for \$6x of cash.

(2) DT is treated as having contributed the \$6x of cash to FT in exchange for deemed issued stock of FT.

(C) Under paragraph (c)(4)(i) of this section, any distribution with respect to the FT specified stock issued to FA will be treated as a distribution to DT, which, in turn, will be treated as making a matching distribution with respect to the deemed instruments that DT is treated as having issued to FA. Under paragraph (c)(4)(ii) of this section, FT is treated as the paying agent of DT with respect to the deemed instruments issued by DT to FA.

Example 2. (i) Facts. DT owns stock of FT representing 60% of the total voting power and value of the stock of FT, and the remaining stock of FT, representing 40% of the total voting power and value, is owned by USP, a domestic corporation that is not an expatriated entity. On February 1, 2015, FA acquires \$6x of FT stock, representing 60%

of the total voting power and value of the stock of FT, from FT in a stock issuance, in exchange for \$6x of cash.

(ii) *Analysis.* (A) Under paragraph (b) of this section, FA's acquisition of the FT specified stock from FT is a specified transaction because stock of an expatriated foreign subsidiary was issued to a specified related person (FA) during the applicable period. Furthermore, the exceptions to recharacterization in paragraph (b)(2) of this section do not apply to the transaction.

(B) FA's acquisition of the FT specified stock is recharacterized under paragraphs (c)(1) and (2) of this section as follows, with the result that FT continues to be a CFC even before its taxable year beginning January 1, 2017:

(1) DT is treated as having issued deemed instruments to FA in exchange for \$6x of cash.

(2) DT is treated as having contributed the \$6x of cash to FT in exchange for deemed issued stock of FT.

(3) DT is treated as owning \$8.40x of the stock of FT, representing 84% of the total voting power and value of the stock of FT. USP owns \$1.60x of the stock of FT, representing 16% of the total voting power and value of the stock of FT.

(C) Under paragraph (c)(4)(i) of this section, any distribution with respect to the FT specified stock issued to FA will be treated as a distribution to DT, which, in turn, will be treated as making a matching distribution with respect to the deemed instruments that DT is treated as having issued to FA. Under paragraph (c)(4)(ii) of this section, FT is treated as the paying agent of DT with respect to the deemed instruments issued by DT to FA.

Example 3. (i) Facts. DT owns stock of FT representing 50% of the total voting power and value of the \$8x of stock of FT outstanding, and the remaining stock of FT, representing 50% of the total voting power and value, is owned by USP, a domestic corporation that is not an expatriated entity. On April 30, 2016, FA and USP each simultaneously acquire \$1x of FT stock from FT in a stock issuance, in exchange for \$1x of cash each.

(ii) *Analysis.* (A) Under paragraph (b) of this section, FA's acquisition of the FT specified stock from FT is a specified transaction because stock of an expatriated foreign subsidiary was issued to a specified related person (FA) during the applicable period.

(B) However, the specified transaction is not recharacterized under paragraphs (c)(1) and (2) of this section because the exception in paragraph (b)(2)(iii) of this section applies. The exception applies because FT remains a controlled foreign corporation immediately after the specified transaction and any related transaction, and the post-transaction ownership percentage with respect to FT is 90% (90%/100%), or at least 90%, of the pre-transaction ownership percentage with respect to FT. The rule in paragraph (b)(2)(iii)(C) of this section does not apply because there is no lower-tier expatriated foreign subsidiary. Although FA (a non-EFS foreign related person) indirectly owns \$4x of FT stock both immediately before and after

the specified transaction and any related transaction, all of that stock is directly owned by DT (a domestic corporation), and as a result, under paragraph (f)(4) of this section, none of that stock is treated as directly or indirectly owned by FA for purposes of calculating the pre-transaction ownership percentage and the post-transaction ownership percentage with respect to FT. Accordingly, under paragraph (f)(8) of this section, the pre-transaction ownership percentage with respect to FT (100% less the percentage of stock (by value) in FT that, immediately before the specified transaction with respect to FT and any related transaction, is owned by non-EFS foreign related persons) is 100 (100% - 0%). Under paragraph (f)(9) of this section, the post-transaction ownership percentage with respect to FT (100% less the percentage of stock (by value) in FT that, immediately after the specified transaction with respect to FT and any related transaction, is owned by non-EFS foreign related persons) is 90 (100% - 10% (\$1x/\$10x)).

Example 4. (i) Facts. On February 1, 2015, FA acquires 60% of the FT stock owned by DT in exchange for \$2.40x of cash in a fully taxable transaction. DT recognizes and includes in income all of the gain (including any gain treated as a deemed dividend pursuant to section 1248(a)) with respect to the FT stock transferred to FA.

(ii) *Analysis.* (A) Under paragraph (b) of this section, FA's acquisition of the FT specified stock is a specified transaction because stock of an expatriated foreign subsidiary was transferred to a specified related person (FA) during the applicable period.

(B) However, the specified transaction is not recharacterized under paragraphs (c)(1) and (c)(3) of this section because the exception in paragraph (b)(2)(ii) of this section applies. The exception applies because DT recognizes and includes in income all of the gain (including any gain treated as a deemed dividend pursuant to section 1248(a)) with respect to the FT specified stock transferred to FA.

Example 5. (i) Facts. On February 1, 2015, DT and FA organize FPRS, a foreign partnership, with nominal capital. DT transfers all of the stock of FT to FPRS in exchange for 40% of the capital and profits interests in the partnership. Furthermore, FA contributes property to FPRS in exchange for the other 60% of the capital and profits interests.

(ii) *Analysis.* (A) Under paragraph (b) of this section, DT's transfer of the FT specified stock is a specified transaction, because stock of an expatriated foreign subsidiary was transferred to a specified related person (FPRS) during the applicable period. The exceptions to recharacterization in paragraph (b)(2) of this section do not apply to the transaction.

(B) DT's transfer of the FT specified stock is recharacterized under paragraphs (c)(1) and (c)(3) of this section as follows, with the result that FT continues to be a CFC even before its taxable year beginning January 1, 2017:

(1) FPRS is treated as having issued 40% of its capital and profits interests to DT in

exchange for deemed instruments treated as having been issued by DT.

(2) DT is treated as continuing to own all of the stock of FT, as well as the FPRS interests.

(C) Under paragraph (c)(4)(i) of this section, any distribution with respect to the FT specified stock transferred to FPRS will be treated as a distribution to DT, which, in turn, will be treated as making a matching distribution with respect to the deemed instruments that DT is treated as having issued to FPRS. Under paragraph (c)(4)(ii) of this section, FT is treated as the paying agent of DT with respect to the deemed instruments issued by DT to FPRS.

Example 6. (i) *Facts.* DT wholly owns FT2, a foreign corporation that is a controlled foreign corporation. FT and FT2 each own 50% of the capital and profits interests in DPRS, a domestic partnership. DPRS wholly owns FT3, a foreign corporation that is a controlled foreign corporation. FT2 and FT3 are expatriated foreign subsidiaries. On April 30, 2016, FS acquires \$9x of the stock of each of FT and FT2, representing 9% of the total voting power and value of the stock of FT and FT2, from FT and FT2, respectively, in a stock issuance, in exchange for cash of \$9x each. Also on April 30, 2016, in a related transaction, FS acquires \$9x of the stock of FT3, representing 9% of the total voting power and value of the stock of FT3, from FT3 in a stock issuance, in exchange for cash of \$9x.

(ii) *Analysis.* (A) Under paragraph (b) of this section, the acquisitions by FS of the specified stock of each of FT, FT2, and FT3 from FT, FT2, and FT3 are specified transactions with respect to each of FT, FT2, and FT3, respectively, because stock of an expatriated foreign subsidiary was issued to a specified related person (FS) during the applicable period.

(B) If FS had acquired only stock of FT and FT2, and had not acquired stock of FT3 in a related transaction, the specified transactions resulting from the acquisitions with respect to FT and FT2 would not have been recharacterized under paragraphs (c)(1) and (2) of this section, because the exception from recharacterization in paragraph (b)(2)(iii) of this section would have applied. FT and FT2 remain controlled foreign corporations immediately after each specified transaction and any related transaction. Under paragraph (f)(9) of this section, the post-transaction ownership percentage with respect to each of FT, FT2, and FT3 (a lower-tier expatriated foreign subsidiary of FT and FT2) would have been $91\% ((100\% - 9\%)/(100\% - 0\%))$, or at least 90%, of the pre-transaction ownership percentage determined under paragraph (f)(8) of this section with respect to each of FT, FT2, and FT3 (100%).

(C) However, for the specified transactions with respect to FT, FT2, and FT3, the post-transaction ownership percentage determined under paragraph (f)(9) of this section with respect to FT3 (the lower-tier expatriated foreign subsidiary of FT and FT2), 100% less the percentage of stock (by value) in FT3 that, immediately after each of the specified transactions with respect to each of FT and FT2 and any related

transaction, is owned by the non-EFS foreign related persons, is $82.81 (100\% - (9\% \times 50\% \times 91\%)) - (9\% \times 50\% \times 91\%) - 9\%$. Accordingly, the post-transaction ownership percentage with respect to FT3 is 82.81% ($82.81/(100\% - 0\%)$), which is less than 90%, of the pre-transaction ownership percentage determined under paragraph (f)(8) of this section with respect to FT3. Thus, the exception from recharacterization in paragraph (b)(2)(iii) of this section does not apply with respect to the specified transactions with respect to FT, FT2, or FT3.

(D) The specified transactions with respect to FT and FT2 are recharacterized under paragraphs (c)(1) and (2) of this section as follows:

(1) DT is treated as having issued 2 deemed instruments worth \$9x each to FA in exchange for \$18x ($\$9x + \$9x$) of cash.

(2) DT is treated as having contributed \$9x of cash to each of FT and FT2 in exchange for deemed issued stock of FT and FT2.

(3) DT is treated as continuing to own all of the stock of FT and FT2.

(E) Under paragraph (c)(4)(i) of this section, any distribution with respect to the FT and FT2 specified stock issued to FS will be treated as a distribution to DT, which, in turn, will be treated as making a matching distribution with respect to the deemed instruments that DT is treated as having issued to FS. Under paragraph (c)(4)(ii) of this section, FT and FT2 are treated as the paying agents of DT with respect to the deemed instruments issued by DT to FS.

(F) The specified transaction with respect to FT3 is recharacterized under paragraphs (c)(1) and (2) of this section as follows:

(1) DPRS is treated as having issued a deemed instrument worth \$9x to FA in exchange for \$9x of cash.

(2) DPRS is treated as having contributed \$9x of cash to FT3 in exchange for deemed issued stock of FT3.

(3) DPRS is treated as continuing to own all of the stock of FT3.

(G) Under paragraph (c)(4)(i) of this section, any distribution with respect to the FT3 specified stock issued to FS will be treated as a distribution to DPRS, which, in turn, will be treated as making a matching distribution with respect to the deemed instruments that DPRS is treated as having issued to FS. Under paragraph (c)(4)(ii) of this section, FT3 is treated as the paying agent of DPRS with respect to the deemed instrument issued by DPRS to FS.

Example 7. (i) *Facts.* The facts are the same as in *Example 1* of this paragraph (g). On April 30, 2016, FA transfers \$4x of the FT disregarded specified stock that it acquired on February 1, 2015 to USP, a domestic corporation that is not an expatriated entity, in exchange for \$4x of cash.

(ii) *Results.* After the transfer, FT remains a foreign related person. Therefore, paragraph (d)(2) of this section does not apply. However, the \$4x of FT disregarded specified stock transferred to USP ceases to be held by a foreign related person, a specified related person, or an expatriated entity (determined without taking into account paragraph (c)(2) or (3) of this section). Therefore, under paragraph (d)(3) of this section, immediately before the transfer of the disregarded

specified stock, DT is deemed to transfer \$4x ($\$6x \times (\$4x/\$6x)$) of the FT deemed issued stock that it is treated as owning to FA, the specified related person, in redemption of \$4x ($\$6x \times (\$4x/\$6x)$) of the DT deemed instruments that FA is treated as owning, and the \$4x of FT deemed issued stock deemed transferred to FA is deemed recapitalized into disregarded specified stock actually held by FA, which is thereafter treated as owned by FA for all purposes of the Code until the transfer to USP.

Example 8. (i) *Facts.* The facts are the same as in *Example 7* of this paragraph (g), except that on April 30, 2016, FA transfers all \$6x of the FT disregarded specified stock to USP in exchange for \$6x of cash.

(ii) *Results.* After the transfer, FT ceases to be a foreign related person (determined without taking into account paragraph (c)(2) or (3) of this section). Therefore, under paragraph (d)(2) of this section, immediately before the transfer of the disregarded specified stock, DT is deemed to transfer the \$6x of FT deemed issued stock that it is treated as owning to FA, the specified related person, in redemption of the \$6x of DT deemed instruments that FA is treated as owning, and the \$6x of FT deemed issued stock deemed transferred to FA is deemed recapitalized into disregarded specified stock actually held by FA, which is thereafter treated as owned by FA for all purposes of the Code until the transfer to USP.

Example 9. (i) *Facts.* The facts are the same as in *Example 7* of this paragraph (g), except that on April 30, 2016, FA transfers \$5.5x of the FT disregarded specified stock to USP in exchange for \$5.5x of cash.

(ii) *Results.* After the transfer, FT ceases to be a foreign related person (determined without taking into account paragraph (c)(2) or (3) of this section). Therefore, under paragraph (d)(2) of this section, immediately before the transfer of the disregarded specified stock, DT is deemed to transfer the \$6x of FT deemed issued stock that it is treated as owning to FA, the specified related person, in redemption of the \$6x of DT deemed instruments that FA is treated as owning, and the \$6x of FT deemed issued stock deemed transferred to FA is deemed recapitalized into disregarded specified stock actually held by FA, which is thereafter treated as owned by FA for all purposes of the Code and \$5.5x of which is transferred to USP. The remaining \$0.5x of the specified stock continues to be treated as owned by FA for all purposes of the Code.

Example 10. (i) *Facts.* The facts are the same as in *Example 1* of this paragraph (g). On April 30, 2016, FA transfers \$5x of the FT disregarded specified stock that it acquired on February 1, 2015 to DS, a domestic corporation wholly owned by DT, in exchange for \$5x of cash.

(ii) *Results.* After the transfer, FT remains a foreign related person because DS is wholly owned by DT. Therefore, paragraph (d)(2) of this section does not apply. Furthermore, the \$5x of FT disregarded specified stock is not, as a result of the transfer, held by a person that is not a foreign related person, a specified related person, or an expatriated entity. Therefore, paragraph (d)(3) of this section does not apply. Because FA, a

specified related person, directly transferred disregarded specified stock of FT in a transaction to which paragraphs (d)(2) and (3) of this section do not apply, under paragraph (d)(4) of this section, FA is treated as transferring the \$5x of deemed instruments of DT allocable to the \$5x of in-group transferred disregarded specified stock (\$6x × (\$5x/\$6x)) to DS.

Example 11. (i) *Facts.* On February 1, 2015, FS acquires \$6x of FT stock, representing 60% of the total voting power and value of the stock of FT, from FT in a stock issuance, in exchange for \$6x of cash. The \$6x of FT stock is specified stock, and the transaction is recharacterized under paragraph (c)(2) of this section. See *Example 1* of this paragraph (g). On April 30, 2016, FA transfers stock of FS representing 60% of the total voting power and value of the stock of FS to USP, a domestic corporation that is not an expatriated entity. As a result of the transfer, FS ceases to be a foreign related person.

(ii) *Results.* After the February 1, 2015 transfer, FT remains a foreign related person because the FT stock is acquired by FS, a foreign related person with respect to DT at that time. Therefore, paragraph (d)(2) of this section does not apply. However, after the April 30, 2016 transfer, because FS ceases to be a foreign related person, it ceases to be a specified related person. Furthermore, the \$6x of disregarded specified stock held before the transaction continues to be held by FS after the transaction, and therefore is not held by a foreign related person, a specified related person, or an expatriated entity after the transaction. Accordingly, under paragraph (d)(3) of this section, immediately before the transfer of FS disregarded specified stock, DT is deemed to transfer \$6x (\$6x × (\$6x/\$6x)) of the FT deemed issued stock that it is treated as owning to FS, the specified related person, in redemption of \$6x (\$6x × (\$6x/\$6x)) of the DT deemed instruments that FS is treated as owning, and the \$6x of FT deemed issued stock deemed transferred to FS is deemed recapitalized into disregarded specified stock actually held by FS, which thereafter is treated as owned by FS for all purposes of the Code, including after the transfer of 60% of the FS stock to USP.

Example 12. (i) *Facts.* The facts are the same as in *Example 1* of this paragraph (g). On April 30, 2016, FP, a foreign corporation that is not a foreign related person acquires \$15x of FT stock, representing 60% of the total voting power and value of the stock of FT, from FT in a stock issuance, in exchange for \$15x of cash.

(ii) *Results.* After the transaction, FT ceases to be a foreign related person. Therefore,

under paragraph (d)(2) of this section, immediately before the issuance of FT stock to FP, DT is deemed to transfer the \$6x of FT deemed issued stock that it is treated as owning to FA, the specified related person, in redemption of the \$6x of DT deemed instruments that FA is treated as owning, and the \$6x of FT deemed issued stock deemed transferred to FA is deemed recapitalized into disregarded specified stock actually held by FA, which thereafter is treated as owned by FA for all purposes of the Code.

Example 13. (i) *Facts.* The facts are the same as in *Example 1* of this paragraph (g). On April 30, 2016, FS acquires \$4x of the FT stock owned by DT in exchange for \$4x of cash in a fully taxable transaction. DT recognizes and includes in income all of the gain (including any gain treated as a deemed dividend pursuant to section 1248(a)) with respect to the FT stock transferred to FS.

(ii) *Results.* (A) The transfer of FT stock by DT to FS is a specified transaction, but it is not recharacterized under paragraphs (c)(1) and (3) of this section because the exception in paragraph (b)(2)(ii) of this section applies. See *Example 4* of this paragraph (g).

(B) After the transfer, FT remains a foreign related person. Therefore, paragraph (d)(2) of this section does not apply. The disregarded specified stock of FT is not, as a result of the transfer, held by a person that is not a foreign related person, a specified related person, or an expatriated entity. Therefore, paragraph (d)(3) of this section does not apply. There has been no direct transfer of specified stock. Therefore, paragraph (d)(4) of this section also does not apply.

(C) Under paragraph (d)(1) of this section, the \$6x of deemed issued stock treated as owned by DT as a result of the specified transaction in which FA acquired FT stock continues to be treated as owned by DT, and the \$6x of deemed instruments treated as issued by DT to FA continue to be treated as owned by FA.

(h) *Applicability date.* Except as otherwise provided in this paragraph (h), this section applies to specified transactions completed on or after September 22, 2014, but only if the inversion transaction was completed on or after September 22, 2014. Paragraph (b)(2)(ii)(A)(2) of this section applies to specified transactions completed on or after November 19, 2015, but only if the inversion transaction was completed on or after September 22, 2014. Paragraphs (d) and (f)(5), (7), and (10) of this section apply to specified transactions completed on or after April 4, 2016, but only if the inversion transaction was

completed on or after September 22, 2014. For inversion transactions completed on or after September 22, 2014, however, taxpayers may elect to apply paragraphs (d) and (f)(5), (7), and (10) of this section to specified transactions completed before April 4, 2016. In addition, for inversion transactions completed on or after September 22, 2014, in lieu of applying paragraphs (d) and (f)(5) and (7) of this section to specified transactions completed on or after September 22, 2014, and before April 4, 2016, taxpayers may elect to apply the principles of § 1.7701(l)-3(c)(3)(iii). Furthermore, for inversion transactions completed on or after September 22, 2014, in lieu of applying paragraph (f)(10) of this section to specified transactions completed on or after September 22, 2014, and before April 4, 2016, taxpayers may elect to define a section 958(a) U.S. shareholder as a United States shareholder with respect to the expatriated foreign subsidiary that owns (within the meaning of section 958(a)) stock in the expatriated foreign subsidiary, but only if such United States shareholder is related (within the meaning of section 267(b) or 707(b)(1)) to the specified related person or is under the same common control (within the meaning of section 482) as the specified related person.

§ 1.7701(l)-4T [Removed]

■ **Par. 12.** Section 1.7701(l)-4T is removed.

■ **Par. 13.** Section 1.7874-1 is amended by:

- 1. Adding a sentence at the end of paragraph (a).
- 2. Revising paragraph (c)(2)(iii).
- 2. Redesignating paragraphs (d) through (h) as paragraphs (e) through (i), respectively.
- 3. Adding a new paragraph (d).
- 4. Revising newly redesignated paragraphs (g) and (i)(2).
- 5. For each paragraph listed in the following table, removing the language in the “Remove” column and adding in its place the language in the “Add” column.

Paragraph	Remove	Add
(a), first sentence	foreign corporation referred to in section 7874(a)(2)(B).	foreign acquiring corporation.
(a), first sentence	expanded affiliated group (EAG) that includes such foreign corporation.	expanded affiliated group.
(b)	the ownership percentage determination required by section 7874(a)(2)(B)(ii).	determining the ownership percentage described in section 7874(a)(2)(B)(ii).
(b)	fraction that determines such percentage (ownership fraction).	ownership fraction.
(c)(1), first sentence	acquisition	domestic entity acquisition.

Paragraph	Remove	Add
(c)(1), second sentence	§ 1.7874–4, see § 1.7874–4(h)	other rules, see paragraph (d) of this section.
(c)(2), introductory text	an acquisition	a domestic entity acquisition.
(c)(2)(i)	Before the acquisition	Before the domestic entity acquisition.
(c)(2)(ii)	acquisition	domestic entity acquisition.
(c)(2)(ii)	acquiring foreign corporation	foreign acquiring corporation.
(c)(3)	acquisition results in	domestic entity acquisition results in.
(c)(3)	former shareholders or partners of the domestic entity.	former domestic entity shareholders or former domestic entity partners.
newly redesignated (e)(2)	acquisition	domestic entity acquisition.
newly redesignated (h), Example 6 (ii), third sentence.	(d)(2)	(e)(2).
newly redesignated (i)(1), first sentence	acquisitions	domestic entity acquisitions.
newly redesignated (i)(1), second sentence	an acquisition	a domestic entity acquisition.
newly redesignated (i)(1), fourth sentence	prior acquisitions	domestic entity acquisitions completed before May 20, 2008.
newly redesignated (i)(1), fifth sentence	(e)	(f).
newly redesignated (i)(1), last sentence	acquisitions	domestic entity acquisitions.

The revisions and additions read as follows:

§ 1.7874–1 Disregard of affiliate-owned stock.

(a) * * * For definitions that apply for purposes of this section, see 1.7874–12.

* * * * *

(c) * * *
(2) * * *

(iii) *Special rule.* If § 1.7874–6(c)(2) applies for purposes of applying section 7874(c)(2)(A) and this section, then, for purposes of paragraph (c)(2) of this section (and so much of paragraph (c)(1) of this section as relates to paragraph (c)(2) of this section), the determination of the EAG after the domestic entity acquisition, as well as the determination of stock held by one or more members of the EAG after the domestic entity acquisition, is made without regard to one or more transfers (other than by issuance), in a transaction (or series of transactions) after and related to the acquisition, of stock of the acquiring foreign corporation by one or more members of the foreign-parented group described in § 1.7874–6(c)(2)(i).

* * * * *

(d) *Interaction of expanded affiliated group rules with other rules—(1) Exclusion rules.* Stock that is excluded from the denominator of the ownership fraction pursuant to § 1.7874–4(b), 1.7874–7(b), 1.7874–8(b), 1.7874–9(b), or section 7874(c)(4) is taken into account for purposes of determining whether an entity is a member of the expanded affiliated group for purposes of applying section 7874(c)(2)(A) and paragraph (b) of this section and determining whether a domestic entity acquisition qualifies as an internal group restructuring or results in a loss of control, as described in paragraphs (c)(2) and (3) of this section, respectively. However, such stock is

excluded from the denominator of the ownership fraction regardless of whether it otherwise would be included in the denominator of the ownership fraction as a result of the application of paragraph (c) of this section. See *Example 8* and *Example 9* of § 1.7874–4(i) for illustrations of the application of this paragraph (d)(1).

(2) *NOCD rule.* Stock of the foreign acquiring corporation treated as received by former domestic entity shareholders or former domestic entity partners, as applicable, under § 1.7874–10(b) is not taken into account for purposes of determining whether an entity is a member of the expanded affiliated group for purposes of applying section 7874(c)(2)(A) and paragraph (b) of this section and determining whether a domestic entity acquisition qualifies as an internal group restructuring or results in a loss of control, as described in paragraphs (c)(2) and (3) of this section, respectively. However, such stock is included in the numerator and denominator of the ownership fraction, except to the extent that it is treated as held by a member of the EAG and is excluded from the numerator or both the numerator and the denominator, as applicable, under section 7874(c)(2)(A) or paragraphs (b) or (c) of this section.

* * * * *

(g) *Treatment of transactions related to the acquisition.* Except as provided in paragraph (c)(2)(iii) of this section, all transactions that are related to an acquisition are taken into account in applying this section.

* * * * *

(i) * * *

(2) *Applicability date of certain provisions of this section.* Except as provided in this paragraph (i)(2), paragraph (c)(2)(iii) of this section applies to domestic entity acquisitions completed on or after April 4, 2016.

Except as provided in this paragraph (i)(2), paragraph (d) of this section (interaction of EAG rules with other rules) applies to domestic entity acquisitions completed on or after July 12, 2018. See §§ 1.7874–4(h) and 1.7874–7T(e), as contained in 26 CFR part 1 revised as of April 1, 2017, for certain coordination rules for domestic entity acquisitions completed before July 12, 2018. Except as provided in this paragraph (i)(2), paragraph (g) of this section applies to domestic entity acquisitions completed on or after September 22, 2014. For domestic entity acquisitions completed before April 4, 2016, however, taxpayers may elect to consistently apply paragraphs (c)(2)(iii) and (g) of this section, and § 1.7874–6(c)(2), (d)(2), and (f)(2)(ii). In addition, for domestic entity acquisitions completed before July 12, 2018, taxpayers may elect to consistently apply paragraph (d) of this section.

§ 1.7874–1T [Removed]

■ **Par. 14.** Section 1.7874–1T is removed.

■ **Par. 15.** Section 1.7874–2 is amended by:

- 1. Revising paragraph (a).
- 2. Removing the language “§ 1.7874–12T” in paragraph (b) introductory text, and adding the language “§ 1.7874–12” in its place.
- 3. Revising paragraphs (b)(7) through (13), (c)(2) and (4), (f)(1) introductory text, (f)(1)(iv), *Example 21* of paragraph (k)(2), and paragraph (l)(2).

The revisions read as follows:

§ 1.7874–2 Surrogate foreign corporation.

(a) *Scope.* This section provides rules for determining whether a foreign corporation is treated as a surrogate foreign corporation under section 7874(a)(2)(B). Paragraph (b) of this section provides definitions and special rules. Paragraph (c) of this section

provides rules to determine whether a foreign corporation has acquired properties held by a domestic corporation (or a partnership).

Paragraph (d) of this section provides rules that apply when two or more foreign corporations complete, in the aggregate, a domestic entity acquisition.

Paragraph (e) of this section provides rules that apply when, pursuant to a plan, a single foreign corporation completes more than one domestic entity acquisition.

Paragraph (f) of this section provides rules to identify the stock of a foreign corporation that is held by reason of holding stock in a domestic corporation (or an interest in a domestic partnership).

Paragraph (g) of this section provides rules that treat certain publicly traded foreign partnerships as foreign corporations for purposes of section 7874.

Paragraph (h) of this section provides rules concerning the treatment of certain options (or similar interests) for purposes of section 7874.

Paragraph (i) of this section provides rules that treat certain interests (including debt, stock, or a partnership interest) as stock of a foreign corporation for purposes of section 7874.

Paragraph (j) of this section provides rules concerning the conversion of a foreign corporation to a domestic corporation by reason of section 7874(b).

Paragraph (k) of this section provides examples that illustrate the rules of this section.

Paragraph (l) of this section provides the applicability dates of this section. For additional definitions that apply for purposes of this section, see § 1.7874–12.

(b) * * *

(7) A former initial acquiring corporation shareholder of an initial acquiring corporation means any person that held stock in the initial acquiring corporation before the subsequent acquisition, including any person that holds stock in the initial acquiring corporation both before and after the subsequent acquisition.

(8) An initial acquisition means, with respect to a subsequent acquisition, a domestic entity acquisition occurring, pursuant to a plan that includes the subsequent acquisition (or a series of related transactions), before the subsequent acquisition.

(9) An initial acquiring corporation means, with respect to an initial acquisition, the foreign acquiring corporation.

(10) A subsequent acquisition means, with respect to an initial acquisition, a transaction occurring, pursuant to a plan that includes the initial acquisition (or a series of related transactions), after the initial acquisition in which a foreign corporation directly or indirectly

acquires (within the meaning of paragraph (c)(4)(ii) of this section) substantially all of the properties held directly or indirectly by the initial acquiring corporation.

(11) A subsequent acquiring corporation means, with respect to a subsequent acquisition, the foreign corporation that directly or indirectly acquires substantially all of the properties held directly or indirectly by the initial acquiring corporation.

(12) Special rule regarding initial acquisitions. With respect to an initial acquisition, the determination of the ownership percentage described in section 7874(a)(2)(B)(ii) is made without regard to the subsequent acquisition and all related transactions occurring after the subsequent acquisition.

(13) Special rule regarding subsequent acquisitions. With respect to a subsequent acquisition (or a similar acquisition under the principles of paragraph (c)(4)(i) of this section) that is an inversion transaction, the applicable period begins on the first date that properties are acquired as part of the initial acquisition.

(c) * * *

(2) Acquisition of stock of a foreign corporation. Except as provided in paragraph (c)(4) of this section, an acquisition of stock of a foreign corporation that owns directly or indirectly stock of a domestic corporation (or an interest in a partnership) shall not constitute an indirect acquisition of any properties held by the domestic corporation (or the partnership). See Example 4 of paragraph (k) of this section for an illustration of the rules of this paragraph (c)(2).

(4) Multiple-step acquisitions—(i) Rule. A subsequent acquisition is treated as a domestic entity acquisition, and the subsequent acquiring corporation is treated as a foreign acquiring corporation. See Example 21 of paragraph (k) of this section for an illustration of this rule. See also paragraph (f)(1)(iv) of this section (treating certain stock of the subsequent acquiring corporation as stock of a foreign corporation that is held by reason of holding stock of, or a partnership interest in, the domestic entity).

(ii) Acquisition of property pursuant to a subsequent acquisition. In determining whether a foreign corporation directly or indirectly acquires substantially all of the properties held directly or indirectly by an initial acquiring corporation, the principles of section 7874(a)(2)(B)(i)

apply, including paragraph (c) of this section other than paragraph (c)(2) of this section. For this purpose, the principles of paragraph (c)(1) of this section, including paragraph (b)(5) of this section, apply by substituting the term “foreign” for “domestic” wherever it appears.

(iii) Additional related transactions. If, pursuant to the same plan (or a series of related transactions), a foreign corporation directly or indirectly acquires (under the principles of paragraph (c)(4)(ii) of this section) substantially all of the properties directly or indirectly held by a subsequent acquiring corporation in a transaction occurring after the subsequent acquisition, then the principles of paragraph (c)(4)(i) of this section apply to such transaction (and any subsequent transaction or transactions occurring pursuant to the plan (or the series of related transactions)).

* * * * *

(f) * * * (1) Certain transactions. For purposes of section 7874(a)(2)(B)(ii), stock of a foreign corporation that is held by reason of holding stock in a domestic corporation (or an interest in a domestic partnership) includes, but is not limited to, the stock described in paragraphs (f)(1)(i) through (iv) of this section.

(iv) Stock of a subsequent acquiring corporation received by a former initial acquiring corporation shareholder pursuant to a subsequent acquisition in exchange for, or with respect to, stock of an initial acquiring corporation that is held by reason of holding stock of, or a partnership interest in, a domestic entity.

* * * * *

(k) * * * (2) * * *

Example 21. Application of multiple-step acquisition rule—(i) Facts. Individual A owns all 70 shares of stock of DC1, a domestic corporation. Individual B owns all 30 shares of stock of F1, a foreign corporation that is a tax resident (as described in § 1.7874–3(d)(11)) of Country X. Pursuant to a reorganization described in section 368(a)(1)(D), DC1 transfers all of its properties to F1 solely in exchange for 70 newly issued voting shares of F1 stock (DC1 acquisition) and distributes the F1 stock to Individual A in liquidation pursuant to section 361(c)(1). Pursuant to a plan that includes the DC1 acquisition, F2, a newly formed foreign corporation that is also a tax resident of Country X, acquires 100 percent of the stock of F1 solely in exchange for 100 newly issued shares of F2 stock (F1 acquisition). After the F1 acquisition, Individual A owns 70 shares of F2 stock, Individual B owns 30 shares of F2 stock, F2

owns all 100 shares of F1 stock, and F1 owns all the properties held by DC1 immediately before the DC1 acquisition. In addition, the form of the transaction is respected for U.S. federal income tax purposes.

(ii) *Analysis*—(A) The DC1 acquisition is a domestic entity acquisition, and F1 is a foreign acquiring corporation, because F1 directly acquires 100 percent of the properties of DC1. In addition, the 70 shares of F1 stock received by A pursuant to the DC1 acquisition in exchange for Individual A's DC1 stock are stock of a foreign corporation that is held by reason of holding stock in DC1. As a result, those 70 shares are included in both the numerator and the denominator of the ownership fraction when applying section 7874 to the DC1 acquisition.

(B) The DC1 acquisition is also an initial acquisition because it is a domestic entity acquisition that, pursuant to a plan that includes the F1 acquisition, occurs before the F1 acquisition (which, as described in paragraph (ii)(C) of this *Example 21*, is a subsequent acquisition). Thus, F1 is the initial acquiring corporation.

(C) The F1 acquisition is a subsequent acquisition because it occurs, pursuant to a plan that includes the DC1 acquisition, after the DC1 acquisition and, pursuant to the F1 acquisition, F2 acquires 100 percent of the

stock of F1 and therefore is treated under paragraph (c)(4)(ii) of this section (which applies the principles of section 7874(a)(2)(B)(i) with certain modifications) as indirectly acquiring substantially all of the properties held directly or indirectly by F1. Thus, F2 is the subsequent acquiring corporation.

(D) Under paragraph (c)(4)(i) of this section, the F1 acquisition is treated as a domestic entity acquisition, and F2 is treated as a foreign acquiring corporation. In addition, under paragraph (f)(1)(iv) of this section, the 70 shares of F2 stock received by Individual A (a former initial acquiring corporation shareholder) pursuant to the F1 acquisition in exchange for Individual A's F1 stock are stock of a foreign corporation that is held by reason of holding stock in DC1. As a result, those 70 shares are included in both the numerator and the denominator of the ownership fraction when applying section 7874 to the F1 acquisition.

(1) * * *

(2) *Applicability date of certain provisions of this section.* Paragraphs (a), (b)(7) through (13), (c)(2) and (4), and (f)(1)(iv) of this section, as well as the introductory text of paragraph (f)(1)

and *Example 21* of paragraph (k)(2), apply to domestic entity acquisitions completed on or after April 4, 2016.

§ 1.7874–2T [Removed]

■ **Par. 16.** Section 1.7874–2T is removed.

■ **Par. 17.** Section 1.7874–3 is amended by:

- 1. Revising paragraph (b)(4).
- 2. Revising the introductory text of paragraph (d).
- 3. Removing paragraphs (d)(1) and (d)(4).
- 4. Redesignating paragraphs (d)(2), (d)(3), (d)(5) through (12), and (d)(13) as paragraphs (d)(1), (d)(2), (d)(3) through (10), and (d)(12), respectively.
- 5. Revising newly redesignated paragraph (d)(8).
- 6. Adding paragraph (d)(11).
- 7. Revising paragraph (f)(2).
- 8. For each paragraph listed in the following table, removing the language in the “Remove” column and adding in its place the language in the “Add” column.

Paragraph	Remove	Add
(b), introductory text	after an acquisition described in section 7874(a)(2)(B)(i).	on the completion date.
(c)(1)(iii)	acquisition described in section 7874(a)(2)(B)(i).	domestic entity acquisition.
newly redesignated (d)(1)(i)	acquisition date	completion date.
newly redesignated (d)(1)(ii)	acquisition date	completion date.
newly redesignated (d)(3), first, second, third, and fifth sentences.	acquisition date	completion date.
newly redesignated (d)(9)	foreign corporation described in section 7874(a)(2)(B).	foreign acquiring corporation.
(f)(1)	acquisitions	domestic entity acquisitions.

The revisions and addition read as follows:

§ 1.7874–3 Substantial business activities.

* * * * *

(b) * * *

(4) *Tax residence of foreign acquiring corporation.* The foreign acquiring corporation is a tax resident of the relevant foreign country. However, this paragraph (b)(4) does not apply if the relevant foreign country does not impose corporate income tax.

* * * * *

(d) *Definitions and special rules.* In addition to the definitions in § 1.7874–12, the following definitions and special rules apply for purposes of this section.

* * * * *

(8) The term *relevant financial statements* means financial statements prepared consistently for all members of the expanded affiliated group in accordance with either U.S. Generally Accepted Accounting Principles (U.S. GAAP) or the International Financial

Reporting Standards (IFRS) used for the expanded affiliated group's consolidated financial statements, but, if, after the domestic entity acquisition, financial statements will not be prepared consistently for all members of the expanded affiliated group in accordance with either U.S. GAAP or IFRS, then, for each member, financial statements prepared in accordance with either U.S. GAAP or IFRS. The relevant financial statements must take into account all items of income generated by all members of the expanded affiliated group for the entire testing period.

* * * * *

(11) The term *tax resident* means, with respect to a foreign country, a body corporate liable to tax under the laws of the country as a resident.

* * * * *

(f) * * *

(2) *Paragraphs (b)(4), (d)(8), and (d)(11) of this section.* The first sentence

of paragraph (b)(4) of this section applies to domestic entity acquisitions completed on or after November 19, 2015, and the second sentence applies to domestic entity acquisitions completed on or after July 12, 2018. Paragraph (d)(8) of this section applies to domestic entity acquisitions completed on or after April 4, 2016. Paragraph (d)(11) of this section applies to domestic entity acquisitions completed on or after July 12, 2018. For domestic entity acquisitions completed on or after June 3, 2015, and before April 4, 2016, however, taxpayers may elect to apply paragraph (d)(8) of this section. For domestic entity acquisitions completed on or after November 19, 2015, and before July 12, 2018, taxpayers may elect to apply the second sentence of paragraph (b)(4) and paragraph (d)(11) of this section.

§ 1.7874–3T [Removed]

■ **Par. 18.** Section 1.7874–3T is removed.

- **Par. 19.** Section 1.7874–4 is amended by:
 - 1. Revising the seventh sentence of paragraph (a), and adding a sentence at the end of paragraph (a).
 - 2. Revising paragraph (d)(1)(ii).
 - 3. Removing paragraph (h).

- 4. Redesignating paragraphs (i), (j), and (k) as paragraphs (h), (i), and (j), respectively.
- 5. In newly redesignated paragraph (j)(1), removing the language “(d)(1)(ii),” from the fourth and seventh sentences

- and adding two sentences at the end of the paragraph.
- 6. For each paragraph listed in the following table, removing the language in the “Remove” column and adding in its place the language in the “Add” column.

Paragraph	Remove	Add
(a), eighth sentence	(i)	(h).
(a), ninth sentence	(j)	(i).
(a), tenth sentence	(k)	(j).
(c)(1)(i), second sentence	(i)	(i).
(c)(1)(ii)(A), last sentence	(j)	(i).
(c)(2), last sentence	(i)	(i).
(d)(1)(i)	§§ 1.7874–7T(b) and 1.7874–10T(b)	§§ 1.7874–7(b) and 1.7874–10(b).
(d)(1)(ii), last sentence	(i)	(i).
newly redesignated (h), introductory text	§ 1.7874–12T	§ 1.7874–12.
newly redesignated (h)(1), last sentence	(j)	(i).
newly redesignated (h)(1), last sentence	(i)(1)	(h)(1).
newly redesignated (h)(2), introductory text, first sentence.	(i)(2)(i)	(h)(2)(i).
newly redesignated (h)(2), introductory text, second sentence.	(i)(2)(ii)	(h)(2)(ii).
newly redesignated (h)(2)(ii)	(i)(1)	(h)(1).
newly redesignated (h)(2)(iii)(A), last sentence	(j)	(i).
newly redesignated (h)(2)(iii)(A), last sentence	(i)(2)(iii)(A)	(h)(2)(iii)(A).
newly redesignated (h)(2)(iii)(C)(2)	(i)(2)(iii)(B)	(h)(2)(iii)(B).
newly redesignated (h)(2)(iv), first sentence	(i)(2)(i)	(h)(2)(i).
newly redesignated (h)(2)(iv), last sentence	(j)	(i).
newly redesignated (h)(2)(iv), last sentence	(i)(2)(iv)	(h)(2)(iv).
newly redesignated (i)(10)	§ 1.7874–7T(b)	§ 1.7874–7(b).
newly redesignated (i)(11)	§ 1.7874–10T(b)	§ 1.7874–10(b).
newly redesignated (i), <i>Example 1</i> (i), second sentence.	(i)(1)	(h)(1).
newly redesignated (i), <i>Example 1</i> (ii), first sentence.	(i)(2)(ii)	(h)(2)(ii).
newly redesignated (i), <i>Example 2</i> (i), second sentence.	(i)(1)	(h)(1).
newly redesignated (i), <i>Example 2</i> (ii), first and fifth sentences.	(i)(2)(iv)	(h)(2)(iv).
newly redesignated (i), <i>Example 3</i> (i), last sentence.	(i)(2)(i)	(h)(2)(i).
newly redesignated (i), <i>Example 3</i> (ii), first and fifth sentences.	(i)(2)(iv)	(h)(2)(iv).
newly redesignated (i), <i>Example 4</i> (ii), first sentence.	(i)(1)	(h)(1).
newly redesignated (i), <i>Example 4</i> (ii), first sentence.	(i)(2)(ii)	(h)(2)(ii).
newly redesignated (i), <i>Example 4</i> (iii), sixth sentence.	(i)(2)(ii)	(h)(2)(ii).
newly redesignated (i), <i>Example 5</i> (ii), first sentence.	(i)(2)(i)	(h)(2)(i).
newly redesignated (i), <i>Example 5</i> (ii), fourth sentence.	§§ 1.7874–7T(b) and 1.7874–10T(b)	§§ 1.7874–7(b) and 1.7874–10(b).
newly redesignated (i), <i>Example 6</i> (ii), first sentence.	(i)(2)(iii)(A)	(h)(2)(iii)(A).
newly redesignated (i), <i>Example 7</i> (ii), first sentence.	(i)(2)(i)	(h)(2)(i).
newly redesignated (i), <i>Example 8</i> (ii), first sentence.	(i)(2)(i)	(h)(2)(i).
newly redesignated (i), <i>Example 8</i> (ii), fifth sentence.	paragraph (h) of this section	§ 1.7874–1(d)(1).
newly redesignated (i), <i>Example 9</i> (i), last sentence.	(i)(1)	(h)(1).
newly redesignated (i), <i>Example 9</i> (ii), first sentence.	(i)(2)(ii)	(h)(2)(ii).
newly redesignated (i), <i>Example 9</i> (ii), fifth sentence.	paragraph (h) of this section	§ 1.7874–1(d)(1).
newly redesignated (i), <i>Example 9</i> (ii), penultimate sentence.	paragraphs (b) and (h) of this section	paragraph (b) of this section and § 1.7874–1(d)(1).
newly redesignated (i), <i>Example 9</i> (iii), first sentence.	(i)(1)	(h)(1).

Paragraph	Remove	Add
newly redesignated (i), <i>Example 9</i> (iii), first sentence.	(i)(2)	(h)(2).
newly redesignated (i), <i>Example 9</i> (iii), fifth sentence.	paragraph (h) of this section	§ 1.7874–1(d)(1).
newly redesignated (i), <i>Example 9</i> (iii), tenth sentence.	paragraphs (b) and (h) of this section	paragraph (b) of this section and § 1.7874–1(d)(1).
newly redesignated (j)(1), first sentence	(k)	(j).
newly redesignated (j)(1), second sentence	(i)(1) and (i)(2)(iv)	(h)(1) and (h)(2)(iv).
newly redesignated (j)(1), fourth sentence	(i)(2)(iii), and (i)(3)	(h)(2)(iii), and (h)(3).
newly redesignated (j)(1), fifth sentence	(i)(1) and (i)(2)(iv)	(h)(1) and (h)(2)(iv).
newly redesignated (j)(1), last sentence	(i)(2)(iii)	(h)(2)(iii).
newly redesignated (j)(1), last sentence	(i)(3)	(h)(3).
newly redesignated (j)(2), introductory text	(k)(3)	(j)(3).
newly redesignated (j)(2)(i)	(i)(2)(iii)	(h)(2)(iii).
newly redesignated (j)(2)(iv)	paragraphs (d) and (h) of this section	Paragraph (d) of this section and § 1.7874–1(d)(1).
newly redesignated (j)(3), first sentence	(k)(1)	(j)(1).

The revisions and addition read as follows:

§ 1.7874–4 Disregard of certain stock related to the domestic entity acquisition.

(a) * * * Paragraph (g) of this section provides rules for the treatment of partnerships, and paragraph (h) of this section provides definitions. * * * See § 1.7874–1(d)(1) for rules addressing the interaction of this section with the expanded affiliated group rules of section 7874(c)(2)(A) and § 1.7874–1.

* * * * *

(d) * * *

(1) * * *

(ii) On the completion date, each five percent former domestic entity shareholder or five percent former domestic entity partner, as applicable, owns (applying the attribution rules of

section 318(a) with the modifications described in section 304(c)(3)(B)) less than five percent (by vote and value) of the stock of (or a partnership interest in) each member of the expanded affiliated group. For this purpose, a five percent former domestic entity shareholder (or five percent former domestic entity partner) is a former domestic entity shareholder (or former domestic entity partner) that, before the domestic entity acquisition, owned (applying the attribution rules of section 318(a) with the modifications described in section 304(c)(3)(B)) at least five percent (by vote and value) of the stock of (or a partnership interest in) the domestic entity. See *Example 5* of this paragraph (i) for an illustration of this paragraph (d).

* * * * *

(j) * * *

(1) * * * Paragraph (d)(1)(ii) of this section applies to domestic entity acquisitions completed on or after July 12, 2018, though taxpayers may elect to consistently apply paragraph (d)(1)(ii) of this section to domestic entity acquisitions completed before July 12, 2018. For domestic entity acquisitions completed before July 12, 2018, see § 1.7874–4(d)(1)(ii) as contained in 26 CFR part 1 revised as of April 1, 2017.

* * * * *

§ 1.7874–5 [Amended]

■ **Par. 20.** For each paragraph listed in the following table, removing the language in the “Remove” column and adding in its place the language in the “Add” column.

Paragraph	Remove	Add
(c)	§ 1.7874–6T	§ 1.7874–6.
(d)	§ 1.7874–12T	§ 1.7874–12.

■ **Par. 21.** Section 1.7874–6 is added to read as follows:

§ 1.7874–6 Stock transferred by members of the EAG.

(a) *Scope.* This section provides rules regarding whether transferred stock is treated as held by members of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874–1. Paragraph (b) of this section sets forth the general rule under which transferred stock is not treated as held by members of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874–1. Paragraph (c) of this section provides exceptions to the general rule. Paragraph (d) of this section provides rules regarding the treatment of partnerships, and paragraph (e) of this section provides rules regarding transactions related to

the acquisition. Paragraph (f) of this section provides definitions. Paragraph (g) of this section provides examples illustrating the application of the rules of this section. Paragraph (h) of this section provides dates of applicability.

(b) *General rule.* Except as provided in paragraph (c) of this section, transferred stock is not treated as held by members of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874–1. Transferred stock that is not treated as held by members of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874–1 is included in the numerator and the denominator of the ownership fraction. See § 1.7874–5(a).

(c) *Exceptions.* Transferred stock is treated as held by members of the EAG for purposes of applying section

7874(c)(2)(A) and § 1.7874–1 if paragraph (c)(1) or (2) of this section applies. Transferred stock that is treated as held by members of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874–1 is excluded from the numerator of the ownership fraction and, depending upon the application of § 1.7874–1(c), may be excluded from the denominator of the ownership fraction. See § 1.7874–1(b) and (c).

(1) *Transfers involving a U.S.-parented group.* This paragraph (c)(1) applies if the following conditions are satisfied:

(i) Before the domestic entity acquisition, the transferring corporation is a member of a U.S.-parented group.

(ii) After the domestic entity acquisition, each of the transferring

corporation (or its successor), any person that holds transferred stock, and the foreign acquiring corporation are members of a U.S.-parented group the common parent of which—

(A) Before the domestic entity acquisition, was a member of the U.S.-parented group described in paragraph (c)(1)(i) of this section; or

(B) Is a corporation that was formed in a transaction related to the domestic entity acquisition, provided that, immediately after the corporation was formed (and without regard to any related transactions), the corporation was a member of the U.S.-parented group described in paragraph (c)(1)(i) of this section.

(2) *Transfers involving a foreign-parented group.* This paragraph (c)(2) applies if the following conditions are satisfied:

(i) Before the domestic entity acquisition, the transferring corporation and the domestic entity are members of the same foreign-parented group.

(ii) After the domestic entity acquisition, the transferring corporation—

(A) Is a member of the EAG; or

(B) Would be a member of the EAG absent one or more transfers (other than by issuance), in a transaction (or series of transactions) after and related to the domestic entity acquisition, of stock of the foreign acquiring corporation by one or more members of the foreign-parented group described in paragraph (c)(2)(i) of this section.

(d) *Treatment of partnerships—(1) Stock held by a partnership.* For purposes of this section, each partner in a partnership, as determined without regard to the application of paragraph (d)(2) of this section, is treated as holding its proportionate share of the stock held by the partnership, as determined under the rules and principles of sections 701 through 777.

(2) *Partnership treated as corporation.* For purposes of this section, if one or more members of an affiliated group, as determined after the application of paragraph (d)(1) of this section, own, in the aggregate, more than 50 percent (by value) of the interests in a partnership, the partnership will be treated as a corporation that is a member of the affiliated group.

(e) *Treatment of transactions related to the acquisition.* Except as provided in paragraphs (c)(1)(ii)(B) and (c)(2)(ii)(B) of this section, all transactions that are related to a domestic entity acquisition are taken into account in applying this section.

(f) *Definitions.* In addition to the definitions provided in § 1.7874–12, the

following definitions apply for purposes of this section.

(1) A *foreign-parented group* means an affiliated group that has a foreign corporation as the common parent corporation. A *member of the foreign-parented group* is an entity included in the foreign-parented group.

(2) *Transferred stock—(i) In general.* Transferred stock means stock of the foreign acquiring corporation described in section 7874(a)(2)(B)(ii) that is received by a transferring corporation and, in a transaction (or series of transactions) related to the domestic entity acquisition, is subsequently transferred.

(ii) *Special rule.* This paragraph (f)(2)(ii) applies in certain cases in which a transferring corporation receives stock of the foreign acquiring corporation described in section 7874(a)(2)(B)(ii) that has the same terms as other stock of the foreign acquiring corporation that is received by the transferring corporation in a transaction (or series of transactions) related to the domestic entity acquisition or that is owned by the transferring corporation prior to the domestic entity acquisition (the stock described in this sentence, collectively, *fungible stock*). Pursuant to this paragraph (f)(2)(ii), if, in a transaction (or series of transactions) related to the domestic entity acquisition, the transferring corporation subsequently transfers less than all of the fungible stock, a pro rata portion of the stock subsequently transferred is treated as consisting of stock of the foreign acquiring corporation described in section 7874(a)(2)(B)(ii). The pro rata portion is based, at the time of the subsequent transfer, on the relative fair market value of the fungible stock that is stock of the foreign acquiring corporation described in section 7874(a)(2)(B)(ii) to the fair market value of all the fungible stock.

(3) A *transferring corporation* means a corporation that is a former domestic entity shareholder or former domestic entity partner.

(4) A *U.S.-parented group* means an affiliated group that has a domestic corporation as the common parent corporation. A *member of the U.S.-parented group* is an entity included in the U.S.-parented group, including the common parent corporation.

(g) *Examples.* The following examples illustrate the application of this section.

Example 1. U.S.-parented group exception not available—(i) Facts. USP, a domestic corporation wholly owned by Individual A, owns all the stock of DT, a domestic corporation, as well as other property. The DT stock does not represent substantially all of the property of USP for purposes of section

7874. Pursuant to a reorganization described in section 368(a)(1)(D), USP transfers all the DT stock to FA, a newly formed foreign corporation, in exchange for 100 shares of FA stock (DT acquisition) and distributes the FA stock to Individual A pursuant to section 361(c)(1).

(ii) *Analysis.* The 100 FA shares received by USP are stock of a foreign acquiring corporation described in section 7874(a)(2)(B)(ii) and, under § 1.7874–5(a), the shares retain their status as such even though USP subsequently distributes the shares to Individual A pursuant to section 361(c)(1). Thus, the 100 FA shares are included in the ownership fraction, unless the shares are treated as held by members of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874–1 and are excluded from the ownership fraction under those rules. For purposes of applying section 7874(c)(2)(A) and § 1.7874–1, the 100 FA shares, which constitute transferred stock under paragraph (f)(2) of this section, are treated as held by members of the EAG only if an exception in paragraph (c) of this section applies. See paragraph (b) of this section. The U.S.-parented group exception described in paragraph (c)(1) of this section does not apply. Although before the DT acquisition, USP (the transferring corporation) is a member of a U.S.-parented group of which USP is the common parent, after the DT acquisition, and taking into account all transactions related to the acquisition, each of USP, Individual A (the person that holds the transferred stock), and FA (the foreign acquiring corporation) are not members of a U.S.-parented group described in paragraph (c)(1)(ii)(A) or (B) of this section. Accordingly, because the 100 FA shares are not treated as held by members of the EAG, those shares are included in the numerator and the denominator of the ownership fraction. Therefore, the ownership fraction is 100/100.

Example 2. U.S.-parented group exception available—(i) Facts. USP, a domestic corporation wholly owned by Individual A, owns all the stock of USS, a domestic corporation, and USS owns all the stock of FT, a foreign corporation. FT owns all the stock of DT, a domestic corporation. FT does not own any other property and has no liabilities. Pursuant to a reorganization described in section 368(a)(1)(F), FT transfers all of its DT stock to FA, a newly formed foreign corporation, in exchange for 100 shares of FA stock (DT acquisition) and distributes the FA stock to USS in liquidation pursuant to section 361(c)(1). In a transaction after and related to the DT acquisition, USP sells 60 percent of the stock of USS (by vote and value) to Individual B.

(ii) *Analysis.* The 100 FA shares received by FT are stock of a foreign acquiring corporation described in section 7874(a)(2)(B)(ii) and, under § 1.7874–5(a), the shares retain their status as such even though FT subsequently distributes the shares to USS pursuant to section 361(c)(1). Thus, the 100 FA shares are included in the ownership fraction, unless the shares are treated as held by members of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874–1 and are excluded from the ownership

fraction under those rules. For purposes of applying section 7874(c)(2)(A) and § 1.7874-1, the 100 FA shares, which constitute transferred stock under paragraph (f)(2) of this section, are treated as held by members of the EAG only if an exception in paragraph (c) of this section applies. See paragraph (b) of this section. The U.S.-parented group exception described in paragraph (c)(1) of this section applies. The requirement set forth in paragraph (c)(1)(i) of this section is satisfied because before the DT acquisition, FT (the transferring corporation) is a member of a U.S.-parented group of which USP is the common parent (the USP group). The requirement set forth in paragraph (c)(1)(ii) of this section is satisfied because after the DT acquisition, and taking into account all transactions related to the acquisition, each of FA (which is both the successor to FT, the transferring corporation, and the foreign acquiring corporation) and USS (the person that holds the transferred stock) are members of a U.S.-parented group of which USS (a member of the USP group before the DT acquisition) is the common parent. Moreover, the DT acquisition qualifies as an internal group restructuring under § 1.7874-1(c)(2). The requirement set forth in § 1.7874-1(c)(2)(i) is satisfied because before the DT acquisition, 80 percent or more of the stock (by vote and value) of DT was held directly or indirectly by USS (the corporation that after the acquisition, and taking into account all transactions related to the acquisition, is the common parent of the EAG). The requirement set forth in § 1.7874-1(c)(2)(ii) is satisfied because after the acquisition, and taking into account all transactions related to the acquisition, 80 percent or more of the stock (by vote and value) of FA (the foreign acquiring corporation) is held directly or indirectly by USS. Therefore, the 100 FA shares are excluded from the numerator, but included in the denominator, of the ownership fraction. Accordingly, the ownership fraction is 0/100.

Example 3. U.S.-parented group exception available—(i) Facts. USP, a domestic corporation wholly owned by Individual A, owns all the stock of USS, a domestic corporation, and USS owns all the stock of DT, also a domestic corporation. DT owns all the stock of FT, a foreign corporation. The FT stock represents substantially all of the property of DT for purposes of section 7874. Pursuant to a reorganization described in section 368(a)(1)(D), DT transfers all the FT stock to FA, a newly formed foreign corporation, in exchange for 100 shares of FA stock (DT acquisition) and distributes the FA stock to USS pursuant to section 361(c)(1). In a related transaction, USS distributes all the FA stock to USP under section 355(c)(1). Lastly, in another related transaction and pursuant to a divisive reorganization described in section 368(a)(1)(D), USP transfers all the stock of USS and FA to DP, a newly formed domestic corporation, in exchange for all the stock of DP and distributes the DP stock to Individual A pursuant to section 361(c)(1).

(ii) **Analysis.** The 100 FA shares received by USS are stock of a foreign acquiring corporation described in section 7874(a)(2)(B)(ii) and, under § 1.7874-5(a), the

shares retain their status as such even though USS subsequently transfers the shares to USP. Thus, the 100 FA shares are included in the ownership fraction, unless the shares are treated as held by members of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874-1 and are excluded from the ownership fraction under those rules. For purposes of applying section 7874(c)(2)(A) and § 1.7874-1, the 100 FA shares, which constitute transferred stock under paragraph (f)(2) of this section, are treated as held by members of the EAG only if an exception in paragraph (c) of this section applies. See paragraph (b) of this section. The U.S.-parented group exception described in paragraph (c)(1) of this section applies. The requirement set forth in paragraph (c)(1)(i) of this section is satisfied because before the DT acquisition, USS (the transferring corporation) is a member of a U.S.-parented group of which USP is the common parent (the USP group). The requirement set forth in paragraph (c)(1)(ii) of this section is satisfied because after the DT acquisition, and taking into account all transactions related to the acquisition, each of USS, DP (the person that holds the transferred stock), and FA (the foreign acquiring corporation) are members of a U.S.-parented group of which DP (a corporation that was formed in a transaction related to the DT acquisition and that, immediately after it was formed (but without regard to any related transactions) was a member of the USP group) is the common parent. Therefore, the 100 FA shares are excluded from the numerator and the denominator of the ownership fraction. Accordingly, the ownership fraction is 0/0.

Example 4. Foreign-parented group exception—(i) Facts. Individual A owns all the stock of FT, a foreign corporation, and FT owns all the stock of DT, a domestic corporation. FT does not own any other property and has no liabilities. Pursuant to a reorganization described in section 368(a)(1)(F), FT transfers all the stock of DT to FA, a newly formed foreign corporation, in exchange for 100 shares of FA stock (DT acquisition) and distributes the FA stock to Individual A in liquidation pursuant to section 361(c)(1).

(ii) **Analysis.** The 100 FA shares received by FT are stock of a foreign acquiring corporation described in section 7874(a)(2)(B)(ii) and, under § 1.7874-5(a), the shares retain their status as such even though FT subsequently distributes the shares to Individual A pursuant to section 361(c)(1). Thus, the 100 FA shares are included in the ownership fraction, unless the shares are treated as held by members of the EAG for purposes of applying section 7874(a)(2)(A) and § 1.7874-1 and are excluded from the ownership fraction under those rules. For purposes of applying section 7874(c)(2)(A) and § 1.7874-1, the 100 FA shares, which constitute transferred stock under paragraph (f)(2) of this section, are treated as held by members of the EAG only if an exception in paragraph (c) of this section applies. See paragraph (b) of this section. The foreign-parented group exception described in paragraph (c)(2) of this section applies. The requirement set forth in paragraph (c)(2)(i) of

this section is satisfied because before the DT acquisition, FT (the transferring corporation) and DT are members of the foreign-parented group of which FT is the common parent. The requirement set forth in paragraph (c)(2)(ii) of this section is satisfied because after the acquisition, and taking into account all transactions related to the acquisition, FT would be a member of the EAG absent the distribution of the FA shares pursuant to section 361(c)(1). Moreover, the DT acquisition qualifies as an internal group restructuring under § 1.7874-1(c)(2). The requirement set forth in § 1.7874-1(c)(2)(i) is satisfied because before the acquisition, 80 percent or more of the stock (by vote and value) of DT was held directly or indirectly by FT, the corporation that, without regard to the distribution of the FA shares pursuant to section 361(c)(1), would be common parent of the EAG after the acquisition. See § 1.7874-1(c)(2)(iii). The requirement set forth in § 1.7874-1(c)(2)(ii) is satisfied because after the acquisition, but without regard to the distribution of the FA shares pursuant to the section 361(c)(1) distribution, FT would directly or indirectly hold 80 percent or more of the stock (by vote and value) of FA (the foreign acquiring corporation). See § 1.7874-1(c)(2)(iii). Therefore, the 100 FA shares are excluded from the numerator, but included in the denominator, of the ownership fraction. Accordingly, the ownership fraction is 0/100.

(iii) **Alternative facts.** The facts are the same as in paragraph (i) of this *Example 4*, except that in a transaction after and related to the DT acquisition, FA issues 200 shares of FA stock to Individual B in exchange for qualified property (within the meaning of § 1.7874-4(h)(2)). The foreign-parented group exception does not apply because after the acquisition, and taking into account FA's issuance of the 200 FA shares to Individual B, FT would not be a member of the EAG absent FT's distribution of the 100 FA shares pursuant to section 361(c)(1). Accordingly, the 100 FA shares received by FT are not treated as held by a member of the EAG for purposes of applying section 7874(c)(2)(A) and § 1.7874-1. As a result, the ownership fraction is 100/300.

(h) **Applicability dates.** Except as otherwise provided in this paragraph (h), this section applies to domestic entity acquisitions completed on or after September 22, 2014. Paragraphs (d)(2) and (f)(2)(ii) of this section apply to domestic entity acquisitions completed on or after April 4, 2016. Taxpayers, however, may elect either to apply paragraph (c)(2) of this section to domestic entity acquisitions completed before September 22, 2014, or to consistently apply paragraphs (c)(2), (d)(2), and (f)(2)(ii) of this section and § 1.7874-1(c)(2)(iii) and (g) to domestic entity acquisitions completed before April 4, 2016.

§ 1.7874-6T [Removed]

■ **Par. 22.** Section 1.7874-6T is removed.

■ **Par. 23.** Section 1.7874–7 is added to read as follows:

§ 1.7874–7 Disregard of certain stock attributable to passive assets.

(a) *Scope.* This section identifies certain stock of a foreign acquiring corporation that is attributable to passive assets and that is disregarded in determining the ownership fraction by value. Paragraph (b) of this section sets forth the general rule regarding when stock of a foreign acquiring corporation is excluded from the denominator of the ownership fraction under this section. Paragraph (c) of this section provides a de minimis exception to the application of the general rule of paragraph (b) of this section. Paragraph (d) of this section provides rules for the treatment of partnerships, and paragraph (e) of this section provides definitions. Paragraph (f) of this section provides examples illustrating the application of the rules of this section. Paragraph (g) of this section provides dates of applicability. The rules provided in this section are also subject to section 7874(c)(4). See § 1.7874–1(d)(1) for rules addressing the interaction of this section with the expanded affiliated group rules of section 7874(c)(2)(A) and § 1.7874–1.

(b) *General rule.* If, on the completion date, more than fifty percent of the gross value of all foreign group property constitutes foreign group nonqualified property, then, for purposes of determining the ownership percentage by value (but not vote) described in section 7874(a)(2)(B)(ii), stock of the foreign acquiring corporation is excluded from the denominator of the ownership fraction in an amount equal to the product of—

(1) The value of the stock of the foreign acquiring corporation, other than stock that is described in section 7874(a)(2)(B)(ii) and stock that is excluded from the denominator of the ownership fraction under § 1.7874–1(b), § 1.7874–4(b), § 1.7874–8(b), § 1.7874–9(b), or section 7874(c)(4); and

(2) The foreign group nonqualified property fraction.

(c) *De minimis ownership.* Paragraph (b) of this section does not apply if—

(1) The ownership percentage described in section 7874(a)(2)(B)(ii), determined without regard to the application of paragraph (b) of this section and §§ 1.7874–4(b) and 1.7874–10(b), is less than five (by vote and value); and

(2) On the completion date, each five percent former domestic entity shareholder or five percent former domestic entity partner, as applicable, owns (applying the attribution rules of section 318(a) with the modifications

described in section 304(c)(3)(B)) less than five percent (by vote and value) of the stock of (or a partnership interest in) each member of the expanded affiliated group. For this purpose, a five percent former domestic entity shareholder (or five percent former domestic entity partner) is a former domestic entity shareholder (or former domestic entity partner) that, before the domestic entity acquisition, owned (applying the attribution rules of section 318(a) with the modifications described in section 304(c)(3)(B)) at least five percent (by vote and value) of the stock of (or a partnership interest in) the domestic entity.

(d) *Treatment of partnerships.* For purposes of this section, if one or more members of the modified expanded affiliated group own, in the aggregate, more than 50 percent (by value) of the interests in a partnership, the partnership is treated as a corporation that is a member of the modified expanded affiliated group.

(e) *Definitions.* In addition to the definitions provided in § 1.7874–12, the following definitions apply for purposes of this section.

(1) *Foreign group nonqualified property—(i) General rule.* Foreign group nonqualified property means foreign group property described in § 1.7874–4(h)(2), other than the following:

(A) Property that gives rise to income described in section 954(h), determined—

(1) In the case of property held by a foreign corporation, by substituting the term “foreign corporation” for the term “controlled foreign corporation;” and

(2) In the case of property held by a domestic corporation, by substituting the term “domestic corporation” for the term “controlled foreign corporation,” without regard to the phrase “other than the United States” in section 954(h)(3)(A)(ii)(I), and without regard to any inference that the tests in section 954(h) should be calculated or determined without taking transactions with customers located in the United States into account.

(B) Property that gives rise to income described in section 954(i), determined by substituting the term “foreign corporation” for the term “controlled foreign corporation.”

(C) Property that gives rise to income described in section 1297(b)(2)(A) or (B) (determined without regard to other passive foreign investment company rules).

(D) Property held by a domestic corporation that is subject to tax as an insurance company under subchapter L of chapter 1 of subtitle A of the Internal

Revenue Code, provided that the property is required to support, or is substantially related to, the active conduct of an insurance business.

(ii) *Special rule.* Foreign group nonqualified property also means any foreign group property that, in a transaction related to the domestic entity acquisition, is acquired in exchange for other property, including cash, if such other property would be described in paragraph (e)(1)(i) of this section had the transaction not occurred.

(2) *Foreign group property* means any property (including excluded property, as described in paragraph (e)(3)(ii) of this section) held on the completion date by the modified expanded affiliated group, other than—

(i) Property that is directly or indirectly acquired in the domestic entity acquisition;

(ii) Stock or a partnership interest in a member of the modified expanded affiliated group; and

(iii) An obligation of a member of the modified expanded affiliated group.

(3) *Foreign group nonqualified property fraction—(i) In general.* Foreign group nonqualified property fraction means a fraction calculated with the following numerator and denominator:

(A) The numerator of the fraction is the gross value of all foreign group nonqualified property, other than excluded property (as described in paragraph (e)(3)(ii) of this section).

(B) The denominator of the fraction is the gross value of all foreign group property, other than excluded property (as described in paragraph (e)(3)(ii) of this section)

(ii) *Excluded property.* For purposes of paragraph (e)(3) of this section, excluded property means property that gives rise to stock that is excluded from the ownership fraction with respect to the domestic entity acquisition under § 1.7874–4(b), § 1.7874–8(b), § 1.7874–9(b), or section 7874(c)(4). For this purpose, only property that was directly or indirectly acquired in a prior domestic entity acquisition (as described in § 1.7874–8(g)(4)) or covered foreign acquisition (as described in § 1.7874–9(d)(4)) with respect to the domestic entity acquisition may be considered to give rise to stock that is excluded from the ownership fraction with respect to the domestic entity acquisition under § 1.7874–8(b) or § 1.7874–9(b). If only a portion of the consideration provided in a prior domestic entity acquisition or covered foreign acquisition consisted of stock of the foreign acquiring corporation, then only a pro rata portion of a property

directly or indirectly acquired in the prior domestic entity acquisition or covered foreign acquisition may be considered excluded property, based on a fraction the numerator of which is the amount of the consideration that consisted of stock of the foreign acquiring corporation and the denominator of which is the total amount of consideration.

(4) *Modified expanded affiliated group* means, with respect to a domestic entity acquisition, the group described in either paragraph (e)(4)(i) of this section or paragraph (e)(4)(ii) of this section. A *member of the modified expanded affiliated group* is an entity included in the modified expanded affiliated group.

(i) When the foreign acquiring corporation is not the common parent corporation of the expanded affiliated group, the expanded affiliated group determined as if the foreign acquiring corporation was the common parent corporation.

(ii) When the foreign acquiring corporation is the common parent corporation of the expanded affiliated group, the expanded affiliated group.

(f) *Examples.* The following examples illustrate the rules of this section.

Example 1. Application of general rule—(i) Facts. Individual A owns all 20 shares of the sole class of stock of FA, a foreign corporation. FA acquires all the stock of DT, a domestic corporation, solely in exchange for 76 shares of newly issued FA stock (DT acquisition). In a transaction related to the DT acquisition, FA issues 4 shares of stock to Individual A in exchange for Asset A, which has a gross value of \$50x. On the completion date, in addition to the DT stock and Asset A, FA holds Asset B, which has a gross value of \$150x, and Asset C, which has a gross value of \$100x. Assets A and B, but not Asset C, are nonqualified property (within the meaning of § 1.7874-4(h)(2)). Further, Asset C was not acquired in a transaction related to the DT acquisition.

(ii) *Analysis.* The 4 shares of FA stock issued to Individual A in exchange for Asset A are disqualified stock under § 1.7874-4(c) and are excluded from the denominator of the ownership fraction pursuant to § 1.7874-4(b). Furthermore, additional shares of FA stock are excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section. This is because on the completion date, the gross value of all foreign group property is \$300x (the sum of the gross values of Assets A, B, and C), the gross value of all foreign group nonqualified property is \$200x (the sum of the gross values of Assets A and B), and thus 66.67% of the gross value of all foreign group property constitutes foreign group nonqualified property (\$200x/\$300x). Because FA has only one class of stock outstanding, the shares of FA stock that are excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section are calculated by multiplying

20 shares of FA stock (100 shares less the 76 shares described in section 7874(a)(2)(B)(ii) and the 4 shares of disqualified stock) by the foreign group nonqualified property fraction. The numerator of the foreign group nonqualified property fraction is \$150x (the gross value of Asset B) and the denominator is \$250x (the sum of the gross values of Assets B and C). Asset A is not taken into account for purposes of the foreign group nonqualified property fraction because it gives rise to FA stock that is excluded under § 1.7874-4(b) (4 shares) and, as a result, is excluded property. Accordingly, 12 shares of FA stock are excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section (20 shares multiplied by \$150x/\$250x). Thus, a total of 16 shares are excluded from the denominator of the ownership fraction (4 + 12). As a result, the ownership fraction by value is 76/84.

Example 2. Application of de minimis exception—(i) Facts. Individual A owns all 96 shares of the sole class of stock of FA, a foreign corporation. Individual B wholly owns DT, a domestic corporation. Individuals A and B are not related. FA acquires all the stock of DT solely in exchange for 4 shares of newly issued FA stock (DT acquisition). On the completion date, in addition to all of the stock of DT, FA holds Asset A, which is nonqualified property (within the meaning of § 1.7874-4(h)(2)).

(ii) *Analysis.* Without regard to the application of §§ 1.7874-4(b) and 1.7874-10(b) as well as paragraph (b) of this section, the ownership percentage described in section 7874(a)(2)(B)(ii) would be less than 5 (by vote and value), or 4 (4/100, or 4 shares of FA stock held by Individual B by reason of owning the DT stock, determined under § 1.7874-2(f)(2), over 100 shares of FA stock outstanding after the DT acquisition). Furthermore, on the completion date, Individual B owns less than 5% (by vote and value) of the stock of FA and DT (the members of the expanded affiliated group). Accordingly, the de minimis exception in paragraph (c) of this section applies. Therefore, paragraph (b) of this section does not apply and the ownership fraction is 4/100.

Example 3. Foreign acquiring corporation not common parent of EAG—(i) Facts. FP, a foreign corporation, owns all 85 shares of the sole class of stock of FA, a foreign corporation. FA acquires all the stock of DT, a domestic corporation, solely in exchange for 65 shares of newly issued FA stock (DT acquisition). On the completion date, FA, in addition to all of the stock of DT, owns Asset A, which has a gross value of \$40x, and Asset B, which has a gross value of \$45x. Moreover, on the completion date, in addition to the 85 shares of FA stock, FP owns Asset C, which has a gross value of \$10x. Assets A and C, but not Asset B, are nonqualified property (within the meaning of § 1.7874-4(h)(2)). Further, Asset B was not acquired in a transaction related to the DT acquisition in exchange for nonqualified property.

(ii) *Analysis.* Under paragraph (e)(2) of this section, Assets A and B, but not Asset C, are foreign group property. Although Asset C is

held on the completion date by FP, a member of the expanded affiliated group, Asset C is not foreign group property because FP is not a member of the modified expanded affiliated group. This is the case because if the expanded affiliated group were determined based on FA as the common parent corporation, FP would not be a member of such expanded affiliated group (see paragraph (e)(4)(i) of this section). Under paragraph (e)(1) of this section, Asset A, but not Asset B, is foreign group nonqualified property. Therefore, on the completion date, the gross value of all foreign group property is \$85x (the sum of the gross values of Assets A and B), and the gross value of all foreign group nonqualified property is \$40x (the gross value of Asset A). Accordingly, on the completion date, only 47.06% of the gross value of all foreign group property constitutes foreign group nonqualified property (\$40x/\$85x). Consequently, paragraph (b) of this section does not apply to exclude any FA stock from the denominator of the ownership fraction.

Example 4. Coordination with serial acquisition rule—(i) Facts. Individual A owns all 30 shares of the sole class of stock of FA, a foreign corporation. In Year 1, FA acquires all the stock of DT1, a domestic corporation, solely in exchange for 40 shares of newly issued FA stock (DT1 acquisition). In Year 2, FA acquires all the stock of DT2, a domestic corporation, solely in exchange for 50 shares of newly issued FA stock (DT2 acquisition). On the completion date for the DT2 acquisition, in addition to the DT2 stock, FA holds Asset A, which has a gross value of \$15x, Asset B, which has a gross value of \$15x, and all the stock of DT1, which has a gross value of \$40x. At all times, DT1 holds only Asset C, which has a gross value of \$30x, and Asset D, which has a gross value of \$10x. Assets A and C, but not Assets B and D, are nonqualified property (within the meaning of § 1.7874-4(h)(2)). In addition, at all times, the fair market value of each share of FA stock is \$1x. Further, there have been no redemptions of FA stock subsequent to the DT1 acquisition. Lastly, under § 1.7874-8, the DT1 acquisition is a prior domestic entity acquisition with respect to the DT2 acquisition and \$40x of FA stock is excluded from the denominator of the ownership fraction with respect to the DT2 acquisition.

(ii) *Analysis.* Shares of FA stock are excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section. This is because on the completion date, the gross value of all foreign group property is \$70x (the sum of the gross values of Assets A, B, C, and D), the gross value of all foreign group nonqualified property is \$45x (the sum of the gross values of Assets A and C), and thus 64.29% of the gross value of all foreign group property constitutes foreign group nonqualified property (\$45x/\$70x). The shares of FA stock that are excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section are calculated by multiplying \$30x (\$120x, the value of all the shares of FA stock, less \$50x, the value of the stock described in section 7874(a)(2)(B)(ii), less \$40x, the value of the stock excluded

under § 1.7874–8(b)) by the foreign group nonqualified property fraction. The property taken into account for purposes of determining the foreign group nonqualified property fraction is Asset A and Asset B. Asset C and Asset D are not taken into account for purposes of the foreign group nonqualified property fraction because they are excluded property. This is because FA indirectly acquired the Assets in the DT1 acquisition (a prior domestic entity acquisition with respect to the DT2 acquisition) and, as a result of that acquisition, \$40x of FA stock is excluded from the denominator of the ownership fraction with respect to the DT2 acquisition under § 1.7874–8(b). Thus, the numerator of the foreign group nonqualified property fraction is \$15x (the gross value of Asset A) and the denominator is \$30x (the sum of the gross values of Asset A, \$15x, and Asset B, \$15x). Accordingly, \$15x of FA stock is excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section (\$30x multiplied by \$15x/\$30x). Thus, a total of \$55x of FA stock is excluded from the denominator of the ownership fraction (\$40x + \$15x), making the denominator \$65x (\$120x – \$55x). As a result, the ownership percentage with respect to the DT2 acquisition by value is 76.92 (\$50x/\$65x).

(ii) *Alternative facts.* The facts are the same as in paragraph (i) of this Example 4, except as follows. Initially, there are 40 shares of FA stock outstanding, all of which are owned by Individual A. At all times, the gross value of asset D is \$20x. In the DT1 acquisition, FA acquires all the stock of DT1 (\$50x fair market value) solely in exchange for 40 shares of newly issued FA stock and \$10x of other property. As in paragraph (i) of this Example 4, shares of FA stock are excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section. This is because on the completion date, the gross value of all foreign group property is \$80x (the sum of the gross values of Assets A, B, C, and D), the gross value of all foreign group nonqualified property is \$45x (the sum of the gross values of Assets A and C), and thus 56.25% of the gross value of all foreign group property constitutes foreign group nonqualified property (\$45x/\$80x). The shares of FA stock that are excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section are calculated by multiplying \$40x (\$130x, the value of all the shares of FA stock, less \$50x, the value of the stock described in section 7874(a)(2)(B)(ii), less \$40x, the value of the stock excluded under § 1.7874–8(b)) by the foreign group nonqualified property fraction. The property taken into account for purposes of determining the foreign group nonqualified property fraction is Asset A, Asset B, and the portion of Asset C and Asset D that is not excluded property. Eighty percent of each of Asset C and Asset D are considered excluded property because FA indirectly acquired Asset C and Asset D in the DT1 acquisition (a prior domestic entity acquisition with respect to the DT2 acquisition); as a result of that acquisition, \$40x of FA stock is excluded from the denominator of the ownership

fraction with respect to the DT2 acquisition under § 1.7874–8(b); and 80% of the consideration provided in the DT1 acquisition consisted of stock of FA (\$40x/\$50x). Thus, the numerator of the foreign group nonqualified property fraction is \$21x (the sum of the gross values of Asset A, \$15x, and the portion of Asset C that is not excluded property, \$6x) and the denominator is \$40x (the sum of the gross values of Asset A, \$15x, Asset B, \$15x, and the portion of Asset C and Asset D that is not excluded property, \$6x and \$4x, respectively). Accordingly, \$21x of FA stock is excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section (\$40x multiplied by \$21x/\$40x). Thus, a total of \$61x of FA stock is excluded from the denominator of the ownership fraction pursuant to paragraph (b) of this section (\$40x + \$21x), making the denominator \$69x (\$130x – \$61x). As a result, the ownership percentage with respect to D2 acquisition by value is 72.46 (\$50x/\$69x).

(g) *Applicability dates.* This section applies to domestic entity acquisitions completed on or after July 12, 2018. For domestic entity acquisitions completed before July 12, 2018, see § 1.7874–7T, as contained in 26 CFR part 1 revised as of April 1, 2017. However, to the extent this section differs from § 1.7874–7T, as contained in 26 CFR part 1 revised as of April 1, 2017, taxpayers may elect to domestically apply the differences to domestic entity acquisitions completed before July 12, 2018.

§ 1.7874–7T [Removed]

■ **Par. 24.** Section 1.7874–7T is removed.

■ **Par. 25.** Section 1.7874–8 is added to read as follows:

§ 1.7874–8 Disregard of certain stock attributable to serial acquisitions.

(a) *Scope.* This section identifies stock of a foreign acquiring corporation that is disregarded in determining an ownership fraction by value because it is attributable to certain prior domestic entity acquisitions. Paragraph (b) of this section sets forth the general rule regarding the amount of stock of a foreign acquiring corporation that is excluded from the denominator of the ownership fraction by value under this section, and paragraphs (c) through (f) of this section provide rules for determining this amount. Paragraph (g) provides definitions. Paragraph (h) of this section provides examples illustrating the application of the rules of this section. Paragraph (i) of this section provides dates of applicability. This section applies after taking into account § 1.7874–2(e). See § 1.7874–1(d)(1) for rules addressing the interaction of this section with the

expanded affiliated group rules of section 7874(c)(2)(A) and § 1.7874–1.

(b) *General rule.* This paragraph (b) applies to a domestic entity acquisition (relevant domestic entity acquisition) when the foreign acquiring corporation (including a predecessor, as defined in § 1.7874–10(f)(1)) has completed one or more prior domestic entity acquisitions. When this paragraph (b) applies, then, for purposes of determining the ownership percentage by value (but not vote) described in section 7874(a)(2)(B)(ii), stock of the foreign acquiring corporation is excluded from the denominator of the ownership fraction in an amount equal to the sum of the excluded amounts computed separately with respect to each prior domestic entity acquisition and each relevant share class.

(c) *Computation of excluded amounts.* With respect to each prior domestic entity acquisition and each relevant share class, the excluded amount is the product of—

(1) The total number of prior acquisition shares, reduced by the sum of the number of allocable redeemed shares for all redemption testing periods; and

(2) The fair market value of a single share of stock of the relevant share class on the completion date of the relevant domestic entity acquisition.

(d) *Computation of allocable redeemed shares—*(1) *In general.* With respect to each prior domestic entity acquisition and each relevant share class, the allocable redeemed shares, determined separately for each redemption testing period, is the product of the number of redeemed shares during the redemption testing period and the redemption fraction.

(2) *Redemption fraction.* The redemption fraction is determined separately with respect to each prior domestic entity acquisition, each relevant share class, and each redemption testing period, as follows:

(i) The numerator is the total number of prior acquisition shares, reduced by the sum of the number of allocable redeemed shares for all prior redemption testing periods.

(ii) The denominator is the sum of—

(A) The number of outstanding shares of the foreign acquiring corporation stock as of the end of the last day of the redemption testing period; and

(B) The number of redeemed shares during the redemption testing period.

(e) *Rules for determining redemption testing periods—*(1) *In general.* Except as provided in paragraph (e)(2) of this section, a redemption testing period with respect to a prior domestic entity acquisition is the period beginning on

the day after the completion date of the prior domestic entity acquisition and ending on the day prior to the completion date of the relevant domestic entity acquisition.

(2) *Election to use multiple redemption testing periods.* A foreign acquiring corporation may establish a reasonable method for dividing the period described in paragraph (e)(1) of this section into shorter periods (each such shorter period, a redemption testing period). A reasonable method would include a method based on a calendar convention (for example, daily, monthly, quarterly, or yearly), or on a convention that triggers the start of a new redemption testing period whenever a share issuance occurs that exceeds a certain threshold. In order to be reasonable, the method must be consistently applied with respect to all prior domestic entity acquisitions and all relevant share classes.

(f) *Appropriate adjustments required to take into account share splits and similar transactions.* For purposes of this section, appropriate adjustments must be made to take into account changes in a foreign acquiring corporation's capital structure, including, for example, stock splits, reverse stock splits, stock distributions, recapitalizations, and similar transactions. Thus, for example, in determining the total number of prior acquisition shares with respect to a relevant share class, appropriate adjustments must be made to take into account a stock split with respect to that relevant share class that occurs after the completion date with respect to a prior domestic entity acquisition.

(g) *Definitions.* In addition to the definitions provided in § 1.7874-12, the following definitions apply for purposes of this section.

(1) A *binding contract* means an instrument enforceable under applicable law against the parties to the instrument. The presence of a condition outside the control of the parties (including, for example, regulatory agency approval) does not prevent an instrument from being a binding contract. Further, the fact that insubstantial terms remain to be negotiated by the parties to the contract, or that customary conditions remain to be satisfied, does not prevent an instrument from being a binding contract. A tender offer that is subject to section 14(d) of the Securities and Exchange Act of 1934, (15 U.S.C. 78n(d)(1)), and Regulation 14D (17 CFR 240.14d-1 through 240.14d-103) and that is not pursuant to a binding contract, is treated as a binding contract made on the date of its announcement,

notwithstanding that it may be modified by the offeror or that it is not enforceable against the offerees.

(2) A *relevant share class* means, with respect to a prior domestic entity acquisition, each separate legal class of shares in the foreign acquiring corporation from which prior acquisition shares were issued. See also paragraph (f) of this section (requiring appropriate adjustments in certain cases).

(3) *Total number of prior acquisition shares* means, with respect to a prior domestic entity acquisition and each relevant share class, the total number of shares of stock of the foreign acquiring corporation that were described in section 7874(a)(2)(B)(ii) as a result of that acquisition (without regard to whether the 60 percent test of section 7874(a)(2)(B)(ii) was satisfied), other than stock treated as received by former domestic entity shareholders or former domestic entity partners under § 1.7874-10(b) or section 7874(c)(4), adjusted as appropriate under paragraph (f) of this section.

(4) A *prior domestic entity acquisition*—(i) *General rule.* Except as provided in this paragraph (g)(4), a prior domestic entity acquisition means, with respect to a relevant domestic entity acquisition, a domestic entity acquisition that occurred within the 36-month period ending on the signing date of the relevant domestic entity acquisition.

(ii) *Exception.* A domestic entity acquisition is not a prior domestic entity acquisition if it is described in paragraph (g)(4)(ii)(A) or (B) of this section.

(A) *De minimis.* A domestic entity acquisition is described in this paragraph (g)(4)(ii)(A) if—

(1) The ownership percentage described in section 7874(a)(2)(B)(ii) with respect to the domestic entity acquisition was less than five (by vote and value); and

(2) The fair market value of the stock of the foreign acquiring corporation described in section 7874(a)(2)(B)(ii) as a result of the domestic entity acquisition (without regard to whether the 60 percent test of section 7874(a)(2)(B)(ii) was satisfied) did not exceed \$50 million, as determined on the completion date with respect to the domestic entity acquisition.

(B) *Foreign-parented group.* A domestic entity acquisition is described in this paragraph (g)(4)(ii)(B) if—

(1) Before the domestic entity acquisition and any related transaction, the domestic entity was a member of a foreign-parented group (as described in § 1.7874-6(f)(1)); and

(2) The domestic entity acquisition qualified for the internal group restructuring exception under § 1.7874-1(c)(2).

(5) A *redeemed share* means a share of stock in a relevant share class that was redeemed (within the meaning of section 317(b)).

(6) A *signing date* means the first date on which the contract to effect the relevant domestic entity acquisition is a binding contract, or if another binding contract to effect a substantially similar acquisition was terminated with a principal purpose of avoiding section 7874, the first date on which such other contract was a binding contract.

(h) *Examples.* The following examples illustrate the rules of this section.

Example 1. Application of general rule—(i) Facts. Individual A wholly owns DT1, a domestic corporation. Individual B owns all 100 shares of the sole class of stock of FA, a foreign corporation. In Year 1, FA acquires all the stock of DT1 solely in exchange for 100 shares of newly issued FA stock (DT1 acquisition). On the completion date with respect to the DT1 acquisition, the fair market value of each share of FA stock is \$1x. In Year 3, FA enters into a binding contract to acquire all the stock of DT2, a domestic corporation wholly owned by Individual C. Thereafter, FA acquires all the stock of DT2 solely in exchange for 150 shares of newly issued FA stock (DT2 acquisition). On the completion date with respect to the DT2 acquisition, the fair market value of each share of FA stock is \$1.50x. FA did not complete the DT1 acquisition and DT2 acquisition pursuant to a plan (or series of related transactions) for purposes of applying § 1.7874-2(e). In addition, there have been no redemptions of FA stock subsequent to the DT1 acquisition.

(ii) *Analysis.* The DT1 acquisition is a prior domestic entity acquisition with respect to the DT2 acquisition (the relevant domestic entity acquisition) because the DT1 acquisition occurred within the 36-month period ending on the signing date with respect to the DT2 acquisition. Accordingly, paragraph (b) of this section applies to the DT2 acquisition. As a result, and because there were no redemptions of FA stock, the excluded amount is \$150x, calculated as 100 (the total number of prior acquisition shares) multiplied by \$1.50x (the fair market value of a single share of FA stock on the completion date with respect to the DT2 acquisition). Accordingly, the numerator of the ownership fraction by value is \$225x (the fair market value of the stock of FA that, with respect to the DT2 acquisition, is described in section 7874(a)(2)(B)(ii)) (150 shares x \$1.50x per share). In addition, the denominator of the ownership fraction is \$375x (calculated as \$525x, the fair market value of all 350 shares of FA stock as of the completion date with respect to the DT2 acquisition, less \$150x, the excluded amount). Therefore, the ownership percentage by value is 60 (\$225x divided by \$375x).

Example 2. Effect of certain redemptions—
(i) *Facts.* The facts are the same as in paragraph (i) of *Example 1* of this paragraph (h), except that in Year 2 FA redeems 50 shares of its stock (the Year 2 redemption).

(ii) *Analysis.* As is the case in paragraph (ii) of *Example 1* of this paragraph (h), the DT1 acquisition is a prior domestic entity acquisition with respect to the DT2 acquisition (the relevant domestic entity acquisition), and paragraph (b) of this section thus applies to the DT2 acquisition. Because of the Year 2 redemption, the allocable redeemed shares, and thus the redemption fraction, must be calculated. For this purpose, the redemption testing period is the period beginning on the day after the completion date with respect to the DT1 acquisition and ending on the day prior to the completion date with respect to the DT2 acquisition. The redemption fraction for the redemption testing period is thus 100/200, calculated as 100 (the total number of prior acquisition shares) divided by 200 (150, the number of outstanding shares of FA stock on the last day of the redemption testing period, plus 50, the number of redeemed shares during the redemption testing period), and the allocable redeemed shares for the redemption testing period is 25, calculated as 50 (the number of redeemed shares during the redemption testing period) multiplied by 100/200 (the redemption fraction for the redemption testing period). As a result, the excluded amount is \$112.50x, calculated as 75 (100, the total number of prior acquisition shares, less 25, the allocable redeemed shares) multiplied by \$1.50x (the fair market value of a single share of FA stock on the completion date with respect to the DT2 acquisition). Accordingly, the numerator of the ownership fraction by value is \$225x (the fair market value of the stock of FA that, with respect to the DT2 acquisition, is described in section 7874(a)(2)(B)(ii)) (150 shares \times \$1.50x per share), and the denominator of the ownership fraction is \$337.50x (calculated as \$450x, the fair market value of all 300 shares of FA stock as of the completion date with respect to the DT2 acquisition, less \$112.50x, the excluded amount). Therefore, the ownership percentage by value is 66.67 (\$225x divided by \$337.50x).

Example 3. Stock split—(i) *Facts.* The facts are the same as in paragraph (i) of *Example 2* of this paragraph (h), except as follows. After the Year 2 redemption, but before the DT2 acquisition, FA undergoes a stock split and, as a result, each of the 150 shares of FA stock outstanding are converted into two shares (Year 2 stock split). Further, pursuant to the DT2 acquisition, FA acquires all the stock of DT2 solely in exchange for 300 shares of newly issued FA stock. Moreover, on the completion date with respect to the DT2 acquisition, the fair market value of each share of FA stock is \$0.75x.

(ii) *Analysis.* As is the case in paragraph (ii) of *Example 1* of this paragraph (h), the DT1 acquisition is a prior domestic entity acquisition with respect to the DT2 acquisition (the relevant domestic entity acquisition), and paragraph (b) of this section thus applies to the DT2 acquisition. In addition, as is the case in paragraph (ii) of *Example 2* of this paragraph (h), the

redemption testing period is the period beginning on the day after the completion date with respect to the DT1 acquisition and ending on the day prior to the completion date with respect to the DT2 acquisition. To calculate the redemption fraction, the total number of prior acquisition shares and the number of redeemed shares during the redemption testing period must be appropriately adjusted to take into account the Year 2 stock split. See paragraph (f) of this section. In this case, the appropriate adjustment is to increase the total number of prior acquisition shares from 100 to 200 and to increase the number of redeemed shares during the redemption testing period from 50 to 100. Thus, the redemption fraction for the redemption testing period is 200/400, calculated as 200 (the total number of prior acquisition shares) divided by 400 (300, the number of outstanding shares of FA stock on the last day of the redemption testing period, plus 100, the number of redeemed shares during the redemption testing period), and the allocable redeemed shares for the redemption testing period is 50, calculated as 100 (the number of redeemed shares during the redemption testing period) multiplied by 200/400 (the redemption fraction for the redemption testing period). In addition, for purposes of calculating the excluded amount, the total number of prior acquisition shares must be adjusted from 100 to 200. See paragraph (f) of this section. Accordingly, the excluded amount is \$112.50x, calculated as 150 (200, the total number of prior acquisition shares, less 50, the allocable redeemed shares) multiplied by \$0.75x (the fair market value of a single share of FA stock on the completion date with respect to the DT2 acquisition). Consequently, the numerator of the ownership fraction by value is \$225x (the fair market value of the stock of FA that, with respect to the DT2 acquisition, is described in section 7874(a)(2)(B)(ii)) (300 shares \times \$0.75x per share), and the denominator of the ownership fraction is \$337.50x (calculated as \$450x, the fair market value of all 600 shares of FA stock as of the completion date with respect to the DT2 acquisition, less \$112.50x, the excluded amount). Therefore, the ownership percentage by value is 66.67 (\$225 divided by \$337.50x).

(i) *Applicability dates.* Except as provided in this paragraph (i), this section applies to domestic entity acquisitions completed on or after April 4, 2016, regardless of when a prior domestic entity acquisition was completed. Paragraphs (g)(3) and (g)(4)(ii) of this section apply to domestic entity acquisitions completed on or after July 12, 2018. However, taxpayers may elect to consistently apply paragraphs (g)(3) and (g)(4)(ii) of this section to domestic entity acquisitions completed on or after April 4, 2016, and before July 12, 2018. For domestic entity acquisitions completed on or after April 4, 2016, and before July 12, 2018, see § 1.7874–8T(g)(3) and (g)(4)(ii) as contained in 26 CFR part 1 revised as of April 1, 2017.

§ 1.7874–8T [Removed]

■ **Par. 26.** Section 1.7874–8T is removed.

■ **Par. 27.** Section 1.7874–9 is added to read as follows:

§ 1.7874–9 Disregard of certain stock in third-country transactions.

(a) *Scope.* This section identifies certain stock of a foreign acquiring corporation that is disregarded in determining the ownership fraction. Paragraph (b) of this section provides a rule that, in a third-country transaction, excludes from the denominator of the ownership fraction stock in the foreign acquiring corporation held by former shareholders of an acquired foreign corporation by reason of holding certain stock in that foreign corporation. Paragraph (c) of this section defines a third-country transaction, and paragraph (d) of this section provides other definitions. Paragraph (e) of this section provides operating rules. Paragraph (f) of this section provides an example illustrating the application of the rules of this section. Paragraph (g) of this section provides the dates of applicability. See § 1.7874–1(d)(1) for rules addressing the interaction of this section with the expanded affiliated group rules of section 7874(c)(2)(A) and § 1.7874–1.

(b) *Exclusion of certain stock of a foreign acquiring corporation from the ownership fraction.* When a domestic entity acquisition is a third-country transaction, stock of the foreign acquiring corporation held by reason of holding stock in the acquired foreign corporation (within the meaning of paragraph (e)(4) of this section) is, to the extent the stock otherwise would be included in the denominator of the ownership fraction, excluded from the denominator of the ownership fraction pursuant to this paragraph.

(c) *Third-country transaction.* A domestic entity acquisition is a third-country transaction if the following requirements are satisfied:

(1) The foreign acquiring corporation completes a covered foreign acquisition pursuant to a plan (or series of related transactions) that includes the domestic entity acquisition.

(2) After the covered foreign acquisition and all related transactions are complete, the foreign acquiring corporation is not a tax resident of the foreign country in which the acquired foreign corporation was a tax resident before the covered foreign acquisition and all related transactions.

(3) The ownership percentage described in section 7874(a)(2)(B)(ii), determined without regard to the

application of paragraph (b) of this section, is at least 60.

(d) *Definitions.* In addition to the definitions provided in § 1.7874–12, the following definitions apply for purposes of this section.

(1) A *foreign acquisition* means a transaction in which a foreign acquiring corporation directly or indirectly acquires substantially all of the properties held directly or indirectly by an acquired foreign corporation (within the meaning of paragraph (e)(2) of this section).

(2) An *acquired foreign corporation* means a foreign corporation whose properties are acquired in a foreign acquisition.

(3) *Foreign ownership percentage* means, with respect to a foreign acquisition, the percentage of stock (by vote or value) of the foreign acquiring corporation held by reason of holding stock in the acquired foreign corporation (within the meaning of paragraph (e)(3) of this section).

(4) *Covered foreign acquisition*—(i) *In general.* Except as provided in paragraphs (d)(4)(ii) and (iii) of this section, a covered foreign acquisition means a foreign acquisition in which, after the acquisition and all related transactions are complete, the foreign ownership percentage is at least 60.

(ii) *Substantial business activities exception.* A foreign acquisition is not a covered foreign acquisition if, on the completion date, the following requirements are satisfied:

(A) The foreign acquiring corporation is a tax resident of a foreign country.

(B) The expanded affiliated group has substantial business activities in the country in which the foreign acquiring corporation is a tax resident when compared to the total business activities of the expanded affiliated group. For this purpose, the principles of § 1.7874–3 apply and the determination of whether there are substantial business activities is made without regard to the domestic entity acquisition.

(iii) *No income tax exception.* A foreign acquisition is not a covered foreign acquisition if—

(A) Before the acquisition and all related transactions, the acquired foreign corporation was created or organized in, or under the law of, a foreign country that does not impose corporate income tax and was not a tax resident of any other foreign country; and

(B) After the acquisition and all related transactions are complete, the foreign acquiring corporation is created or organized in, or under the law of, a foreign country that does not impose

corporate income tax and is not a tax resident of any other foreign country.

(5) A *tax resident* of a foreign country has the meaning set forth in § 1.7874–3(d)(11).

(e) *Operating rules.* The following rules apply for purposes of this section.

(1) *Acquisition of multiple foreign corporations that are tax residents of the same foreign country.* When multiple foreign acquisitions occur pursuant to the same plan (or a series of related transactions) and two or more of the acquired foreign corporations were tax residents of the same foreign country before the foreign acquisitions and all related transactions, then those foreign acquisitions are treated as a single foreign acquisition and those acquired foreign corporations are treated as a single acquired foreign corporation for purposes of this section.

(2) *Acquisition of properties of an acquired foreign corporation.* For purposes of determining whether a foreign acquisition occurs, the principles of section 7874(a)(2)(B)(i) and § 1.7874–2(c) and (d) (regarding acquisitions of properties of a domestic entity and acquisitions by multiple foreign corporations) apply with the following modifications:

(i) The principles of § 1.7874–2(c)(1) (providing rules for determining whether there is an indirect acquisition of properties of a domestic entity), including § 1.7874–2(b)(5) (providing rules for determining the proportionate amount of properties indirectly acquired), apply by substituting the term “foreign” for “domestic” wherever it appears.

(ii) The principles of § 1.7874–2(c)(2) (regarding acquisitions of stock of a foreign corporation that owns a domestic entity) apply by substituting the term “domestic” for “foreign” wherever it appears.

(3) *Computation of foreign ownership percentage.* For purposes of determining a foreign ownership percentage, the principles of all rules applicable to calculating an ownership percentage apply (including §§ 1.7874–2, 1.7874–4, 1.7874–5, 1.7874–7, and section 7874(c)(4)) with the following modifications:

(i) Stock of a foreign acquiring corporation described in section 7874(a)(2)(B)(ii) is not taken into account.

(ii) The principles of this section, section 7874(c)(2)(A), and §§ 1.7874–1, 1.7874–6, 1.7874–8, and 1.7874–10 do not apply.

(iii) The principles of § 1.7874–7 apply by, in addition to the exclusions listed in § 1.7874–7(e)(2)(i) through (iii), also excluding from the definition of

foreign group property any property held directly or indirectly by the acquired foreign corporation immediately before the foreign acquisition and directly or indirectly acquired in the foreign acquisition.

(4) *Stock held by reason of holding stock in an acquired foreign corporation.* For purposes of determining stock of a foreign acquiring corporation held by reason of holding stock in an acquired foreign corporation, the principles of section 7874(a)(2)(B)(ii) and §§ 1.7874–2(f) and 1.7874–5 apply.

(5) *Change in the tax residency of a foreign corporation.* For purposes of this section, a change in a country in which a foreign corporation is a tax resident is treated as a transaction. Further, for purposes of this section, if a foreign acquiring corporation changes the country in which it is a tax resident in a manner that would not otherwise be considered to result in a foreign acquisition (for example, by changing where it is managed and controlled), then the foreign acquiring corporation is treated as—

(i) Both an acquired foreign corporation and a foreign acquiring corporation; and

(ii) Directly or indirectly acquiring all of the properties held directly or indirectly by the acquired foreign corporation solely in exchange for stock of the foreign acquiring corporation.

(f) *Example.* The following example illustrates the rules of this section.

Example. Third-country transaction—(i) *Facts.* FA, a newly formed foreign corporation that is a tax resident of Country Y, acquires all the stock of DT, a domestic corporation that is wholly owned by Individual A, solely in exchange for 65 shares of newly issued FA stock (DT acquisition). Pursuant to a plan that includes the DT acquisition, FA acquires all the stock of FT, a foreign corporation that is a tax resident of Country X and wholly owned by Individual B, solely in exchange for the remaining 35 shares of newly issued FA stock (FT acquisition). After the FT acquisition and all related transactions, the expanded affiliated group does not have substantial business activities in Country Y when compared to the total business activities of the expanded affiliated group, as determined under the principles of § 1.7874–3 and without regard to the DT acquisition.

(ii) *Analysis.* As described in paragraphs (A) through (C) of this *Example*, the requirements set forth in paragraphs (c)(1) through (3) of this section are satisfied and, as result, the DT acquisition is a third-country transaction.

(A) The FT acquisition is a foreign acquisition because, pursuant to the FT acquisition, FA (a foreign acquiring corporation) acquires 100 percent of the stock of FT and is thus treated as indirectly acquiring 100 percent of the properties held by FT (an acquired foreign corporation). See

§ 1.7874–2(c)(1) and paragraph (e)(2) of this section. Moreover, Individual B is treated as receiving 35 shares of FA stock by reason of holding stock in FT. See § 1.7874–2(f)(1)(i) and paragraph (e)(4) of this section. As a result, not taking into account the 65 shares of FA stock held by Individual A (a former domestic entity shareholder), 100 percent (35/35) of the stock of FA is held by reason of holding stock in FT and, thus, the foreign ownership percentage is 100. See paragraph (e)(3) of this section. Accordingly, the FT acquisition is a covered foreign acquisition. Therefore, because the FT acquisition occurs pursuant to a plan that includes the DT acquisition, the requirement set forth in paragraph (c)(1) of this section is satisfied.

(B) The requirement set forth in paragraph (c)(2) of this section is satisfied because, after the FT acquisition and all related transactions, the foreign country in which FA is a tax resident (Country Y) is different than the foreign country in which FT was a resident (Country X) before the FT acquisition and all related transactions.

(C) The requirement set forth in paragraph (c)(3) of this section is satisfied because, not taking into account paragraph (b) of this section, the ownership fraction is 65/100 and the ownership percentage is 65.

(D) Because the DT acquisition is a third-country transaction, the 35 shares of FA stock held by reason of holding stock in FT are excluded from the denominator of the ownership fraction. See paragraph (b) of this section. As a result, the ownership fraction is 65/65 and the ownership percentage is 100. The result would be the same if instead FA had directly acquired all of the properties held by FT in exchange for FA stock, for example, in a transaction that would qualify for U.S. federal income tax purposes as an asset reorganization under section 368.

(iii) *Alternative facts.* The facts are the same as in paragraph (i) of this example, except that before the FT acquisition, but in a transaction related to the FT acquisition, FT becomes a tax resident of Country Y by reincorporating in Country Y. As is the case in paragraph (ii) of this *Example*, the requirements set forth in paragraphs (c)(1) and (3) of this section are satisfied. The requirement set forth in paragraph (c)(2) of this section is satisfied because, after the FT acquisition and any related transactions, the foreign country of which FA is a tax resident (Country Y) is different than the foreign country of which FT was a tax resident (Country X) before the FT acquisition and the reincorporation. See paragraph (e)(5) of this section. Accordingly, the DT acquisition is a third-country transaction and the consequences are the same as in paragraph (ii)(D) of this *Example*.

(iv) *Alternative facts.* The facts are the same as in paragraph (i) of this *Example*, except that, instead of FA acquiring all of the stock of FT, FS, a newly formed foreign corporation that is wholly owned by FA and that is a tax resident of Country X, acquires all the stock of FT solely in exchange for 35 shares of newly issued FA stock (FT acquisition). As a result of the FT acquisition, FS and FA are each treated as indirectly acquiring 100 percent of the properties held by FT. See § 1.7874–2(c)(1)(i) and (iii) and

paragraph (e)(2) of this section. Accordingly, each of FS's and FA's indirect acquisition of properties of FT (an acquired foreign corporation) is a foreign acquisition. However, FS's indirect acquisition of FT's properties is not a covered foreign acquisition because no shares of FS stock are held by reason of holding stock in FT; thus, with respect to this foreign acquisition, the foreign ownership percentage is zero. See § 1.7874–2(f) and paragraphs (e)(3) and (4) of this section. FA's indirect acquisition of FT's properties is a covered foreign acquisition because 35 shares of FA stock (the shares received by Individual B) are held by reason of holding stock in FT; thus, the foreign ownership percentage is 100 percent (35/35). See § 1.7874–2(f)(1)(i) and paragraphs (e)(3) and (4) of this section. Accordingly, because the FT acquisition occurs pursuant to a plan that includes the DT acquisition, the requirement set forth in paragraph (c)(1) of this section is satisfied. Further, as is the case in paragraphs (ii)(B) through (C) of this *Example*, the requirements set forth in paragraphs (c)(2) and (3) of this section are satisfied. Therefore, the DT acquisition is a third-country transaction and the consequences are the same as in paragraph (ii)(D) of this *Example*.

(g) *Applicability dates.* This section applies to domestic entity acquisitions completed on or after July 12, 2018. For domestic entity acquisitions completed before July 12, 2018, see § 1.7874–9T, as contained in 26 CFR part 1 revised as of April 1, 2017. However, to the extent this section differs from § 1.7874–9T, as contained in 26 CFR part 1 revised as of April 1, 2017, taxpayers may elect to consistently apply the differences to domestic entity acquisitions completed before July 12, 2018.

§ 1.7874–9T [Removed]

■ **Par. 28.** Section 1.7874–9T is removed.

■ **Par. 29.** Section 1.7874–10 is added to read as follows:

§ 1.7874–10 Disregard of certain distributions.

(a) *Scope.* This section identifies distributions made by a domestic entity that are disregarded in determining an ownership fraction. Paragraph (b) of this section provides the general rule that former domestic entity shareholders or former domestic entity partners are treated as receiving additional stock of the foreign acquiring corporation when the domestic entity has made non-ordinary course distributions (NOCDs). Paragraph (c) of this section identifies distributions that, in whole or in part, are outside the scope of this section. Paragraph (d) of this section provides a de minimis exception to the application of the general rule in paragraph (b) of this section. Paragraph (e) of this section provides rules concerning the treatment

of distributions made by a predecessor, and paragraph (f) of this section provides rules for identifying a predecessor. Paragraph (g) of this section provides a special rule for certain distributions described in section 355. Paragraph (h) of this section provides rules regarding the allocation of NOCD stock. Paragraph (i) of this section addresses cases in which there are multiple foreign acquiring corporations, and paragraph (j) of this section addresses cases in which multiple domestic entities are treated as a single domestic entity. Paragraph (k) of this section provides definitions. Paragraph (l) of this section provides dates of applicability. See § 1.7874–1(d)(2) for rules addressing the interaction of this section with the expanded affiliated group rules of section 7874(c)(2)(A) and § 1.7874–1.

(b) *General rule regarding NOCDs.* Except as provided in paragraph (d) of this section, for purposes of determining the ownership percentage by value (but not vote) described in section 7874(a)(2)(B)(ii), former domestic entity shareholders or former domestic entity partners, as applicable, are treated as receiving, by reason of holding stock or partnership interests in a domestic entity, stock of the foreign acquiring corporation with a fair market value equal to the amount of the non-ordinary course distributions (NOCDs), determined as of the date of the distributions, made by the domestic entity during the look-back period. The stock of the foreign acquiring corporation treated as received under this paragraph (b) (NOCD stock) is in addition to stock of the foreign acquiring corporation otherwise treated as received by the former domestic entity shareholders or former domestic entity partners by reason of holding stock or partnership interests in the domestic entity.

(c) *Distributions that are not NOCDs.* If only a portion of a distribution is an NOCD, section 7874(c)(4) may apply to the remainder of the distribution. This section does not, however, create a presumption that section 7874(c)(4) applies to the remainder of the distribution.

(d) *De minimis exception to the general rule.* Paragraph (b) of this section does not apply if—

(1) The ownership percentage described in section 7874(a)(2)(B)(ii), determined without regard to the application of paragraph (b) of this section and §§ 1.7874–4(b) and 1.7874–7(b), is less than five (by vote and value); and

(2) On the completion date, each five percent former domestic entity

shareholder or five percent former domestic entity partner, as applicable, owns (applying the attribution rules of section 318(a) with the modifications described in section 304(c)(3)(B)) less than five percent (by vote and value) of the stock of (or a partnership interest in) each member of the expanded affiliated group. For this purpose, a five percent former domestic entity shareholder (or five percent former domestic entity partner) is a former domestic entity shareholder (or former domestic entity partner) that, before the domestic entity acquisition, owned (applying the attribution rules of section 318(a) with the modifications described in section 304(c)(3)(B)) at least five percent (by vote and value) of the stock of (or a partnership interest in) the domestic entity.

(e) *Treatment of distributions made by a predecessor.* For purposes of this section, a corporation or a partnership (relevant entity), including a domestic entity, is treated as making the following distributions made by a predecessor with respect to the relevant entity:

(1) A distribution made before the predecessor acquisition with respect to the predecessor; and

(2) A distribution made in connection with the predecessor acquisition to the extent the property distributed is directly or indirectly provided by the predecessor. See paragraph (k)(1)(iv) of this section.

(f) *Rules for identifying a predecessor—(1) Definition of predecessor.* A corporation or a partnership (tentative predecessor) is a predecessor with respect to a relevant entity if—

(i) The relevant entity completes a predecessor acquisition; and

(ii) After the predecessor acquisition and all related transactions are complete, the tentative predecessor ownership percentage is at least 10.

(2) *Definition of predecessor acquisition—(i) In general.* Predecessor acquisition means a transaction in which a relevant entity directly or indirectly acquires substantially all of the properties held directly or indirectly by a tentative predecessor.

(ii) *Acquisition of properties of a tentative predecessor.* For purposes of determining whether a predecessor acquisition occurs, the principles of section 7874(a)(2)(B)(i) apply, including § 1.7874-2(c) other than § 1.7874-2(c)(2) and (4) (regarding acquisitions of properties of a domestic entity), without regard to whether the tentative predecessor is domestic or foreign.

(iii) *Lower-tier entities of a predecessor.* If, before a predecessor

acquisition and all related transactions, the predecessor held directly or indirectly stock in a corporation or an interest in a partnership, then, for purposes of this section, the relevant entity is not considered to directly or indirectly acquire the properties held directly or indirectly by the corporation or partnership.

(3) *Definition of tentative predecessor ownership percentage.* Tentative predecessor ownership percentage means, with respect to a predecessor acquisition, the percentage of stock or partnership interests (by value) in a relevant entity held by reason of holding stock or partnership interests in the tentative predecessor. For purposes of computing the tentative predecessor ownership percentage, the following rules apply:

(i) For purposes of determining the stock or partnership interests in a relevant entity held by reason of holding stock or partnership interests in the tentative predecessor, the principles of section 7874(a)(2)(B)(ii) and §§ 1.7874-2(f)(1)(i) through (iii) and 1.7874-5 apply.

(ii) For purposes of determining the stock or partnership interests in a relevant entity included in the numerator of the fraction used to compute the tentative predecessor ownership percentage, the rules of paragraph (f)(3)(i) of this section apply, and all the rules applicable to calculating the numerator of an ownership fraction with respect to a domestic entity acquisition apply, except that—

(A) The principles of section 7874(c)(2)(A) and §§ 1.7874-1 and 1.7874-6 do not apply; and

(B) The principles of paragraph (b) of this section do not apply.

(iii) For purposes of determining stock or partnership interests in a relevant entity included in the denominator of the fraction used to compute the tentative predecessor ownership percentage, the principles of section 7874(a)(2)(B)(ii) and all rules applicable to calculating the denominator of an ownership fraction with respect to a domestic entity acquisition apply, except that—

(A) The principles of section 7874(c)(2)(A) and §§ 1.7874-1 and 1.7874-6 do not apply; and

(B) The principles of §§ 1.7874-4 and 1.7874-7 through 1.7874-9 do not apply.

(g) *Rule regarding direction of a section 355 distribution.* For purposes of this section, if a domestic corporation (distributing corporation) distributes the stock of another domestic corporation (controlled corporation) pursuant to a

transaction described in section 355, and, immediately before the distribution, the fair market value of the stock of the controlled corporation owned by the distributing corporation and any related person (determined under section 7874(d)(3), without regard to whether the person is foreign) represents more than 50 percent of the fair market value of the stock of the distributing corporation, then, the controlled corporation is deemed, on the date of the distribution, to have distributed the stock of the distributing corporation. The deemed distribution is equal to the fair market value of the stock of the distributing corporation (but not taking into account the fair market value of the stock of the controlled corporation) on the date of the distribution.

(h) *Allocation of NOCD stock.* NOCD stock is allocated among the former domestic entity shareholders or former domestic entity partners, as applicable, based on the amount of NOCDs that the former domestic entity shareholders or former domestic entity partners, as applicable, are treated as having received under this paragraph (h). Under this paragraph (h), a pro rata portion of each distribution during a look-back year is treated as comprising an NOCD with respect to the look-back year, based on a fraction the numerator of which is the amount of NOCDs during the look-back year and the denominator of which is the amount of distributions during the look-back year. Thus, each former domestic entity shareholder or former domestic entity partner, as applicable, is treated as receiving an amount of NOCD stock equal to the amount of NOCDs treated as received by the former domestic entity shareholder or former domestic entity partner, as applicable.

(i) *Multiple foreign acquiring corporations.* If there are multiple foreign acquiring corporations with respect to a domestic entity acquisition, then the foreign acquiring corporation or corporations as to which NOCD stock is considered comprised is based on the proportion of consideration directly or indirectly provided by a foreign acquiring corporation in the domestic entity acquisition relative to the total amount of consideration directly or indirectly provided by the foreign acquiring corporations in the domestic entity acquisition. For purposes of this paragraph (i), consideration is not considered directly provided by a foreign acquiring corporation if it was indirectly provided by another foreign acquiring corporation. In addition, for purposes of this paragraph (i), consideration provided in the domestic

entity acquisition does not include money or other property described in paragraph (k)(1)(iii) of this section.

(j) *Multiple domestic entities.* If pursuant to § 1.7874-2(e) two or more domestic entities are treated as a single domestic entity, then the determination of the amount of NOCDs made by the single domestic entity is made by—

(1) Applying the rules of this section to each domestic entity on a separate basis, with the result that the amount of NOCDs made by each domestic entity is separately computed; and

(2) Treating the amount of NOCDs made by the single domestic entity as the sum of the separately computed NOCDs made by each domestic entity.

(k) *Definitions.* In addition to the definitions provided in § 1.7874-12, the following definitions apply for purposes of this section.

(1) A *distribution* means the following:

(i) Any distribution made by a corporation with respect to its stock other than—

(A) A distribution to which section 305 applies;

(B) A distribution to which section 304(a)(1) applies; and

(C) Except as provided in paragraphs (k)(1)(iii) and (iv) of this section, a distribution pursuant to section 361(c)(1) (other than a distribution to which section 355 applies).

(ii) Any distribution by a partnership (other than a distribution pursuant to section 752(b) to the extent that the transaction giving rise to such distribution does not reduce the partnership's value).

(iii) In the case of a domestic entity, a transfer of money or other property to the former domestic entity shareholders or former domestic entity partners that is made in connection with the domestic entity acquisition to the extent the money or other property is directly or indirectly provided by the domestic entity.

(iv) In the case of a predecessor, a transfer of money or other property to the former owners of the predecessor that is made in connection with the predecessor acquisition to the extent the money or other property is directly or indirectly provided by the predecessor.

(2) *Distribution history period*—(i) *In general.* Except as provided in paragraph (k)(2)(ii) or (iii) of this section, a distribution history period means, with respect to a look-back year, the 36-month period preceding the start of the look-back year.

(ii) *Formation date less than 36 months but at least 12 months before look-back year.* If the formation date is less than 36 months, but at least 12

months, before the start of a look-back year, then the distribution history period with respect to that look-back year means the entire period, starting with the formation date, that precedes the start of the look-back year.

(iii) *Formation date less than 12 months before look-back year.* If the formation date is less than 12 months before the start of a look-back year, then there is no distribution history period with respect to that look-back year.

(3) *Formation date* means, with respect to a domestic entity, the date that the domestic entity was created or organized, or, if earlier, the earliest date that any predecessor of the domestic entity was created or organized.

(4) *Look-back period* means, with respect to a domestic acquisition, the 36-month period ending on the completion date or, if shorter, the entire period, starting with the formation date, that ends on the completion date.

(5) *Look-back year* means, with respect to a look-back period, the following:

(i) If the look-back period is 36 months, the three consecutive 12-month periods that comprise the look-back period.

(ii) If the look-back period is less than 36 months, but at least 24 months—

(A) The 12-month period that ends on the completion date;

(B) The 12-month period that immediately precedes the period described in paragraph (k)(5)(ii)(A) of this section; and

(C) The period, if any, that immediately precedes the period described in paragraph (k)(5)(ii)(B) of this section.

(iii) If the look-back period is less than 24 months, but at least 12 months—

(A) The 12-month period that ends on the completion date; and

(B) The period, if any, that immediately precedes the period described in paragraph (k)(5)(iii)(A) of this section.

(iv) If the look-back period is less than 12 months, the entire period, starting with the formation date, that ends on the completion date.

(6) *NOCDs* mean, with respect to a look-back year, the excess of all distributions made during the look-back year over the NOCD threshold for the look-back year.

(7) *NOCD threshold* means, with respect to a look-back year, the following:

(i) If the look-back year has at least a 12-month distribution history period, 110 percent of the sum of all distributions made during the distribution history period multiplied

by a fraction. The numerator of the fraction is the number of days in the look-back year and the denominator is the number of days in the distribution history period with respect to the look-back year.

(ii) If the look-back year has no distribution history period, zero.

(1) *Applicability date.* This section applies to domestic entity acquisitions completed on or after July 12, 2018. For domestic entity acquisitions completed before July 12, 2018, see § 1.7874-10T, as contained in 26 CFR part 1 revised as of April 1, 2017. However, to the extent this section differs from § 1.7874-10T, as contained in 26 CFR part 1 revised as of April 1, 2017, taxpayers may elect to consistently apply the differences to domestic entity acquisitions completed before July 12, 2018.

§ 1.7874-10T [Removed]

■ **Par. 30.** Section 1.7874-10T is removed.

■ **Par. 31.** Section 1.7874-11 is added to read as follows:

§ 1.7874-11 Rules regarding inversion gain.

(a) *Scope.* This section provides rules for determining the inversion gain of an expatriated entity for purposes of section 7874. Paragraph (b) of this section provides rules for determining the inversion gain of an expatriated entity. Paragraph (c) of this section provides special rules with respect to certain foreign partnerships in which an expatriated entity owns an interest. Paragraph (d) of this section provides additional definitions. Paragraph (e) of this section provides an example that illustrates the rules of this section. Paragraph (f) of this section provides the applicability dates.

(b) *Inversion gain*—(1) *General rule.* Except as provided in paragraphs (b)(2) and (3) of this section, inversion gain includes income (including an amount treated as a dividend under section 78) or gain recognized by an expatriated entity for any taxable year that includes any portion of the applicable period by reason of a direct or indirect transfer of stock or other properties or license of any property either as part of the domestic entity acquisition, or after such acquisition if the transfer or license is to a specified related person.

(2) *Exception for property described in section 1221(a)(1).* Inversion gain does not include income or gain recognized by reason of the transfer or license, after the domestic entity acquisition, of property that is described in section 1221(a)(1) in the hands of the transferor or licensor.

(3) *Treatment of partnerships.* Except to the extent provided in paragraph (c) of this section and section 7874(e)(2), inversion gain does not include income or gain recognized by reason of the transfer or license of property by a partnership.

(c) *Transfers and licenses by partnerships.* If a partnership that is a foreign related person transfers or licenses property, a partner of the partnership shall be treated as having transferred or licensed its proportionate share of that property, as determined under the rules and principles of sections 701 through 777, for purposes of determining the inversion gain of an expatriated entity. See section 7874(e)(2) for rules regarding the treatment of transfers and licenses by domestic partnerships and transfers of interests in certain domestic partnerships.

(d) *Definitions.* The definitions provided in § 1.7874–12 apply for purposes of this section.

(e) *Example.* The following example illustrates the rules of this section.

Example—(i) *Facts.* On July 1, 2016, FA, a foreign corporation, acquires all the stock of DT, a domestic corporation, in an inversion transaction. When the inversion transaction occurred, DT wholly owned FS, a foreign corporation that is a controlled foreign corporation (within the meaning of section 957(a)). During the applicable period, FS sells to FA property that is not described in section 1221(a)(1) in the hands of FS. Under section 951(a)(1)(A), DT has a \$80x gross income inclusion that is attributable to FS's gain from the sale of the property. Under section 960(a)(1), DT is deemed to have paid \$20x of the post-1986 foreign income taxes of FS by reason of this income inclusion and includes \$20x in gross income as a deemed dividend under section 78. Accordingly, DT recognizes \$100x (\$80x + \$20x) of gross income because of FS's sale of property to FA.

(ii) *Analysis.* Pursuant to section 7874(a)(2)(A), DT is an expatriated entity. Under paragraph (b)(1) of this section, DT's \$100x gross income recognized under sections 951(a)(1)(A) and 78 is inversion gain, because it is income recognized by an expatriated entity during the applicable period by reason of an indirect transfer of property by DT (through its wholly-owned CFC, FS) after the inversion transaction to a specified related person (FA). Sections 7874(a)(1) and (e) therefore prevent the use of certain tax attributes (such as net operating losses) to reduce the U.S. tax owed with respect to DT's \$100x gross income recognized under sections 951(a)(1)(A) and 78.

(f) *Applicability dates.* Except as otherwise provided in this paragraph (f), this section applies to transfers and licenses of property completed on or after November 19, 2015, but only if the inversion transaction was completed on

or after September 22, 2014. For inversion transactions completed on or after September 22, 2014, however, taxpayers may elect to apply paragraph (b) of this section by excluding the phrase “(including an amount treated as a dividend under section 78)” for transfers and licenses of property completed on or after November 19, 2015, and before April 4, 2016.

§ 1.7874–11T [Removed]

■ **Par. 32.** Section 1.7874–11T is removed.

■ **Par. 33.** Section 1.7874–12 is added to read as follows:

§ 1.7874–12 Definitions.

(a) *Definitions.* Except as otherwise provided, the following definitions apply for purposes of this section and §§ 1.367(b)–4, 1.956–2, 1.7701(l)–4, and 1.7874–1 through 1.7874–11.

(1) An *affiliated group* has the meaning set forth in section 1504(a) but without regard to section 1504(b)(3), except that section 1504(a) is applied by substituting “more than 50 percent” for “at least 80 percent” each place it appears. A *member of the affiliated group* is an entity included in the affiliated group.

(2) The *applicable period* means, with respect to an inversion transaction, the period described in section 7874(d)(1). However, see also § 1.7874–2(b)(13) in the case of a subsequent acquisition (or a similar acquisition under the principles of § 1.7874–2(c)(4)(i)) that is an inversion transaction.

(3) The *completion date* means, with respect to a domestic entity acquisition, the date that the domestic entity acquisition and all transactions related to the domestic entity acquisition are complete.

(4) A *controlled foreign corporation* (or *CFC*) has the meaning provided in section 957.

(5) A *domestic entity acquisition* means an acquisition described in section 7874(a)(2)(B)(i).

(6) A *domestic entity* means, with respect to a domestic entity acquisition, a domestic corporation or domestic partnership described in section 7874(a)(2)(B)(i). A reference to a domestic entity includes a successor to such domestic corporation or domestic partnership, including a corporation that succeeds to and takes into account amounts with respect to the domestic entity pursuant to section 381.

(7) An *expanded affiliated group* (or *EAG*) means, with respect to a domestic entity acquisition, an affiliated group that includes the foreign acquiring corporation, determined as of the completion date. A *member of the EAG*

is an entity included in the EAG, and a reference to a member of the EAG includes a predecessor with respect to such member.

(8) An *expatriated entity* means, with respect to an inversion transaction—
(i) The domestic entity; and
(ii) A United States person that, on any date on or after the completion date, is or was related (within the meaning of section 267(b) or 707(b)(1)) to the domestic entity.

(9) *Expatriated foreign subsidiary*—(i) *General rule.* Except as provided in paragraph (a)(9)(ii) of this section, an expatriated foreign subsidiary means a foreign corporation that is a CFC (determined without applying subparagraphs (A), (B), and (C) of section 318(a)(3) so as to consider a United States person as owning stock which is owned by a person who is not a United States person) and in which an expatriated entity is a United States shareholder (determined without applying subparagraphs (A), (B), and (C) of section 318(a)(3) so as to consider a United States person as owning stock which is owned by a person who is not a United States person).

(ii) *Exception to the general rule.* A foreign corporation is not an expatriated foreign subsidiary if, with respect to the inversion transaction as a result of which the foreign corporation otherwise would be an expatriated foreign subsidiary—

(A) On the completion date, the foreign corporation was both a CFC (determined without applying subparagraphs (A), (B), and (C) of section 318(a)(3) so as to consider a United States person as owning stock which is owned by a person who is not a United States person) and a member of the EAG; and

(B) On or before the completion date, the domestic entity was not a United States shareholder (determined without applying subparagraphs (A), (B), and (C) of section 318(a)(3) so as to consider a United States person as owning stock which is owned by a person who is not a United States person) with respect to the foreign corporation.

(10) A *foreign acquiring corporation* means, with respect to a domestic entity acquisition, the foreign corporation described in section 7874(a)(2)(B). A reference to a foreign acquiring corporation includes a successor to the foreign acquiring corporation, including a corporation that succeeds to and takes into account amounts with respect to the foreign acquiring corporation pursuant to section 381.

(11) A *foreign related person* means, with respect to an inversion transaction, a foreign person that is related (within

the meaning of section 267(b) or 707(b)(1) to, or under the same common control as (within the meaning of section 482), a person that is an expatriated entity with respect to the inversion transaction.

(12) A *former domestic entity partner* of a domestic entity that is a domestic partnership is any person that held an interest in the partnership before the domestic entity acquisition, including any person that holds an interest in the partnership both before and after the domestic entity acquisition.

(13) A *former domestic entity shareholder* of a domestic entity that is a domestic corporation is any person that held stock in the domestic corporation before the domestic entity acquisition, including any person that holds stock in the domestic corporation both before and after the domestic entity acquisition.

(14) An *interest in a partnership* includes a capital or profits interest.

(15) An *inversion transaction* means a domestic entity acquisition in which the foreign acquiring corporation is treated as a surrogate foreign corporation under

section 7874(a)(2)(B), taking into account section 7874(a)(3).

(16) A *non-EFS foreign related person* means, with respect to an inversion transaction, a foreign related person that is not an expatriated foreign subsidiary.

(17) The *ownership fraction* means, with respect to a domestic entity acquisition, the ownership percentage described in section 7874(a)(2)(B)(ii), expressed as a fraction.

(18) A *specified related person* means, with respect to an inversion transaction—

(i) A non-EFS foreign related person;

(ii) A domestic partnership in which a non-EFS foreign related person is a partner; and

(iii) A domestic trust of which a non-EFS foreign related person is a beneficiary.

(19) A *United States person* means a person described in section 7701(a)(30).

(20) A *United States shareholder* has the meaning provided in section 951(b).

(b) *Applicability dates.* Except as otherwise provided in this paragraph (b), this section applies to domestic entity acquisitions completed on or after September 22, 2014. The following

apply to domestic entity acquisitions completed on or after April 4, 2016: paragraph (a)(8) of this section; in paragraph (a)(6) of this section, the phrase “, including a corporation that succeeds to and takes into account amounts with respect to the domestic entity pursuant to section 381”; and the second sentence of paragraph (a)(10) of this section. For domestic entity acquisitions completed on or after September 22, 2014, and before April 4, 2016, however, taxpayers, may elect to apply the provisions in the immediately prior sentence.

§ 1.7874–12T [Removed]

Par. 34. Section 1.7874–12T is removed.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: June 22, 2018.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2018–14693 Filed 7–11–18; 8:45 am]

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