Supporting Statement for Paperwork Reduction Act Submissions

CMS-855O Medicare Enrollment Application Package Revision

A. **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 be enrolled in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services and/or prescribing Medicare Part D drugs for Medicare beneficiaries. The CMS-855O allows a physician or other eligible professional to enroll in Medicare without being approved for billing privileges.

There are two principal facets of this submission:

1. Change the title of the CMS-855O to "Medicare Enrollment Application - Enrollment for Eligible Ordering, Certifying, and Prescribing Physicians and Other Eligible Professionals" – Pursuant to a final rule titled "Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2015" (CMS-4159-F), which was published in the **Federal Register** on May 23, 2014, provisions in 42 CFR section 423.120(c) require physicians and other eligible professionals who prescribes Part D drugs to either enroll in or opt-out of the Medicare program or opt out in order to prescribe Part D drugs. The term "other professionals" is necessary because there are certain individuals who are authorized by state law to prescribe drugs but who do not fall within the definition of "eligible professionals" at section 1848(k)(3)(B) of the Social Security Act. Since the physicians and other eligible professionals submitting this application are not enrolling in Medicare to submit claims but are only enrolling in Medicare to order or certify certain Medicare items or services, or to prescribe Part D drugs, CMS has changed the title of the CMS-855O from Medicare "Registration" application to Medicare "Enrollment" application to be in compliance with the definition of enrollment in 42 CFR section 424.502, which states that "enrollment" includes the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services. Therefore, the use of the word "enrollment" better captures the actual purpose of this form. Section 424.507(b) uses the term "certify" as opposed to "refer." "Certify" is the appropriate term to use when alluding to such services. We are therefore utilizing this term (as opposed to "refer") for the title and scope of the form.

2. Corrections to the content of the CMS-855O - Where appropriate, CMS has changed: (1) all references to the word "register" or any of its iterations to "enroll" or any of its iterations; and (2) all references to the word "refer" or any of its iterations to "certify" or any of its iterations. The term "non-physician practitioners" has been removed and replaced with the term "eligible professionals" and/or "other professionals." This revision of the CMS-855O includes enrollment for the prescribing of Part D drugs by physicians or other eligible professionals. CMS also added a check box to allow licensed retired

physicians to enroll for the purpose of prescribing Part D drugs. CMS added Interventional Cardiology as a physician specialty and split a physician specialty from "Oral Surgeons (Dentist Only)" to two specialties – "Oral Surgeon" and "Dentist," and added five specialty types to the "Eligible Professional" section of the form for consistency with other CMS-855 enrollment applications. The "Contact Person" section was changed from required to optional for those providers who do not wish to add an additional contact person.

Editorial and formatting corrections were made in response to comments received during the revision of the current version of this application. Other minor editorial and formatting corrections were made to better clarify some of the instructions for the providers completing this application.

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

JUSTIFICATION

1. *Need and Legal Basis*

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

- Sections 1124(a)(1) 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 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(j)(1)(C) of the Act requires us to consult with providers and suppliers of services before making changes in provider 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(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 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.
- 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.

- 42 C.F.R. section 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. section 424.502, the definition of "enrollment" includes the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services.
- Under 42 C.F.R. § 423.120(c), in order for a Part D drug to be covered, the prescribing physician or eligible professional must be enrolled in Medicare or have validly opted-out of Medicare. We must therefore include Part D prescribers within the scope of this form.
- Section 1848(k)(3)(B) defines the terms "eligible professionals" and "other professionals."
- 42 C.F.R. section 413.75(b) defines licensed residents.
- 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.
- 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.
- We are authorized to collect information on the CMS-855O (Office of Management and Budget (OMB) approval number 0938-1135) to enroll suppliers under the Medicare program as established by Title XVIII of the Act.

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 and/or prescribing Medicare Part D drugs, including the information necessary to uniquely identify and enumerate the provider/supplier.

2. *Purpose and users of the information*

The CMS-855O is submitted when the applicant requests enrollment in Medicare for the sole purpose of ordering and certifying certain Medicare items and services or for prescribing Medicare Part D drugs.

The application is used by Medicare contractors to collect data to help ensure that the applicant has the necessary credentials to order and certify certain Medicare items and services or to prescribe Medicare Part D drugs. This includes ensuring that the physician is not excluded or

debarred from the Medicare program.

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 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 suppliers to upload supporting documentation (required for enrollment) 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.

4. *Duplication and Similar Information*

There is no duplicative information collection instrument or process.

5. *Small Business*

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

6. *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 and/or prescribe Part D drugs. In addition, Medicare contractors must ensure that the ordering/certifying/prescribing physicians or other eligible professionals meet all statutory and regulatory requirements and are properly credentialed.

To ensure uniform data submissions, CMS requires that all changes to previously submitted enrollment data be reported via this enrollment application.

7. *Special Circumstances*

There are no special circumstances associated with this collection.

8. *Federal Register Notice/Outside Consultation*

No comments were received in response to the 60-day comment period December 11, 2015 (80 FR 76994). The Agency will publish a 30-day FR Notice.

9. *Payment/Gift to Respondents*

N/A.

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.

11. *Sensitive Questions*

There are no sensitive questions associated with this collection.

12. *Burden Estimate (hours and cost)*

A. Burden Estimate (hours)

The currently approved total annual hour burden for the respondents for the CMS-855O is 24,125 hours. This estimate was calculated based on when/why a provider must complete and submit the CMS-855O application. The hours were determined as follows: 20,000 hours for initial enrollment + 4,000 hours for reporting changes of enrollment information + 125 hours for reporting a voluntary withdrawal of enrollment information.

For this proposed revision of the CMS-855O, CMS has recalculated the estimated burden hours. CMS believes this recalculation is necessary because over the years of numerous revisions to this data collection tool, the number of affected users, actual data collected and the collection methods have changed significantly. CMS believes these new burden hours accurately reflect 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. The new estimates for completing the CMS-855O Medicare enrollment application form for initial enrollment, reporting changes in enrollment information and voluntarily withdrawal of enrollment information are taken directly from the actual applications processed for calendar year 2014. The new figures are exact and therefore more accurate than the prior estimates. In addition, CMS assessed (via PECOS) how many providers are currently prescribing based on their National Provider Identifier (NPI) and Prescription Drug Event (PDE) data but are not currently enrolled in PECOS.

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

- There are currently 420,000 providers currently prescribing Part D drugs based on their NPI and PDE data but are not currently enrolled in PECOS.
- The calculations CMS is estimating for the percentages of those 420,000 providers are the same percentages as the providers who use the CMS-855O to change their enrollment information or voluntarily withdrawal enrollment information during calendar year 2014. For example, during calendar year 2014, there were 28,000 applications for initial enrollment using the CMS-855O. During the same time, there were 700 respondents using the CMS-855O to report changes of information. The change of information reporting was 2.5% of the initial enrollments. Therefore, for the 420,000 providers who will complete the CMS-855O to prescribe Part D drugs, CMS estimates 2.5%, or 10,500 respondents will utilize the CMS-855O to report a change of information.
- Completion of the CMS-855O takes 0.5 hours for initial enrollments and changes of enrollment information, and 0.25 hours for reporting voluntary withdrawals of enrollment information from the Medicare program.

CMS estimates the new total burden hours for this information collection to be 243,600 hours. These figures are calculated based on when/why a respondent must complete and submit this enrollment application (CMS-855O). The figures are reflected below and in the calculations in Part II of the 83 Worksheets.

CMS is requesting approval of the revised number of burden hours as follows:

HOURS ASSOCIATED WITH COMPLETING THE INITIAL CMS-855O ENROLLMENT APPLICATION

CMS-855O – 448,000 respondents @ 0.5 hour each = 224,000 hours

HOURS ASSOCIATED WITH REPORTING CHANGES OF ENROLLMENT INFORMATION:

CMS-855O – 11,200 respondents @ 0.5 hours each = 5,600 hours

HOURS ASSOCIATED WITH REPORTING A VOLUNTARY WITHDRAWAL OF ENROLLMENT INFORMATION:

CMS-855O – 56,000 respondents @ 0.25 hours each = 14,000 hours

B. Burden Estimate (cost)

The currently approved total annual cost burden for the respondents for the CMS-855O is $502,381.25. This estimate was calculated based on when/why a provider must complete and submit the CMS-855O application. The costs were determined as follows: $417,000 for initial enrollment + $83,400 for reporting changes of enrollment information + $1,981.25 for reporting a voluntary withdrawal of enrollment.

For this proposed revision of the CMS-855O, CMS has recalculated the estimated burden cost. CMS believes this recalculation is necessary because over the years of numerous revisions to this data collection tool, 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-855O. CMS is basing the new burden amounts on data compiled from PECOS. The new estimates for completing the CMS-855O Medicare enrollment application form for initial enrollment, reporting changes in enrollment information and voluntarily withdrawal of enrollment information are taken directly from the actual applications processed for calendar year 2014, as calculated in the burden hour section of this statement. The new figures are exact and therefore more accurate than the prior estimates. In addition, CMS assessed (via PECOS) how many providers are currently prescribing based on their NPI and PDE data but are not currently enrolled in PECOS. Furthermore, CMS used the hourly wage calculations which were taken from the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2014 (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000), indicating the mean hourly wage for the general categories of "Office and Administrative Support Occupations", "Physicians and Surgeons" and "Health Diagnosing and Treating Practitioners."

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

- There are currently 420,000 providers currently prescribing Part D drugs based on their NPI and PDE data but are not currently enrolled in PECOS.
- The calculations CMS is estimating for the percentages of those 420,000 providers are the same percentages as the providers who use the CMS-855O to change enrollment information or voluntarily withdrawal enrollment information during calendar year 2014, as detailed in the burden hour section.
- Completion of the CMS-855O takes 0.5 hours for initial enrollments and changes of enrollment information, and 0.25 hours for reporting voluntary withdrawals of enrollment information from the Medicare program.
- Cost to the respondents is calculated as follows based on the following assumption:
    - The CMS-855O can be completed by administrative staff and reviewed and signed by professional staff, and
    - The record keeping burden is included in the time determined for completion by administrative staff.
- The cost per respondent per form has been determined using as follows :
    - The most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2014, the mean hourly wage for the general category of "Office and

Administrative Support Occupations" is $17.08 per hour (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000). With fringe benefits and overhead, the total per hour rate is $34.16.

- The most recent wage data provided by the BLS for May 2014 (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000), the mean hourly wage for the general category of "Physicians and Surgeons" is $93.74, and the mean hourly wage for the general BLS category of "Health Diagnosing and Treating Practitioners, All Other" is $40.89. With fringe benefits and overhead, the respective totals per hour rates are $187.48 and $81.78.

HOURS ASSOCIATED WITH COMPLETING THE INITIAL CMS-855O ENROLLMENT APPLICATION

CMS-855O – 448,000 respondents @ 0.5 hours each

The cost per respondent per form has been determined using the follow wages:

- $15.00 (reporting Office and Administrative Support Occupations wage for 25 minutes)
- $15.60 (reporting Physicians and Surgeons wage for 5 minutes)

CMS 8550 = $30.60

448,000 respondents @ 0.5 hours each
$30.60 x 224,000 hours = $6,854,400

HOURS ASSOCIATED WITH REPORTING CHANGES OF ENROLLMENT INFORMATION:

CMS-855O – 11,200 respondents @ 0.5 hours each

The cost per respondent per form has been determined using the follow wages:

- $15.00 (reporting Office and Administrative Support Occupations wage for 25 minutes)
- $15.60 (reporting Physicians and Surgeons wage for 5 minutes)

CMS 8550 = $30.60

11,200 respondents @ 0.5 hours each
$30.60 x 5,600 hours = $171,360

HOURS ASSOCIATED WITH REPORTING A VOLUNTARY WITHDRAW OF ENROLLMENT INFORMATION:

CMS-855O – 56,000 respondents @ 0.25 hours each

The cost per respondent per form has been determined using the follow wages:

- $6.00 (reporting Office and Administrative Support Occupations wage for 10 minutes)
- $15.60 (reporting Physicians and Surgeons wage for 5 minutes)

CMS 8550 = $21.60

56,000 respondents @ 0.25 hours each
$21.60 x 14,000 hours = $302,400

CMS estimates the new total burden cost for this information collection to be approximately $7,328,160. These figures are calculated based on when/why a respondent must complete and submit this enrollment application (CMS-855O). The figures are reflected below and in the calculations in Part II of the 83 Worksheets.

The CMS-855O is completed by the provider and its administrative staff. Ultimately, completion and submission of the CMS-855O by the provider is considered a routine business function for the provider.

13. *Cost to Respondents (Capital)*

There are no capital costs associated with this collection.

14. *Cost to Federal Government*

Medicare contractors currently finalize approximately 1.3 million provider/supplier enrollment applications a year. The form changes will not result in any additional cost to the federal government because Medicare contractors are already processing applications from individuals who are enrolling solely to prescribe Part D drugs. Applications will continue to be processed in the normal course of Federal duties.

15. *Changes in Burden/Program Changes*

The burden increase is based the new burden amounts of data compiled from PECOS. The new estimates for completing the CMS-855O Medicare enrollment application form for initial enrollment, reporting changes in enrollment information, and voluntarily withdrawal of enrollment information are taken directly from the actual applications processed for calendar year 2014 in PECOS. The new figures are exact and therefore more accurate than the prior estimates. In addition, CMS assessed (via PECOS) how many providers are currently prescribing based on their NPI and PDE data but are not currently enrolled in PECOS and therefore will complete and submit the revised CMS-855O as Part D drug prescribers. Those assessed providers were added to the burden estimates.

CMS estimates the new total annual burden associated with this information collection is approximately 243,600 hours.

16. *Publication/Tabulation*

N/A.

17. *Expiration Date*

We are planning on displaying the revision approval date and the expiration date.

18. *Certification Statement*

There are no exceptions to item 19 of OMB Form 83-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

N/A.