

Supporting Statement for Paperwork Reduction Act Submissions
CMS-855B Medicare Enrollment Application for Clinics/Group Practices and Other Suppliers Revision
CMS-855B/OMB Control Number: 0938-1377)

BACKGROUND

The primary function of the CMS-855B Medicare enrollment application for suppliers/providers is to gather information from the supplier that tells us who the supplier is, whether the supplier/provider meets certain qualifications to be a Medicare health care provider or supplier, where the supplier/provider practices or renders services, and other information necessary to establish correct claims payments.

CMS-1730-P: CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements

The rule proposes to modify § 424.67 to allow Opioid Treatment Programs enroll with either the CMS-855B or the CMS-855A. and 2.) A Federal Register notice was published on June 30, 2020 (85 FR 39408), as part of a notice of proposed rulemaking (“Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements” (CMS-1730-P)).

Section 5012 of the 21st Century Cures Act, which amended sections 1834(u), 1861(s)(2), and 1861(iii) of the Act, established a new Medicare home infusion therapy benefit. Section 1861(iii)(3)(D)(i)(IV) of the Act permits the Secretary to establish requirements for qualified home infusion therapy suppliers that the Secretary determines appropriate. Section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

42 C.F.R. § 424.68(c)(1)(i), proposes a home infusion therapy supplier must complete in full and submit the Form CMS-855B application (“Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers”) (OMB Control No.: 0938-1377), or its electronic or successor application, to its applicable Medicare contractor. The Form CMS-855B is typically completed by suppliers other than individual physicians and practitioners. We thus believe that the Form CMS-855B is the most suitable enrollment application for home infusion therapy suppliers. In addition, we propose in § 424.68(c)(1)(ii) that the home infusion therapy supplier must certify via the Form CMS-855B that it meets and will continue to meet the specific requirements and standards for enrollment described in § 424.68 and part 424, subpart P. This is to help ensure that the home infusion therapy supplier fully understands its obligation to maintain constant compliance with the requirements associated with home infusion therapy supplier enrollment.

In accordance with section 3708 of the CARES Act, these changes are required to take effect within 6 months of enactment of the law. We are addressing changes in the regulations in this IFC to ensure these requirements are issued within the timeframe required by statute. We also believe that enacting these provisions at this time will afford flexibility for suppliers seeking to order home infusion therapy services during the PHE for the COVID-19 pandemic.

We generally estimate that: (1) there are about 600 home infusion therapy suppliers that would be eligible for Medicare enrollment under our proposed provisions, all of whom would enroll in the initial year of our requirements; and (2) 50 home infusion therapy suppliers would annually enroll in year 2 and in year 3. This results in a total of 700 home infusion therapy suppliers enrolling over the next 3 years.

There are not any proposed changes to the Form CMS-855B.

A. JUSTIFICATION

1. Need and Legal Basis

Various sections of the Social Security Act (Act), the United States Code (U.S.C.), Internal Revenue Service Code (Code) and the Code of Federal Regulations (CFR) require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before payment can be made.

- 42 CFR 424.500 state the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies.
- Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person.
- Section 1842(r) of the Act requires us to establish a system for furnishing a unique identifier for each provider/supplier who furnishes services for which payment may be made. In order to do so, we need to collect information unique to that provider or supplier.
- Section 1866(j)(1)(C) of the Act requires us to consult with providers and suppliers of services before making changes in provider/supplier enrollment forms.
- The Balanced Budget Act of 1997 (BBA) (Public Law 105-33) section 4313, amended sections 1124(a) (1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and Social Security Number (SSN) of each provider or supplier, each person with ownership or control interest in the provider or supplier, as well as any managing employees. The Secretary of Health and Human Services (the Secretary) signed and sent to the Congress a “Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as Required by the Balanced Budget Act” on January 26, 1999, with mandatory collection of SSNs and EINs effective on or about April 26, 1999.
- Section 31001(I) of the Debt Collection Improvement Act of 1996 (DCIA) (Public Law 104-134) amended 31 U.S.C. 7701 by adding paragraph (c) to require that any person or entity doing business with the Federal Government provide their Tax Identification Number (TIN).
- Section 1866(b)(2)(D) and 1842(h)(8) of the Act require denial of enrollment (directly or indirectly) of persons convicted of a felony for a period not less than 10 years from the date of conviction.
- Section 424.502, defines enrollment and enrollment related terms.
- Sections 1102 and 1871 of the Act, provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program
- The Internal Revenue (IRS) Code, section 3402(t) requires us to collect additional information about the proprietary/non-profit structure of a Medicare provider/supplier to allow exclusion of non-profit organization from the mandatory 3% tax withholding.
- The IRS section 501(c) requires each Medicare provider/supplier to report information about its proprietary/non-profit structure to the IRS for tax withholding determination.
- The Patient Protection and Affordable Care Act, section 3109(a) allows certain Medicare supplier types to be exempt from the accreditation requirement.
- Section 1866(j)(2)(A) of the Act requires the Secretary, in consultation with the Department of Health and Human Services' Office of the Inspector General, to establish procedures under which screening is conducted with respect to providers/suppliers of medical or other items or services and suppliers under Medicare, Medicaid, and CHIP.
- Section 1866(j)(2)(B) of the Act requires the Secretary to determine the level of screening to be conducted according to the risk of fraud, waste, and abuse with respect to the category of provider or supplier.
- Section 1848(k)(3)(B) defines covered professional services and eligible professionals.

- Section 3004(b)(1) of the Public Health Service Act (PHSA) requires the Secretary to adopt an initial set of standards, implementation guidance, and certification criteria and associated standards and implementation specifications will be used to test and certify complete EHRs and EHR modules in order to make it possible for eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology.
- The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), section 135(a) amended section 1834(e) of the Social Security Act and required the Secretary to designate organizations to accredit suppliers, including but not limited to suppliers, physicians, non-physician practitioners and Independent Diagnostic Testing Facilities, that furnish the technical component of advanced diagnostic imaging services.
- Section 2205 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT for Patients and Communities Act requires a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) beginning on or after January 1, 2020.
- Section 6401(a) of the Affordable Care Act (ACA) requires the Secretary to impose a fee on each "institutional provider of medical or other items or services and suppliers." The fee is to be used by the Secretary to cover the cost of program integrity efforts including the cost of screening associated with provider/supplier enrollment processes, including those under section 1866(j) and section 1128J of the Social Security Act.
- Section 6201(c), of the Affordable Care Act (ACA) Subtitle C, requires DHHS to obtain state and national background checks on prospective employees, including national fingerprint-based criminal history record checks.
- Section 508 of the Rehabilitation Act of 1973, as incorporated with the Americans with Disabilities Act of 2005 requires all Federal electronic and information technology to be accessible to people with disabilities, including employees and members of the public.

The CMS-855 applications collect this information, including the information necessary to uniquely identify and enumerate the provider/supplier. Additional information necessary to ensure that providers and suppliers meet all applicable Medicare requirements and to process claims accurately and timely are also collected on the CMS-855 applications. This information also ensures that the data collected allows CMS to make correct payments to providers and suppliers under the Medicare program as established by Title XVIII of the Act.

2. Purpose and users of the information

Section 424.500 state the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers except for physicians and practitioners who have entered into a private contract with a beneficiary as described in part 405, subpart D of this chapter. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies. Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person.

The CMS-855B is submitted by an applicant to the Medicare Administrative Contractors (MACs) to initially apply for a Medicare billing number, and thereafter to revalidate Medicare enrollment, reactivate Medicare enrollment, enroll with another MAC in a different geographic location, to report a change to current Medicare enrollment information, and to voluntary terminate the supplier's or provider's Medicare enrollment, as applicable. It is used by new applicants as well as suppliers/providers already enrolled in Medicare but need to submit the form for a reason other than initial enrollment into the Medicare program. A medical practice, group/clinic or other supplier/provider that will bill for Medicare Part B services (e.g., group practices, clinics,

independent laboratories, opioid treatment programs, portable x-ray suppliers) complete this form for the submittal reasons above.

The MAC establishes Medicare Identification Numbers. The MACs store these numbers and information in CMS' Provider Enrollment, Chain and Ownership System (PECOS). The application is used by the CMS' contractors to collect data ensures that the applicant has the necessary information for unique identification. The license numbers that come through paper applications are validated against state licensing websites. All the license numbers are captured and stored in the MAC database. Social Security Numbers (SSNs) are validated against the Social Security Administration database (SSA) and only the valid entries are allowed to proceed in the process of getting a Medicare billing number. International Tax Identification Numbers (ITINs) are not validated. However, if a user enters ITIN, additional forms of identification (e.g., driver's license, passport or birth certificate) are required. Both ITINs and SSNs are captured in the MAC database and disseminated only to approved CMS stakeholders. Mailing address, practice location address and contact information is captured to contact the supplier. Specialty type is captured to identify the specialty of the supplier. The information obtained is to help prevent fraud by allowing vetting of the suppliers as well as to ensure a supplier is not illegitimately attempting to get a Medicare billing number. In addition, the information collected allows CMS and the MACs to determine relationships among those with Medicare billing numbers. For example, a supplier who enrolls as a group practice may also have an individual Medicare billing number for private practice as well as part ownership in a hospital. This information is determined during the enrollment process. If any relationship is prohibited by CMS regulation, the supplier would be denied a Medicare billing number and other measures may be taken, such as revocation of the supplier's individual Medicare billing number or an enrollment bar so the supplier will not get a Medicare billing number for a set number of years, depending on the enrollment bar issued to the supplier.

The collection and verification of this information defends and protects our beneficiaries from illegitimate suppliers. These procedures also protect the Medicare Trust Fund against fraud. It gathers information that allow Medicare contractors to ensure that the supplier is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. The data collected also ensures that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare, including information that allows the Medicare contractor to correctly price, process and pay the applicant's claims. This is sole instrument implemented for this purpose.

3. Improved Information Techniques

This collection lends itself to electronic collection methods and is currently available through the CMS website. The Provider Enrollment, Chain and Ownership System (PECOS) is a secure, intelligent and interactive national data storage system maintained and housed within the CMS Data Center with limited user access through strict CMS systems access protocols. Access to the data maintained in PECOS is limited to CMS and Medicare contractor employees responsible for provider/supplier enrollment activities. The supplier has access to its own records. PECOS is an electronic Medicare enrollment system through which providers and suppliers can: submit Medicare enrollment applications, view and print enrollment information, update enrollment information, complete the enrollment revalidation process, voluntarily withdraw from the Medicare program, and track the status of a submitted Medicare enrollment application. The data stored in PECOS mirrors the data collected on the CMS-855s (Medicare Enrollment Applications) and is maintained indefinitely as both historical and current information. CMS also supports an Internet-based provider/supplier CMS-855 enrollment platform which allows the provider/supplier to complete an online CMS-855 enrollment application and transmit it to the Medicare contractor database for processing. Then the data is transferred from the Medicare contractor processing database into PECOS by the Medicare contractor. CMS also has the ability to allow suppliers to upload supporting documentation (required for

enrollment) electronically. CMS has also adopted an electronic signature standard; however, suppliers will have the choice to e-sign via the CMS website or to submit a hard copy of the CMS-855B certification page with an original signature. Periodically, CMS will require adjustment to the format of the CMS-855 form (either paper, electronic or both) for clarity or to improve form design. These adjustments do not alter the current OMB data collection approval. Currently, approximately 36% of individual provider/suppliers use the electronic method of enrolling in the Medicare program via the PECOS system.

4. Duplication and Similar Information

There is no duplicative information collection instrument or process. CMS revised this form to ensure there was no duplication for the supplier completing the form.

For example, CMS:

- Added a checkbox above the Remittance Notice/Special Payments address, "Check here if your Remittance Notice/Special Payments should be mailed to your Correspondence Address in section 2A4 and skip this section." The checkbox will be used to reduce possible duplication of reporting the same correspondence address twice.
- Deleted subsection "New Enrollees and Those with a New Tax ID Number." This information is included in the subsection "Who Should Complete This Application."
- Deleted subsection "Enrolled Medicare Suppliers" because the definitions were redundant. There is a definition section at the beginning of the form. Duplicating the definitions in this subsection would require the supplier to read the definitions twice.
- Removed middle column of the table for Final Adverse Legal Actions. The middle column was, "Billing Number Information." CMS can derive the billing number information from the next section in the application and therefore the collection would be redundant.
- Deleted the question, "Is this technician employed by a hospital?" with yes/no checkboxes and "If yes, provide the name of the hospital here:" with a line space for the answer. CMS can derive and add this information to enrollment records independent of a self-reporting requirement.

5. Small Business

A Medicare billing number is required of all health care suppliers/providers who wish to submit claims for payment to the Medicare Trust Fund so it will affect small businesses who wish to have a Medicare billing number. However, these businesses have always been required to provide CMS with the same information in order to enroll in the Medicare program to submit information for CMS to ensure the suppliers are legitimate and to collect information to successfully process their Medicare claims.

6. Less Frequent Collections

This information is collected on an as needed basis. The information provided on these forms is necessary for initial enrollment in the Medicare program. It is essential to collect this information the first time a provider/supplier enrolls with a Medicare contractor so that CMS' contractors can uniquely identify the provider/supplier, ensure the provider's/supplier's eligibility and legitimacy, to determine if the provider/supplier meets all statutory and regulatory requirements, are properly credentialed in their specialty (if applicable), and to collect relevant information to process the provider's/supplier's claims in a timely and accurate manner.

After the initial enrollment and approval, the information collected is less frequent and often initialized by the supplier for reasons such as a change of information, enrollment within another MACs jurisdiction, and to voluntarily withdraw from the Medicare program. It will be collected to complete the enrollment revalidation process every five years. In addition, to ensure uniform data submissions, CMS requires that all changes to previously submitted enrollment data be reported via this enrollment application.

7. Special Circumstances

The collected information is necessary for initial enrollment in the Medicare program. After the initial enrollment and approval, the information collected is less frequent and often initialized by the supplier for reasons such as a change of information, enrollment within another MACs jurisdiction, and to voluntarily withdraw from the Medicare program. It will be collected to complete the enrollment revalidation process every five years. Otherwise, there are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

Federal Register Notice

Serving as the 60-day notice, the proposed rule (CMS-1730-P, RIN 0938-AU06) published in the Federal Register on June 30, 2020 (85 FR 39408). Comment have been addressed in Appendix A. The final rule published on November 4, 2020 (85 FR 70298).

Outside Consultation

No outside consultation was sought.

9. Payment/Gift to Respondents

The function of the CMS-855B form is to collect and verify data that proves the legitimacy of the enrolling supplier and to collect information for correct claims payment. Once completed, submitted, processed, and accepted, the respondent will be able to receive payment for medical procedures and/or services rendered to Medicare beneficiaries in accordance with the Medicare claims payment system.

10. Confidentiality

CMS will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. Privileged or confidential commercial or financial information is protected from public disclosure by Federal law 5 U.S.C. 522(b)(4) and Executive Order 12600.

The data will be provided from CMS' database of enrolled Medicare providers and suppliers. The SORN title is Provider Enrollment, Chain and Ownership System (PECOS), number 09-70-0532 (July 31, 2019; 84 FR 37393).

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

A. Time Estimates

For this proposed revision of the CMS-855B, CMS has recalculated the estimated burden hours. CMS believes this recalculation is necessary because this data collection tool has not been properly revised since 2011. In addition, the number of affected users, actual data collected and the collection methods have changed significantly. CMS believes these new burden hours accurately reflects the current burden for the purposes of this application when completing this proposed revision of the CMS-855B. CMS is basing the new burden amounts on data compiled from PECOS and the Medicare Administrative Contractors (MACs). The new estimates for completing the CMS-855B Medicare enrollment application form for the six submission reasons shown in the burden tables (initial enrollment, enrolling with another MAC, revalidation, reactivation, reporting a change of Medicare enrollment information, and voluntary termination of Medicare enrollment) are taken directly from the actual

applications processed for calendar year 2018. The new figures of processed applications are exact and therefore more accurate than the prior estimates.

The hour burden to the respondents is calculated based on the following assumptions:

- MACs currently process approximately 107,332 CMS-855B applications per year + 1,900 from the Support Act = 109,232 (as seen in Tables 1 and 3).
- Completion of the CMS-855B hour burden depends on the reason for submittal.
- Hour burden of the respondents is calculated as follows based on the following assumption:
 - The CMS-855B will likely be completed by administrative staff (BLS category = medical secretaries),
 - The record keeping burden is included in the time determined for completion by medical secretaries,
 - The CMS-855B applications are reviewed and signed by the enrolling or enrolled supplier (BLS category = health diagnosing and treating practitioners).
- The hours are calculated based on the respondent's submission reason, which also determines the time it takes for completion and submission as well as the cost per individual submission completion (as seen in Table 2).

Table 1 – Total Number of CMS-855Bs Processed per Year by Reason for Submittal (2018)

Reason for Submittal	Total Number of CMS-855Bs Processed per year (2018)
Initial Enrollment	15,187 + 1,900 = 17,797
Enrolling with Another MAC	37
Revalidation	31,211
Reactivation	1,316
Reporting a Change of Medicare Enrollment Information	55,650

Reason for Submittal	Hours for Completion by Medical Secretaries per CMS-855B	Hours for a Health Diagnosing and Treating Practitioner to Review and Sign CMS-855B	Total Hours for Completion per CMS-855B	Cost for Completion by Medical Secretaries per CMS-855B	Cost for Review and Signature by a Health Diagnosing and Treating Practitioner per CMS-855B	Total Cost of Completion per CMS-855B
Initial Enrollment	2.5	0.5	3	\$109.86	\$295.56	\$405.42
Enrolling with Another MAC	1.5	0.5	2	\$73.24	\$197.04	\$270.28
Revalidation	1.5	0.5	2	\$73.24	\$197.04	\$270.28
Reactivation	1.5	0.5	2	\$73.24	\$197.04	\$270.28
Reporting a Change of Medicare Enrollment Information	0.75	0.25	1	\$36.62	\$98.52	\$135.14
Voluntary Termination of Medicare Enrollment	0.42	0.08	0.5	\$18.31	\$49.26	\$67.57
Voluntary Termination of Medicare Enrollment			3,931			
GRAND TOTAL (Total Processed CMS-855Bs for All Reasons for Submission)			109,942			

Table 2 – Individual Burden Hours and Costs for Completion of the CMS-855B per Reason for Submittal

B. Cost Estimates

For this proposed revision of the CMS-855B, CMS has recalculated the estimated burden cost. CMS believes this recalculation is necessary because this data collection tool has not been revised since 2011, as noted in the hour burden estimates for the revised CMS-855B above. In addition, the number of affected users, actual data collected and the collection methods have changed significantly. CMS believes this new burden cost accurately reflects the current burden for the purposes of this application when completing this proposed revision of the CMS-855B. CMS is basing the new burden amounts on data compiled from PECOS and the Medicare Administrative Contractors (MACs). The new cost estimates for completing an individual CMS-855B Medicare enrollment application form for the six submission reasons shown above in table 2 (initial enrollment, revalidation, reactivation, enrolling with another MAC, reporting

a change of Medicare enrollment information, and voluntary termination of Medicare enrollment) are taken directly from the actual applications processed for calendar year 2018. The new figures are exact and therefore more accurate than the prior estimates.

To derive average costs, CMS used data from the U.S. Bureau of Labor Statistics' (BLS) May 2019 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). For the purposes of this application, CMS used the wages under the general categories of "Medical Secretaries," and "Health Diagnosing and Treating Practitioners." In this regard, CMS adjusted the employee hourly wage estimates by a factor of 100 percent. This is necessarily an estimated adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and CMS believes that doubling the hourly wage to estimate total cost is an accurate estimation method that has been used successfully in previous burden calculations.

The cost burden to the respondents is calculated based on the following assumptions:

- MACs currently process approximately 109,232 supplier CMS-855B applications per year.
- 1,900 supplier applications have been added to the total initial applications processed to accommodate the Support Act of 2018, as described above.
- Completion of the CMS-855B costs burden depends on the reason for submittal and respondent.
 - The reason for submittal of the CMS-855B determines the hour burden.
 - The hour burden and the respondents determine the cost burden, as seen in Table 2 (above).
- Cost to the respondents is calculated as follows based on the following assumptions:
 - The CMS-855B will likely be completed by administrative staff (BLS category = medical secretaries),
 - The record keeping burden is included in the time determined for completion by the medical secretary,
 - The most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2019, the mean hourly wage for the general category of "Medical Secretary" is \$18.31 per hour (see http://www.bls.gov/oes/current/oes_nat.htm). With fringe benefits and overhead, the total per hour rate is \$36.62.
 - The most recent wage data provided by the BLS for May 2019 (see http://www.bls.gov/oes/current/oes_nat.htm), the mean hourly wage for the general category of "Health Diagnosing and Treating Practitioners" is \$49.26. With fringe benefits and overhead, the total hourly rate is \$98.52.

The three-year summary of all burden hours and costs are reflected in Table 4 (below).

Home Infusion Therapy Supplier Enrollment (CMS-1730-P)

CMS added 700 suppliers to the initial enrollment count to accommodate the 21st Century Cures Act. Section 5012 of the 21st Century Cures Act establishes a new home infusion therapy (HIT) benefit, which using existing accreditation statistics and our internal data, we generally estimate that: (1) there are about 600 home infusion therapy suppliers that would be eligible for Medicare enrollment under our proposed provisions, all of whom would enroll in the initial year of our requirements; and (2) 50 home infusion therapy suppliers would annually enroll in year 2 and in year 3. This results in a total of 700 home infusion therapy suppliers enrolling over the next 3 years. CMS contacted Medicare Administrative Contractors

(MACs), both through conference calls and through focus groups to determine how the application was typically completed (by medical secretaries and reviewed and signed by the health diagnosing and treating practitioners).

Consistent with Form CMS-855B projections made in recent rulemaking efforts, it would take each home infusion therapy supplier an average of 2.5 hours to obtain and furnish the information on the Form CMS-855B. Per our experience, the home infusion therapy supplier’s medical secretary would be responsible for securing and reporting data on the Form CMS-855B and that this task takes approximately 2 hours.

Additionally, the form would be reviewed and signed by a health diagnosing and treating practitioner of the home infusion therapy supplier, a process we estimate takes 30 minutes. Therefore, we project a first-year burden of 1,500 hours (600 suppliers x 2.5 hr) at a cost of \$73,500 (600 suppliers x ((2 hr x \$36.62/hr) + (0.5 hr x \$98.52/hr)), a second-year burden of 125 hours (50 suppliers x 2.5 hr) at a cost of \$6,125 (50 suppliers x ((2 hr x \$36.62/hr) + (0.5 hr x \$98.52/hr)), and a third-year burden of 125 hours (50 suppliers x 2.5 hr) at a cost of \$6,125 (50 suppliers x ((2 hr x \$36.62/hr) + (0.5 hr x \$98.52/hr)). In aggregate, we estimate a burden of 1,750 hours (1,500 hr + 125 hr + 125 hr) at a cost of \$85,750. When averaged over the typical 3-year OMB approval period, we estimate an annual burden of 583 hours (1,750 hr/3) at a cost of \$28,583 (\$85,750/3).

Table 4 – Individual Burden Hours and Costs Related to Rulemaking CMS-1730-P

Explanation	Number of Respondents	Number of Responses	Hours per Completion of Form CMS- 855B	Total Hours	Cost for Completion by Medical Secretaries	Cost for Review and Signature by a Health Diagnosing and Treating Practitioner	Total Cost of Completion per CMS-855B
Home Infusion Therapy Enrollment (Year 1)	600	1	2.5	1,500	\$36.62	\$98.52	\$73,500
Home Infusion Therapy Enrollment (Year 2)	50	1	2.5	125	\$36.62	\$98.52	\$6,125
Home Infusion Therapy Enrollment (Year 3)	50	1	2.5	125	\$36.62	\$98.52	\$6,125
Total 3-year burden	700	1		1,750			\$85,750

Table 3 – Summary of Burden Hours and Costs for Three Years

Regulation Section(s)	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$) includes 100% fringe benefits	Total Cost (\$)
Initial Enrollments - Medicare Enrollment Application for Clinics, Groups and Other Suppliers (CMS-855B)	17,087	17,087 per year	0.5 hours by Health Diagnosing and Treating Practitioners 2.5 hours by Medical Secretaries 3 hours total	51,261 Hours	Health Diagnosing and Treating Practitioners at \$295.56 per hour Medical Secretaries at \$109.86 per hour \$405.42 total	\$20,782,234.62
Enrolling with another Medicare Administrative Contractor - (MAC) – Medicare Enrollment Application for Clinics, Groups and Other Suppliers (CMS-855B)	37	37 per year	0.5 hours by Health Diagnosing and Treating Practitioners 1.5 hours by Medical Secretaries 2 hours total	74 hours	Health Diagnosing and Treating Practitioners at \$197.04 per hour Medical Secretaries at \$73.24 per hour \$270.28 total	\$20,000.72
Revalidation - Medicare Enrollment Application for Clinics, Groups and Other Suppliers (CMS-855B)	31,211	31,211 per year	0.5 hours by Health Diagnosing and Treating Practitioners 1.5 hours by Medical Secretaries 2 hours total	62,422 hours	Health Diagnosing and Treating Practitioners at \$197.04 per hour Medical Secretaries at \$73.24 per hour \$270.28 total	\$16,871,418.16
Reactivation - Medicare Enrollment Application for Clinics, Groups and Other Suppliers (CMS-855B)	1,316	1,316 per year	0.5 hours by Health Diagnosing and Treating Practitioners 1.5 hours by Medical Secretaries 2 hours total	2,632 hours	Health Diagnosing and Treating Practitioners at \$197.04 per hour Medical Secretaries at \$73.24 per hour \$270.28 total	\$711,376.96

Reporting a Change of Information - Medicare Enrollment Application for Clinics, Groups and Other Suppliers (CMS-855B)	55,650	55,650 per year	0.25 hours by Health Diagnosing and Treating Practitioners 0.75 hours by Medical Secretaries 1 hour total	55,650 hours	Health Diagnosing and Treating Practitioners at \$98.52 per hour Medical Secretaries at \$36.62 per hour \$135.14 total	\$7,520,514.00
Voluntarily Withdrawing from Medicare - Medicare Enrollment Application for Clinics, Groups and Other Suppliers (CMS-855B)	3,931	3,931 per year	0.08 hours by Health Diagnosing and Treating Practitioners 0.42 hours by Medical Secretaries 0.5 hours total	1,965.5 hours	Health Diagnosing and Treating Practitioners at \$49.26 per hour Medical Secretaries at \$18.31 per hour \$67.57 total	\$132,808.84
Home Infusion Therapy– Supplier Enrollment	700		1.5 hours by Health Diagnosing and Treating Practitioners 6 hours by Medical Secretaries 7.5 hours	1,750 hours	Health Diagnosing and Treating Practitioners at \$98.52 per hour Medical Secretaries at \$36.62 per hour 135.14 total	\$28,583
Annual Burden Totals	109,932 Respondents	109,932 Responses	18 Hours Total	177,754.5 Annual Hours	\$1,554.12 Total Annually	\$46,066,936.30 Annually
Three Year Burden Total	328,396 Respondents	328,396 Responses	54 Hours Total	529,765.5 Total Hours	4,392.06 Total	\$138,143,642.90 Three Year Total

13. Cost to Respondents (Capital)

There are no capital costs associated with this collection.

14. Cost to Federal Government

The application form revisions will not result in any additional cost to the federal government because the application revisions are designed for better flow and to reduce the burden on the supplier and the contractor. Medicare contractors currently finalize approximately 1.3 million provider/supplier enrollment applications a year. The CMS-855B form changes will not result in any additional cost to the federal government because Medicare contractors are already processing applications from suppliers who are enrolling or enrolled in the Medicare program. Applications will continue to be processed in the normal course of Federal duties.

15. Changes in Burden/Program Changes

The proposed changes in this revision request is associated with the June 30, 2020 (85 FR 39408) Notice of Proposed Rulemaking (Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements” (CMS-1730-P)). As a result of implementing a new requirement of Home Infusion Therapy (HIT) suppliers, the burden hours have increased by a total of 583 hours annually (1,750 for 3-years).

16. Publication/Tabulation

A list of participating providers/suppliers can be accessed at <https://www.medicare.gov/physiciancompare/>. However, this list is not based on this information collection. It is based on 0938-0373 (Medicare Participating Physician or Supplier Agreement - CMS-460).

17. Expiration Date

The expiration date will be displayed on the top, right-hand corner of page 1 of the CMS-855B application.