**Supporting Statement A for Paperwork Reduction Act Submissions**

**Medicare Enrollment Application**

**(CMS-855O, OMB 0938-1135)**

**BACKGROUND**

The primary function of the CMS-855O is to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications to enroll in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services. The CMS-855O allows a physician or other eligible professional to enroll in Medicare without approval for billing privileges.

The goal of evaluating and revising the CMS-855O enrollment application is to simplify and clarify the information collection without jeopardizing our need to collect specific information. In addition, periodically new congressional legislation or regulations require CMS to update the Medicare Provider Enrollment Applications (CMS-855s). The majority of these changes are minor in nature for the purposes of provider/supplier enrollment, such as introductory information simplification for the providers/suppliers completing this application (which also allows the CMS-855O language to sync with the other CMS-855 applications’ language), minor instruction clarification in the sections and subsections for the provider/supplier, adding NPI information and a list of commonly used acronyms, adding new physician specialties for the provider/supplier to choose from,

spelling and formatting corrections, and the removal of unnecessary data fields. Minor editorial and clerical corrections were made to better clarify the current data collection.

No additional material data collection has been added in this revision.

1. **JUSTIFICATION**
2. *Need and Legal Basis*

Various sections of the Act and the Code of Federal Regulations require providers/suppliers to furnish information concerning the identification of individuals who order and certify medical services to beneficiaries before payment can be made.

* Sections l 124(a)(l) and 1124A of the Act 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.
* 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/supplier or other person.
* Section 1842(r) of the Act requires us to establish a system for furnishing a unique identifier for each physician 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, including the identity of the ordering or certifying physician.
* Section 1866(G)(l)(c) of the Act requires us to consult with providers and suppliers of services before making changes in provider/supplier enrollment forms.
* 31 U.S.C. section 7701(c) requires that any person or entity doing business with the federal government must provide their Tax Identification Number (TIN).
* Section 1866(i)(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 providers/suppliers under Medicare, Medicaid, and CHIP.
* Section 1866(i)(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.
* The Patient Protection and Affordable Care Act (PPACA), section 6405 - "Physicians Who Order Items or Services Required to be Medicare Enrolled Physicians or Eligible Professionals" contains a requirement for certain physicians and other eligible professionals to enroll in the Medicare program for the sole purpose of ordering or certifying items or services for Medicare beneficiaries.
* Section 3708 of the CARES Act allows Nurse Practitioners (NPs), Clinical Nurse Specialists (CNS’), or Physician Assistants (PAs) to order and certify patients for eligibility under the Medicare home health benefit, and allows NPs, CNSs or PAs to perform the role originally reserved for a physician in establishing HHA policies that govern the services (and supervision of such services) provided to patients under the Medicare home health benefit.
* 42 CFR 424.507 uses the term "certify" as opposed to "refer." "Certify" is the appropriate term to use when referring to such services.
* Under 42 CFR 424.502, the definition of "enrollment" includes the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.
* Section 1848(k)(3)(B) defines the terms "eligible professionals."
* 42 CFR 413.75(b) defines licensed residents.
* Section 3004(b)(l) 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.
* Federal law 5 U.S.C. 522(b)(4) requires privileged or confidential commercial or financial information protection from public disclosure.
* Executive Order 12600 requires the pre-disclosure of notification procedures for confidential commercial information.
* 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.

This Medicare Enrollment Application collects information necessary to help CMS determine whether a physician or other eligible professional meets certain qualifications to be enrolled in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services, including the information necessary to uniquely identify and enumerate the provider/supplier.

1. *Purpose and users of the information*

Physicians and practitioners complete the Form CMS-855O (Medicare Enrollment Application - Enrollment for Eligible Ordering, Certifying Physicians and Other Eligible Professionals) if they are enrolling in Medicare not to obtain Medicare billing privileges but strictly to order, refer, or certify certain Medicare items and services. It is used by Medicare contractors to collect data that helps ensure the applicant has the necessary credentials to order and certify certain Medicare items and services.

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 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. Correspondence address and contact information is captured to contact the provider/supplier.

The collection and verification of this information defends and protects our beneficiaries from illegitimate providers/suppliers. These procedures also protect the Medicare Trust Fund against fraud.  It gathers information that allow Medicare contractors to ensure that the physician or eligible professional 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 order and certify health care services. This is sole instrument implemented for this purpose.

1. *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 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 now has the ability to allow providers/suppliers to upload supporting documentation electronically. CMS has also adopted an electronic signature standard; however, practitioners will have the choice to e-sign via the CMS website or to submit a hard copy of the CMS-855O 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 50% of individual providers/suppliers use the electronic method of enrolling in the Medicare program via the PECOS system.

1. *Duplication and Similar Information*

There is no duplicative information collection instrument or process.

1. *Small Business*

The CMS-855O is not completed by small businesses and therefore will not affect small businesses.

1. *Less Frequent Collections*

After initial enrollment, this information is collected on an as needed basis. The information provided on the CMS-855O is necessary for identification of certain physician and other eligible professionals in the Medicare program. It is essential to collect this information for all ordering/certifying physicians and other eligible professionals to ensure each applicant has the necessary credentials to order and certify certain Medicare items and services. In addition, Medicare contractors must ensure that the ordering/certifying physicians or other eligible professionals meet all statutory and regulatory requirements and are properly credentialed.

After the initial enrollment and approval, the information collected is less frequent and often initialized by the individual for either a change of information or to opt out of the Medicare program to solely order and certify. To ensure uniform data submissions, CMS requires that all changes to previously submitted enrollment data be reported via this enrollment application or its equivalent in the PECOS system.

1. *Special Circumstances*

 There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

* Report information to the agency more often than quarterly;
* 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.
1. *Federal Register Notice/Outside Consultation*

A 60-day Notice published in the Federal Register on April 9, 2021 (86 FR 18536). No outside consultation was sought. Comments were not received.

1. *Payment/Gift to Respondents*

There are no payments or gifts to respondents as the respondents are ordering or certifying services or items for Medicare beneficiaries to receive from Medicare enrolled physicians or other professionals. The respondents are ordering or certifying the need for such services or items only.

1. *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 SORN title is Provider Enrollment, Chain and Ownership System (PECOS), number 09-70-0532.

1. *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.

1. *Burden Estimates (time and cost)*

According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2019 (see <https://www.bls.gov/oes/current/oes_nat.htm>).), the mean hourly wage for the general category of ‘‘Health Diagnosing and Treating Practitioners, All Others’’ is $49.26. With fringe benefits and overhead, the per hour rate are $98.52. We also project that, on average, it takes individuals approximately .5 hours to complete and submit the Form CMS–855O or an opt-out affidavit.

The following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

**National Occupational Employment and Wage Estimates**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **BLS Occupation Title** | **Occupation Code** | **Mean Hourly Wage ($/hour)** | **Fringe Benefits and Overhead ($/hour)** | **Adjusted Hourly Wage ($/hour)** |
| Health Diagnosing and Treating Practitioners, All Others’ | 43-9199 | 49.26 | 49.26 | 98.52 |

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough 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 we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

*Burden Estimates*

For this proposed revision of the CMS-855O, CMS has recalculated the estimated burden cost. CMS believes this recalculation is necessary because the previous burden was based on averaging enrollment data from the PECOS system from 2017 through 2019 with the addition of the provider/supplier types who may now complete the CMS-855O due to section 3708 of the CARES Act. 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-855O. CMS is basing the new burden amounts on data compiled from PECOS for calendar year 2019. The new cost estimates for completing a CMS-855O Medicare enrollment application for the three submission reasons shown below in the annual burden summary table (initial enrollment, reporting a change of Medicare enrollment information, and voluntary termination of Medicare enrollment) are taken directly from the actual applications processed for calendar year 2019, with the addition of the expansion of provider/supplier types who may now complete the CMS-855O due to the enactment of section 3708 of the CARES Act. The new figures from PECOS are exact and therefore more accurate than the prior estimates.

The CMS-855O form is completed by the individuals in the general category of health diagnosing and treating practitioners. Respondent burden is calculated based on the following assumptions:

* Completion of the CMS-855O takes 0.5 hours for initial enrollments, changes of enrollment information, and reporting voluntary withdrawals of enrollment information from the Medicare program.
* Record keeping time is included in the total of 0.5 hours for completion of the CMS-855O.

Completing the Initial Enrollment Application

Based on the expansion of home health services under section 3708 of the CARES Act, we previously estimated an additional three-year burden of 4,000 hours (0.5 hours x 8,000 respondents) at a cost of $394,080. This has been added to the calendar year PECOS CMS-855O application counts for calendar year 2019.

CMS is requesting approval of our revised burden estimates as follows:

***Annual Burden Summary***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Requirements** | **Respondents** | **Responses** | **Time (hours)** | **Cost ($)** |
| Initial Enrollment Application | 37,098 + 8,000 (CARES Act x 3 years) = 45,098  | 45,098  | 22,549  | $2,221,527.48 |
| Changes of Enrollment Information  | 2,731 | 2,731 | 1,365.5 | $134,529.06 |
| Reporting a Voluntary Withdrawal | 12,380  | 12,380 | 6,190 | $609,838.80 |
| **Cumulative Annual Year Totals** | **60,209** | **60,209** | **30,104.5** | **$2,965,895.34** |
| **Cumulative Three Year Totals**  | **180,627** | **180,627** | **90,313.5** | **$8,897,686.02** |

1. *Cost to Respondents (Capital)*

There are no capital costs associated with this collection.

1. *Cost to Federal Government*

Medicare contractors currently finalize approximately 1.3 million provider/supplier enrollment applications a year. The cost to Medicare contractors is built into their Medicare contracts.

1. *Changes in Burden/Program Changes*

As previously explained, section 3708 of the CARES Act expands § 424.507(b)(1) to allow NPs, CNSs, and PAs to certify the need for home health services. This will require the completion of the CMS-855O application. This burden is reflected in the burden estimate.

The burden hour changes are shown in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Requirements | Currently Approved | New Estimate | Currently Approved | New Estimate |
|  | Respondents/Responses |  Time (hours) |
| Initial Enrollment Application | 36,000 | 45,098 | 18,000 | 22,549  |
| Changes of Enrollment Information | 11,200 | 2,731 | 5,600 | 1,366 |
| Reporting a Voluntary Withdrawal | 56,000 | 12,380 | 14,000 | 6,190 |
| **TOTAL** | **103,200** | **60,209** | **37,600** | **30,105** |

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With the use of the PECOS system, updated information technology allows CMS to accurately count the hours per submittal reason and consequently, total annual hours.  There are three submission reasons for completion of the CMS-855O enrollment application (initial enrollment, reporting a change of Medicare enrollment information, and voluntary termination of Medicare enrollment).  Currently, the burden hours for the entirety of all submission reasons and respondents is 30,105 hours annually (over a three-year period 90,314 hours) with approximately 60,209 respondents. Both the burden hour per submission reason as well as the respondents are valued and calculated in this burden estimate.? It’s all explained in #12.

1. *Publication/Tabulation*

The results from this data collection will not be published.

1. *Expiration Date*

We display the expiration date in the upper right hand corner of the first page of the CMS-855O application.