Supporting Statement Part A
Medicare Program/Home Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation in 42 CFR 424.22
CMS-10311, OCN 0938-1083

Background

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program, and are described in section 1861(m) of the Social Security Act (the Act) (42 U.S.C. 1395x). These services must be furnished by, or under arrangement with a home health agency (HHA) that participates in the Medicare program, be provided under a plan of care certified or recertified by the patient's physician, (42 CFR 424.22), and performed on a visiting basis in the beneficiary's home. They may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Speech-Language Pathology, Physical Therapy, or Occupational Therapy.
- Medical Social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.

As described in section 1814(a)(2)(c) and section 1835(a) (2)(A) of the Act, a physician must certify that a home health patient is homebound and needs or needed skilled nursing care on an intermittent basis, physical or speech therapy or (with certain restrictions) occupational therapy. The Act thus requires that the physician fulfill a role that is sometimes thought of as a "gatekeeper" of Medicare's home health benefit. The physician is required to sign the patient's individual home health plan of care and to certify or recertify that the patient is homebound and in need of skilled services, in order for the HHA to be reimbursed for providing Medicare covered services. The certification and recertification content requirements are stipulated in 42 CFR 424.22.

The Home Health Prospective Payment System (HH PPS) final rule for Calendar Year 2010 (74 FR 58121) finalized a change in the physician certification and recertification requirements by requiring the physician to include a brief narrative describing the clinical justification for management and evaluation visits (i.e., skilled oversight of unskilled care) when management and evaluation visits are the only skilled service that the home health patient needs in order to qualify for Medicare's home health benefit. The narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum. This change supports Medicare's home health coverage criteria for skilled services as stipulated in 42 CFR 409.42. Medicare contractors described a program vulnerability associated with patients who meet the home health skilled services eligibility requirement solely because of the need for management and evaluation visits. Additionally, the requirement was a first step in adopting the HHS Office of

the Inspector General (OIG)'s recommendation that CMS better define the home health eligibility skilled services requirements.

The HH PPS final rule for Calendar Year 2011 (75 FR 70427) changed the certification requirements for HHAs again. This rule implemented a provision of the Affordable Care Act as a condition for payment. The Affordable Care Act mandates that, prior to certifying a patient's eligibility for the HH benefit, the physician must document that the physician or an allowed non-physician practitioner (NPP) had a face-to-face encounter with the patient. Additionally, the Affordable Care Act allows the Secretary to determine a reasonable timeframe for the encounter to occur. The certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted NPPs perform the face-to-face encounter. In order to implement this provision of the Affordable Care Act, we finalized regulations at §424.22 (that require the face-to-face patient encounter to be related to the primary reason the patient requires home health services and to occur no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care.

Additionally, we finalized documentation requirements associated with the face-to-face encounter by stipulating that the physician responsible for certifying the patient for home care must document on the certification itself (or as an addendum to the certification) why the clinical findings of the encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services. The documentation must be clearly titled, dated, and signed by the certifying physician and include the date of the encounter. We also finalized that the non-physician practitioner performing the face-to-face encounter must document the clinical findings of that face-to-face patient encounter and communicate those findings to the certifying physician.

In the CY 2015 HH PPS final rule (79 FR 66032), we simplified the face-to-face encounter regulations, reduced burden for HHAs and physicians, and mitigated instances where physicians and HHAs unintentionally fail to comply with certification requirements. We finalized the elimination of the narrative requirement at §424.22(a)(1)(v). The certifying physician is still required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner, as defined in §424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility. In addition, in the CY HH PPS 2015 final rule, we clarified that a face-to-face encounter is required for certifications, rather than initial episodes, and that a certification (versus a recertification) is generally considered to be any time a new start of care assessment is completed to initiate care.

A. Justification

1. Need and Legal Basis

   Section (o) of the Act (42 U.S.C. 1395x) specifies certain requirements that a HHA must meet in order to participate in the Medicare program. To qualify for Medicare coverage of home

health services a Medicare beneficiary must meet each of the following requirements as stipulated in §409.42: be confined to the home or an institution that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1) or 1919 of the Act; be under the care of a physician as described in §409.42(b); be under a plan of care that meets the requirements specified in §409.43; the care must be furnished by or under arrangements made by a participating HHA, and the beneficiary must be in need of skilled services as described in §409.42(c). Subsection 409.42(c) requires that the beneficiary need at least one of the following services as certified by a physician in accordance with §424.22: Intermittent skilled nursing services and the need for skilled services which meet the criteria in §409.32; Physical therapy which meets the requirements of §409.44(c), Speech-language pathology which meets the requirements of §409.44(c); or have a continuing need for occupational therapy that meets the requirements of §409.44(c), subject to the limitations described in §409.42(c)(4).

On March 23, 2010 the Affordable Care Act (Pub. L., 111-148) was enacted. Section 6407(a) (amended by section 10605) of the Affordable Care Act amends the requirements for physician certification of home health services contained in Sections 1814(a)(2)(C) and 1835(a)(2)(A) by requiring that, prior to certifying a patient as eligible for Medicare's home health benefit, the physician must document that the physician himself or herself or a permitted non-physician practitioner has had a face-to-face encounter (including through the use of tele-health services, subject to the requirements in section 1834(m) of the Act)", with the patient.

In order to simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements, in the CY 2015 HH PPS final rule (79 FR 66032), we eliminated the face-to-face encounter narrative requirement at §424.22(a)(1)(v). The certifying physician is still required to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner as defined in §424.22(a)(1)(v)(A), and to document the date of the encounter as part of the certification of eligibility. In addition, due to confusion regarding when the certifying physician is required to document that a face-to-face encounter occurred with the patient, we clarified that a face-to-face encounter is required for certifications, rather than initial episodes, and that a certification (versus a recertification) is generally considered to be any time a new start of care assessment is completed to initiate care.

2. Information Users

The primary users of this information will be Federal and State surveyors, CMS, and CMS contractors. The conditions of participation (CoPs) at 42 CFR 484, Subparts B and C; conditions for payment at 42 CFR 424.22; and accompanying requirements specified in other regulations are used by Federal or State surveyors as a basis for determining whether a HHA qualifies for approval or re-approval under Medicare. CMS and CMS contractors use the patient's medical record as a basis for determining whether the patient was eligible for the

Medicare home health benefit and whether the medical record meets the criteria for coverage and Medicare payment.

3. Use of Information Technology

HHAs and other providers may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation in no way prescribes how the HHA or other providers should prepare or maintain these records. HHAs and other providers are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Efforts

These requirements are specified in ways that do not require a HHA or other providers to duplicate their efforts. If a HHA or other provider already maintains these general records, regardless of format, they are in compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records from one HHA or other provider to another acceptable.

5. Small Businesses

These requirements will not have a significant impact on most HHAs and other providers (such as physicians, physician practices, or acute/post-acute care hospitals or facilities) that are small entities because the cost of meeting the requirements in this rule is less than 1 percent of total HHA Medicare revenue and these requirements reduce the cost of compliance for other providers. Further, most of the requirements in the CY 2015 final rule are part of HHA and other provider standard practices. We understand that there are different sizes of HHAs and other providers and that the burden for HHAs and other providers of different sizes will vary. A portion of the time and cost burden for providers is directly related to patient care and the staff necessary to provide care. A consistently smaller patient census leads to reduced burden due to less data collection and less patient rights orientation, etc.

6. Less Frequent Collection

CMS does not collect information directly from HHAs or other providers. In most cases, the CY 2015 HH PPS final rule does not prescribe the manner, timing, or frequency of the records or information that must be available. HHA and other provider records are reviewed at the time of a survey for initial or continued participation in the Medicare program and during medical review as a basis for determining whether the patient was eligible for the Medicare home health benefit and whether the services provided met the criteria for coverage and Medicare payment. Less frequent information collection would impede efforts to establish compliance with the Medicare CoPs or Medicare coverage requirements.

7. Special Circumstances

Absent a legislative amendment, we are unable to anticipate any circumstances that would change the requirements of this package.

8. Federal Register/Outside Consultation

The 60-day Federal Register final rule published on July 29, 2016 (81 FR 49985). The 30-day Federal Register notice published on October 31, 2016 (81 FR 75409).

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

Normal medical confidentiality practices are observed.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

In eliminating the face-to-face encounter narrative requirement, we assumed there will be a one-time burden for the HHA to modify the certification form, which the HHA provides to the certifying physician. The revised certification form must allow the certifying physician to certify that a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed NPP as defined in §424.22(a)(1)(v)(A). In addition, the certification form must allow the certifying physician to document the date that the face-to-face encounter occurred.

We estimate that it will take a home health clerical staff person 15 minutes (15/60 = 0.25 hours) to modify the certification form, and the HHA administrator 15 minutes (15/60 = 0.25 hours) to review the revised form. The clerical time plus administrator time equals a one-time burden of 30 minutes or (30 / 60) = 0.50 hours per HHA. For all 11,327 HHAs, the total time required will be (0.50 x 11,327) = 5,664 hours. At $31.36 per hour for an office employee, the cost per HHA will be (0.25 x $31.36) = $7.84. At $106.00 per hour for the administrator's time, the cost per HHA will be (0.25 x $106.00) = $26.50. Therefore, the total one-time cost per HHA will be $34.34, and the total one-time cost for all HHAs will be ($34.34 x 11,327) =$388,969.

In the CY 2011 HH PPS final rule (75 FR 70455), we estimated that the certifying physician's burden for composing the face-to-face encounter narrative, which includes how the clinical findings of the encounter support eligibility (writing, typing, or dictating the face-to-face encounter narrative), signing, and dating the patient's face-to-face encounter, was 5 minutes for

each certification (5 / 60 = 0.0833 hours).

Although we finalized elimination of the narrative, the certifying physician will still be required to document the date of the face-to-face encounter as part of the certification of eligibility. We estimate that it will take no more than 1 minute for the certifying physician to document the date that the face-to-face encounter occurred (1 / 60 = 0.0166 hours). The estimated burden for the certifying physician to continue to document the date of the face-to-face encounter will be 0.0166 hours per certification or 54,084 hours total (0.0166 hours x 3,258,095 initial home health episodes). The estimated cost for the certifying physician to continue to document the date of the face-to-face encounter will be $2.72 per certification (0.0166 x $163.90) or $8,862,018 total ($2.72 x 3,258,095) for CY 2015. Therefore, in eliminating the face-to-face encounter narrative requirement, we estimate that burden and costs will be reduced for certifying physicians by 217,315 hours (271,399 – 54,084) or $35,610,9784 ($44,472,996 - $8,862,018).

To determine when documentation of a patient's face-to-face encounter is required under sections 1814(a)(2)(C) and 1835 (a)(2)(A) of the Act, in the CY 2015 HH PPS final rule (79 FR 66032), we finalized a clarification that the face-to-face encounter requirement is applicable for certifications rather than initial episodes. A certification (versus recertification) is generally considered to be any time that a new start of care OASIS is completed to initiate care.

We estimate that of the 6,276,792 home health episodes in CY 2015, 3,258,095 start of care assessments were performed on initial home health episodes. An additional 602,418 episodes will require documentation of a face-to-face encounter for subsequent episodes that were initiated with a new start of care OASIS assessment. We estimate that it will take no more than one minute for the certifying physician to document the date that the face-to-face encounter occurred (1 / 60 = 0.0166 hours). The estimated burden for the certifying physician to document the date of the face-to-face encounter for each certification (any time a new start of care OASIS is completed to initiate care) will be 0.0166 hours or 10,000 total hours (0.0166 hours x 602,418 additional home health episodes). The estimated cost for the certifying physician to document the date of the face-to-face encounter for each additional home health episode will be $2.72 per certification (0.0166 x $163.90) or $1,638,577 total ($2.72 x 602,418).

Table 1
HH Face-to-Face Assumptions and Estimates

# of Medicare-billing HHAs, from CY 2015 claims with matched OASIS assessments	11,327
Hourly rate of an office employee (Executive Secretaries and Executive Administrative Assistants, 43-6014)	$31.36
Hourly rate of an administrator (General and Operations Managers, 11-1021)	$106.00
Hourly rate of Family and General Practitioners (29-1062)	$163.90

All salary information is from the Bureau of Labor Statistics website at http://www.bls.gov/oes/current/naics4_621600.htm and includes a fringe benefits package worth 100 percent of the base salary. The mean hourly wage rates are based on May 2015 BLS data for each discipline, for those providing "home health care services."

Table 2
HH FACE-TO-FACE ENCOUNTER
ONE-TIME ESTIMATED BURDEN: Form Revision by HHA

	Number of HHAs	Time per HHA (minutes)	Time per HHA (hours)	Total time, all HHAs (hours)	Hourly rate	Cost per HHA	Total cost
Assumes 11,327 HHAs							
One Time Only Form Revision by HHA							
Form development (Clerk)	11,327	15	0.25	2,832	$31.36	$7.84	$88,804
Form development (Administrator)	11,327	15	0.25	2,832	$106.00	$26.50	$300,166
Subtotal costs, Form revision	11,327	30	0.50	5,664	$137.36	$34.34	$388,969

Table 3
HH FACE-TO-FACE ENCOUNTER
ESTIMATED BURDEN REDUCTION FOR CERTIFYING PHYSICIANS
(No Longer Drafting a Face-to-Face Encounter Narrative)

Physician Annual Burden for Verification & Completion of Home Health Initial Certifications							
	Number of certifica-tions	Time per certification (minutes)	Time per certification (hours)	Total time, (hours)	Hourly rate	Cost Per certification	Total cost
Physician	3,258,095	(4)	(.0667)	(217,315)	$163.90	($10.93)	($35,610,978)

Table 4
HH FACE-TO-FACE ENCOUNTER
ANNUAL BURDEN ESTIMATE: Physician Certification (for additional certifications)

Physician Annual Burden for Verification & Completion of Home Health Initial Certifications							
	Number of certifica-tions	Time per certification (minutes)	Time per certification (hours)	Total time, (hours)	Hourly rate	Cost Per certification	Total cost
Physician	602,418	1	.0166	10,000	$163.90	$2.72	$1,638,577

13. Capital Costs

There are no additional capital costs.

14. Cost to Federal Government

There are minimal costs associated with these requirements that are accrued at the Federal level and especially at the regional office (RO) levels. For example, RO staff is responsible for acting on the information collections requirements discussed in this package as it relates to home health compliance. The coverage and payment requirements associated with the home health face-to-face physician encounter provision does not create additional federal level costs; payment contractors use the data collected as part of their usual and customary claims processing and review activities.

15. Changes to Burden

The CY 2015 HH PPS final rule implemented policy changes to the face-to-face encounter requirements at §424.22(1)(1)(v) that result in an estimated net reduction in burden of 207,315 hours or $33,972,401 for certifying physicians (see Tables 3 and 4). The finalized policy changes to the face-to-face encounter requirements at §424.22(a)(1)(v) will result in a

one-time burden of 5,664 hours or $388,969 for HHAs to revise the certification form (see Table 2).

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

Upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This section does not apply because statistical methods are not associated with this collection.