Supporting Statement for Paperwork Reduction Act Submissions
Medicare Enrollment Application Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers
CMS 855S/OMB 0938-1056

BACKGROUND

The primary function of the CMS 855S Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier enrollment application is to gather information from a supplier that tells us who it is, whether it meets certain qualifications to be a health care supplier, where it renders its services or supplies, the identity of the owners of the enrolling entity, and information necessary to establish correct claims payment.

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 suppliers to furnish information concerning the identification of individuals or entities that furnish medical supplies and services to beneficiaries before payment can be made.

- 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.
- 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.
- Sections 1834(a)(20)(A) and 1834 (a)(20)(F) of the Act requires the Secretary to establish and implement quality standards for DMEPOS suppliers to be applied and accredited by recognized independent accreditation organizations.
- Section 1834(a)(20)(G)(i) of the Act allows certain Medicare supplier types to be exempt from the accreditation requirement.
- Section 1834(j) of the Act states that no payment may be made for items furnished by a supplier of durable medical equipment, prosthetics, and supplies (DMEPOS) unless that supplier obtains, and renews at such intervals as we may require, a billing number. In order to issue a billing number, we need to collect information unique to that supplier.
- 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 1866(j) of the Act requires the revalidation of all provider and supplier enrollment data every five years – every three years for DMEPOS suppliers.
- 42 CFR Section 424.57 requires DMEPOS suppliers comply with 30 specific standards in order to receive and maintain Medicare billing privileges.
- 42 CFR Section 424.58 requires accreditation in order to qualify for the Medicare program.
- Section 501(c) of the Code requires each Medicare provider/supplier to report information about its proprietary/non-profit structure for tax withholding.

- Section 3402(t) of the Code requires the collection of information necessary to withhold 3% of payments for tax withholding from Medicare providers/suppliers.
- 31 U.S.C. 7701(c) requires that any person or entity doing business with the Federal Government must provide their Tax Identification Number (TIN).
- 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.
- Executive Order 12600 requires the pre-disclosure of notification procedures for confidential commercial information.
- 42 CFR Section 424.58 requires accreditation in order to qualify for the Medicare program.
- 42 CFR Section 455.460 requires the collection of applicable application fees prior to executing a provider agreement from a prospective or re-enrolling provider other than individual physicians or non-physician practitioners.
- 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.
- CMS is authorized to collect information on the form CMS 855S (Office of Management and Budget (OMB) approval number 0938-1057) to ensure that correct payments are made to suppliers under the Medicare program as established by Title XVIII of the Act.

The legal authorities for the proposed provision follow:

- Section 1856(b) of the Act provides that the Secretary shall establish by regulation other standards for Medicare+Choice organizations and plans "consistent with, and to carry out, this part." In addition, section 1856(b) states that these standards have superseded any state law or regulation (other than those related to licensing or plan solvency) for all MA organizations.
- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers in the Medicare program.

2. Information Users

The application is used by the National Supplier Clearinghouse Medicare Administrative Contractor (NSC MAC) to collect data to assure the applicant has the necessary professional and/or business credentials to provide the health care services and supplies for which they intend to bill Medicare including information that allows the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) to correctly price, process and pay the applicant's claims. In addition, submission of this application is a business requirement for health care suppliers who wish to enroll in the Medicare program as DMEPOS suppliers and be reimbursed for Medicare submitted claims.

3. Use of Information Technology

This collection lends itself to electronic collection methods and is currently available through the CMS website. 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 855S certification page with an original signature.

4. Duplication of Efforts

There is no duplicative information collection instrument or process.

5. Small Business

This application form will affect small businesses; however, these businesses have always been required to provide CMS with the same information to identify the DMEPOS supplier in order to enroll in the Medicare Program and for CMS to successfully process their claims.

With regard to the proposed rule, the enrollment requirement would not have a significant economic impact on a substantial number of small businesses because the number of non-enrolled MA providers and suppliers is small in comparison to the general nationwide population of providers and suppliers. Moreover, many MA providers and suppliers are already enrolled in Medicare and would therefore not be affected by this rule.

6. Less Frequent Collection

The information provided on the CMS-855S is necessary for initial enrollment in the Medicare program. It is essential to collect this information the first time a supplier enrolls with a Medicare contractor so that CMS' contractors can ensure that the supplier meets all statutory and regulatory requirements necessary for enrollment and that claims are paid correctly.

This information is also regularly collected every three years for DMEPOS supplier revalidation of enrollment information as required by 42 CFR Section 424.57(e).

This information is also collected as needed for DMEPOS supplier to report changes of enrollment information as required by 42 CFR Section 424.57(c)(2).

To ensure uniform data submissions, CMS requires that all changes to previously submitted enrollment data be reported via the appropriate provider/supplier enrollment application (either via paper application or electronically).

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 July 15, 2016 (81 FR 46162), proposed rule (CMS-1654-P, RIN 0938-AS81) serves as the 60-day Federal Register 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. 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 Estimate (Hours and Wages)

This iteration increases the number of respondents but makes no changes to the application or to the time per response. The increased number of respondents has resulted in an increase in out total time estimate. For details, see section 15 of this Supporting Statement.

Hours

ICR regarding the Enrollment of MA Providers, Suppliers, and First-Tier, Downstream, and Related Entities (FDRs) (§422.222) (New)

10,666 respondents @ 6 hours = 63,996 hours

ICR regarding the completion of the initial enrollment or reactivation application (No Change):

5,162 self-reporting respondents @ 4 hours for each application = 20,648 hours

ICR regarding the reporting changes of enrollment information (No Change):

68,681 total respondents

34,341 self-reporting respondents @ 30 minutes for information reporting = 17,171 hours

ICR regarding the completion of the revalidation of enrollment information (No Change):

10,796 self-reporting respondents @ 1 hour for information reporting = 10,796 hours
10,796 self-reporting respondents @ 30 minutes for recordkeeping = 5,398 hours
10,796 hours + 5,398 hours = 16,194 total hours

The National Supplier Clearinghouse currently processes approximately 100,600 supplier enrollment applications a year. This requirement is and will continue to be a part of doing business with Medicare.

Costs

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (>http://www.bls.gov/oes/current/oes_nat.htm<). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

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

- 50% of all submitted CMS 855S applications will be completed by the individual supplier (respondent) at a wage rate of $150 per hour.
- The other 50% will be completed by professional staff (attorney or accountant) using the average professional wage of $150 per hour or by administrative staff using the average administrative wage of $20 per hour.
- The CMS 855S will be completed by the DMEPOS supplier or professional staff (attorney or accountant) for initial enrollments, reactivation applications and revalidations of enrollment information.
- The CMS 855S will be completed by administrative staff for revalidation record keeping and reporting changes of information.
- The total cost for professional staff completing a CMS 855S for initial enrollment or reactivation application is $600 (4 hours x $150/hour).
- The total cost for professional and administrative staff completing a CMS 855S for revalidation of enrollment information, including record keeping is $160 (1 hour x $150/hour + 1/2 hour x $20/hour).
- The total cost for administrative staff completing a CMS 855S for reporting changes of enrollment information is $10 (1/2 hour x $20/hour).

CMS estimates the new total burden cost for this information collection to be $10,335,330. These

figures are calculated based on when/why a supplier must complete and submit this enrollment application.

CMS is requesting approval of the revised burden cost as follows:

Costs associated with the Enrollment of MA Providers, Suppliers, and First-Tier, Downstream, and Related Entities (FDRs) (§422.222) (New)

Based on our experience, administrative staff typically complete the applicable Form CMS-855 enrollment form for unenrolled organizations.

The mean hourly wage for the general category of Office and Administrative Support Occupations (BLS Occupation Code: 29-0000) is $17.47/hour or $34.94/hour when adjusted by 100% to account for fringe benefits and overhead.

10,666 respondents @ 6 hours = 63,996 hours
63,996 hours x $34.94/hour = $2,236,020.24

Costs associated with completing the initial enrollment or reactivation application:

5,162 paid respondents/5,162 self-reporting respondents = 10,323 @ 4 hours for each application ($600) = $6,193,800

Costs associated with completing the revalidation of enrollment information:

10,796 paid respondents/10,796 self-reporting respondents = 21,592 @ 1 hour for information reporting ($150) = $3,238,800

10,796 paid respondents/10,796 self-reporting respondents = 21,592 @ 30 minutes for record keeping ($10) = $215,920

$3,238,800 + $215,920 = $3,454,720 total cost (revalidation of enrollment information)

Costs associated with reporting changes of enrollment information:

34,341 paid respondents/34,341 self-reporting respondents = 68,681 @ 30 minutes for information reporting ($10) = $686,810

The National Supplier Clearinghouse currently processes approximately 100,600 supplier enrollment applications a year.

13. Capital Cost

There is no capital cost associated with this collection.

14. Cost to Federal Government

There is no additional cost to the Federal government. Applications will be processed in the normal course of Federal duties.

15. Changes to Burden

Our July 15, 2016 (81 FR 46162) proposed rule entitled “CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B” (CMS-1654-P, RIN 0938-AS81) sets out a new §422.222 under which providers and suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Social Security Act, must be enrolled in Medicare in an approved status in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an Medicare Advantage organization. The provision would help ensure that providers and suppliers that furnish MA services are qualified to do so and meet all applicable Medicare requirements.

The proposed rule would add 10,666 respondents which translates to an additional 63,996 hours. The CMS-855S form remains unchanged as does our 6-hour per response estimate.

Form	Organizations (6 hours/application)
CMS-855S	10,666 respondents x 6 hours 63,996 hours 10,666 respondents x 6 hours = 63,996 hours @ $34.94 = $2,236,020.24

16. Publication/Tabulation Dates

N/A

17. Expiration Date

We plan on displaying the revision and expiration dates.