

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 be enrolled 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 being approved for billing privileges.

There is one facet of this submission:

In CMS-4182-F (RIN 0938-AT08), published on April 16, 2018 (83 FR 16440), CMS eliminated the Part D enrollment requirement. Instead CMS will compile a “Preclusion List” which would consist of certain prescribers who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. Under this rule, CMS makes the Preclusion List available to Part D sponsors and a Part D sponsor must reject a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an individual on the Preclusion List.

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

A. 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 1866G)(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(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 of medical or other items or services and 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.
- 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.
- 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, 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.

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. 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. 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 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.

8. Federal Register Notice/Outside Consultation

The November 28, 2017 (82 FR 56336), proposed rule (CMS-4182-P, RIN 0938-AT08) serves as the 60-day Federal Register notice. Burden associated with the Changes of Enrollment Information and Reporting a Voluntary Withdrawal are unchanged by the proposed rule.

We did not receive any comments pertaining to our proposed requirements. Consequently, we are finalizing them as proposed.

The final rule published on April 16, 2018 (83 FR 16440) and is effective on June 15, 2018.

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. 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 (time and cost)

Wages

The most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2016, the mean hourly wage for the general category of “Office and Administrative Support Workers, All Other” is \$17.33 per hour (see https://www.bls.gov/oes/current/oes_nat.htm). With fringe benefits and overhead, the total per hour rate is \$34.66.

The most recent wage data provided by the BLS for May 2016 (see http://www.bls.gov/oes/current/oes_nat.htm), the mean hourly wage for the general category of “Physicians and Surgeons” is \$101.04. With fringe benefits and overhead, the total per hour rate is \$202.08.

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 (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Office and Administrative Support Workers, All Other	43-9199	17.33	17.33	34.66
Physicians and Surgeons	29-1060	101.04	101.04	202.08

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

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 by PECOS.

The CMS-855O form is completed by the provider and its administrative staff. Respondent burden is calculated based on the following assumptions:

- 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 that the revised total burden for this information collection to be 33,600 hours at a cost of \$2,492,718. These figures are calculated based on when/why a respondent must complete and submit this enrollment application (CMS-855O).

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

Completing the Initial Enrollment Application

14,000 hours = 28,000 respondents x 0.5 hours/response

Costs have been determined using the follow time and wage estimates:

25 min at \$34.66/hr for Office and Administrative Support Workers
 11,667 hours = 28,000 respondents x 25 min/response
 \$404,378.22 = 11,667 hours x \$34.66/hr

5 min at \$202.08/hr for Physicians and Surgeons
 2,333 hours = 28,000 respondents x 5 min/response
 \$471,452.64 = 2,333 hours x \$202.08/hr

\$875,830.86 = \$404,378.22 + \$471,452.64

Reporting Changes of Enrollment Information

5,600 hours = 11,200 respondents x 0.5 hours/response

Costs have been determined using the follow time and wage estimates:

25 min at \$34.66/hr for Office and Administrative Support Workers
 4,667 hours = 11,200 respondents x 25 min/response
 \$161,758.22 = 4,667 hours x \$34.66/hr

5 min at \$202.08/hr for Physicians and Surgeons
 933 hours = 11,200 respondents x 5 min/response
 \$188,540.64 = 933 hours x \$202.08/hr

\$350,298.86 = \$161,758.22 + \$188,540.64

Reporting a Voluntary Withdrawal of Enrollment Information

14,000 hours = 56,000 respondents x 0.25 hours/response

Costs have been determined using the follow time and wage estimates:

10 min at \$34.66/hr for Office and Administrative Support Workers
 9,333 hours = 56,000 respondents x 10 min/response
 \$323,482 = 9,333 hours x \$34.66/hr

5 min at \$202.08/hr for Physicians and Surgeons
 4,667 hours = 56,000 respondents x 5 min/response
 \$943,107 = 4,667 hours x \$202.08/hr

\$1,266,589 = \$323,482 + \$943,107

Annual Burden Summary

CMS-855O	Respondents	Responses	Time (hours)	Cost (\$)
Initial Enrollment Application	28,000	28,000	14,000	875,830
Changes of Enrollment Information	11,200	11,200	5,600	350,299
Reporting a Voluntary Withdrawal	56,000	56,000	14,000	1,266,589
TOTAL	95,200	95,200	33,600	2,492,718

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 cost to Medicare contractors is built into their Medicare contracts.

15. Changes in Burden/Program Changes

CMS-4182-F rescinds the Part D enrollment requirements in 42 CFR 423.120, therefore, all references to Part D enrollment for prescribers of Part D drugs have been eliminated from this PRA package and the CMS-855O Medicare Application Form. The burden hour and cost changes are shown in the table below.

As demonstrated in the following table, we have revised our burden estimates associated with Initial Enrollment Application by -420,000 respondents/responses (515,200 – 95,200) and -210,000 hours (243,600 – 33,600).

CMS-8550	Currently Approved	New Estimates	Difference	Currently Approved	New Estimates	Difference
	Respondents/Responses			Time (hours)		
Initial Enrollment Application	448,000	28,000	(420,000)	224,000	14,000	(210,000)
Changes of Enrollment Information	11,200	11,200	0 (no change)	5,600	5,600	0 (no change)
Reporting a Voluntary Withdrawal	56,000	56,000	0 (no change)	14,000	14,000	0 (no change)
TOTAL	515,200	95,200	(420,000)	243,600	33,600	(210,000)

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 83-1.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

N/A.