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.

Our November 15, 2016 (81 FR 80170) final rule entitled "CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B" (CMS-1654-F, RIN 0938-AS81) adds 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. This provision has been added to ensure that providers and suppliers that furnish MA services are qualified to do so and that they meet all applicable Medicare requirements.

Based on the CMS-1654-F final rule, this iteration of the CMS-855S information collection request revises the burden estimates (number of respondents and hours) that are currently approved by OMB (see May 9, 2016, NOA). This iteration does not revise the -855S form or our per hour response burden estimates.

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 0938-1056) to ensure that correct payments are made to suppliers under the Medicare program as established by Title XVIII of the Act.

The CMS-855S Supplier Enrollment Application collects this information, including the information necessary to uniquely identify and enumerate the supplier. Additional information necessary to process claims accurately and timely is also collected on the Application.

The enrollment provision in the aforementioned final rule is needed to help ensure that providers and suppliers that furnish MA services are qualified to do so and meet all applicable Medicare requirements. We are finalizing this provision as proposed. The legal authorities for this provision include:

- 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 CMS-855 is submitted at the time the applicant first requests a Medicare billing number. The application is used by the National Supplier Clearinghouse Medicare Administrative Contractor (NSC MAC) to collect data to ensure that 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. 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, transmit it to the Medicare contractor database for processing and then the data is transferred from the Medicare contractor processing database into PECOS by the Medicare contractor. 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.

Historically, PECOS began housing provider/supplier information in 2003 in compliance with the Government Paperwork Elimination Act.

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 previously-mentioned final rule, the new enrollment requirement will 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 rulemaking.

6. Less Frequent Collection

This information is collected on an as needed basis. 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 424.57(e).

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

To ensure uniform data submissions, CMS also 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) served as the 60-day Federal Register notice. The rule did not receive any PRA-related comments.

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)

The following estimates the number of providers and suppliers that will complete each form include, as applicable, initially enrolling and revalidating providers and suppliers, as well as those submitting a change of information involving the submission in question. We note, though, that these numbers are merely averages; the actual numbers will vary each year.

12.1 Wage Estimates

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.

Table 1 - National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Office and Administrative Support Operations	43-0000	17.47	17.47	34.94

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.

12.2 Requirements and Burden Estimates

New Requirements/Burden Associated with Medicare Advantage Provider and Supplier Enrollment (CMS-1654-F)

The CMS-1654-F final rule adds 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. This provision has been added to ensure that providers and suppliers that furnish MA services are qualified to do so and that they meet all applicable Medicare requirements.

Based on the CMS-1654-F final rule, this iteration of the CMS-855S information collection request revises the burden estimates (number of respondents and hours) that are currently approved by OMB (see May 9, 2016, NOA). This iteration does not revise any the -855S form nor our per hour response burden estimates.

Based on our experience, and for purposes of this Supporting Statement, we believe the estimates should be based on the following assumptions:

- It will take the supplier four (4) hours to complete and submit a CMS-855S initial enrollment, or reactivation application.
- It will take the supplier 1 ½ hours to complete and submit a CMS-855S revalidation application.
- It will take the supplier 30 minutes to complete and submit a CMS-855S change of information request.
- The CMS-855S will be completed by office and administrative staff at a rate of $34.94 per the above-mentioned May 2015 BLS estimates.

CMS used a 6 hour burden in the final rule. However, based on a reevaluation of the burden and the most recent data from CMS, we believe that the 4 hour burden is the more accurate. These reduced estimates have been decreased based on improved Internet-based PECOS enrollment processes.

Accordingly, we project the following additional time and costs associated with this requirement.

Table 1 – Burden of Producing Information for the CMS-855S Application Per §422.222

Provision	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($/hr)	Total Cost ($)
§422.222	0938-1056	10,666	10,666	4	42,664	34.94	1,490,680

The chart below shows how CMS estimated the additional respondents (64,000 total), separated by CMS-855 application. For the purposes of this Supporting Statement, the figure of 10,666 respondents is shown in the fourth line, (CMS-855S).

	Individuals (32,000 total respondents)	**Organizations (32,000 total respondents)**
CMS-855I (32,000) Physicians (16,000) $194.66/hour Non-physician Practitioners (16,000) $93.30/hour	32,000 respondents 16,000 physicians 16,000 non-physician practitioners	--
CMS-855A (10,666) $34.94/hour	--	10,666 respondents
CMS-855B (10,666) $34.94/hour	--	10,666 respondents
CMS-855S (10,666) $34.94/hour	--	10,666 respondents
Sub-total respondents	32,000 respondents	32,000 respondents
Total	64,000 respondents	

Currently Approved Estimates

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

10,323 total respondents

Time: **5,162** self-reporting respondents x **4 hours** for each application = **20,648 hours**

If the DMEPOS supplier hires a professional to complete the CMS-855S application (paid respondent) there is no time burden on the DMEPOS supplier.

Cost: **10,323** total responses (5,162 paid respondents + 5,162 self-reporting respondents) x **$600/response** = **$6,193,800**

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

68,681 total respondents

Time: **34,341** self-reporting respondents x **30 minutes** for information reporting = **17,171 hours**

If the DMEPOS supplier hires a professional to complete the CMS-855S application (paid respondent) there is no time burden on the DMEPOS supplier.

Cost: **68,681** total responses (34,341 paid respondents + 34,341 self-reporting respondents) x **$10/response** = **$686,810**

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

21,592 total respondents

Time 1: **10,796** self-reporting respondents x **1 hour** for information reporting = **10,796 hours**
Time 2: **10,796** self-reporting respondents x **30 minutes** for recordkeeping = **5,398 hours**

10,796 hours + **5,398 hours** = **16,194 total hours**

If the DMEPOS supplier hires a professional to complete the CMS-855S application (paid respondent) there is no time burden on the DMEPOS supplier.

Cost: **21,592** responses x **$150/response** = **$3,238,800**
21,592 responses x **$10/response** = **$215,920**

$3,238,800 + **$215,920** = **$3,454,720**

Using the number of respondents cited above, Table 2 outlines the currently approved burden associated with the CMS-855S:

Table 2 – Currently Approved Burden (Time) of Producing Information for the CMS-855S Application

Provision	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Total Cost ($)

Initial and Reactivations*	0938-1056	5,162	5,162	4	20,648	6,193,800
Revalidations	0938-1056	21,592	21,592	1.5	16,194	3,454,720
Change of Information	0938-1056	68,681	68,681	0.5	17,171	686,810
TOTAL	**---**	**95,435**	**95,435**	**varies**	**54,013**	**10,335,330**

*The currently approved information collection request inadvertently set out 5,162 respondents when it should have been 10,323. 10,323 was set out in the Supporting Statement, but 5,162 was entered into the ROCIS system. This correction is also discussed under section 15 of this Supporting Statement.

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 cost to be $10,335,330. These figures are calculated based on when/why a supplier must complete and submit this enrollment application.

12.3 Total Burden

Table 4 outlines the total burden of the information collection addressed in this Supporting Statement. Specifically, the table:

- Combines the total costs from Tables 1 and 3 with those in Table 4.
- Includes the new hour and cost burdens associated with CMS-1654-F. (Although, as mentioned previously, the number of respondents for the CMS-855S extension package is not changing, the chart includes said respondents.)

Table 4 – Total Burden of Producing Information for the CMS-855S Application

Provision	Respondents	Responses	Total Annual Burden (hours)	Total Cost ($)
§422.222 (New)	10,666	10,666	42,664	1,490,680
Currently Approved	95,435	95,435	54,013	10,335,330

Correction	5,161	5,161	n/a	n/a
TOTAL	**111,262**	**111,262**	**96,677**	**11,826,010**

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

As stated previously, under new §422.222 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.

In aggregate, the rule will add 10,666 CMS-855S respondents, which translates to an additional 42,664 hours. The CMS-855S form remains unchanged as does our 4 -hour per response estimate.

Table 5 – CMS-855S Burden Change Associated with CMS-1654-F

Form	**Organizations (6 hours/application)**
CMS-855S	10,666 respondents x 4 hours 42,664 hours 10,666 respondents x 4 hours = 63,996 hours @ $34.94 = $1,490,680

The currently approved hourly wage estimates used a flat $20/hour wage for administrative staff and a flat $150/hour wage for professionals, such as attorneys. This iteration adjusts the hourly wage estimates by using the May 2015 BLS wage estimates and occupations. We adjusted BLS' mean hourly wage by 100% to account for fringe benefits.

Table 6 outlines the total burden and cost change associated with our (1) revision to the CMS-855S extension package estimates and (2) enrollment requirements as part of CMS-1654-F:

Table 6 – Change

Provision	**Currently Approved Burden**	**Burden Associated with CMS-1654-F**	**Correction**	**Difference in Burden**	**New Request**
Respondents	95,435	10,666	5,161	+15,827	111,262

Hour Burden	54,013	63,996	n/a	+63,996	118,009

For the initial application, the currently approved information collection request inadvertently set out 5,162 respondents when it should have been 10,323 respondents. 10,323 was set out in the Supporting Statement, but 5,162 was entered into the ROCIS system. This correction is also discussed under section 12 of this Supporting Statement.

16. Publication/Tabulation Dates

N/A

17. Expiration Date

We plan on displaying the expiration date.