

Supporting Statement for Paperwork Reduction Act Submissions

Medicare Enrollment Application: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers - CMS-855S (OMB Control Number: 0938-1056)

A. BACKGROUND

The primary function of the Form CMS-855S Medicare enrollment application for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is to gather information from the supplier that tells us who the supplier is, whether the supplier meets certain qualifications to be a Medicare DMEPOS supplier, the supplier's location, and other information necessary to establish correct claims payments.

There are three principal purposes of this Paperwork Reduction Act (PRA) information collection request (ICR):

- Request an extension of the Form CMS-855S. The current OMB approval expires on December 31, 2025. We are requesting an extension to December 31, 2028.
- Make various modest changes to the Form CMS-855S. These changes are addressed in the spreadsheet included with this PRA package. Section 12 below addresses the burden associated with these revisions.
- Request OMB approval for ICR burden associated with provision in CMS-1828-P. CMS on July 2, 2025, published in the Federal Register a proposed rule titled, "Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; and Other Medicare and Medicaid Policies" (90 FR 29108) (CMS-1828-P). This proposed rule proposed a number of provisions regarding the requirement in 42 Code of Federal Regulations (CFR) § 424.57 that DMEPOS suppliers be accredited by a CMS-approved DMEPOS accreditation organization (AO) in order to enroll in the Medicare program. One such provision in new § 424.551 would require a DMEPOS supplier undergoing a change in majority ownership to enroll as a new DMEPOS supplier, undergo a survey by a DMEPOS AO, and be newly accredited by a DMEPOS AO. This would require the DMEPOS supplier's completion of an initial Form CMS-855S as a new supplier. This ICR outlines and requests approval for the burden associated with this proposed requirement.

B. JUSTIFICATION

1. Need and Legal Basis

As already noted, this ICR is needed to secure OMB approval of our (1) requests for an extension of the Form CMS-855S; and (2) our proposed changes to the Form CMS-855S and the burdens associated with completing the form. The most relevant statutes and regulations are as follows:

- 42 CFR Part 424, subpart P state the requirements for enrollment, periodic resubmission and

certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers, who must meet and maintain these enrollment requirements to bill the Medicare program.

- Title XVII of the Act ensures that the data collected allows CMS to make correct payments to providers and suppliers in the Medicare program.
- 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 provider/supplier 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.
- 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.
- 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.
- Section 31001(I) of the Debt Collection Improvement Act of 1996 (DCIA) (Public Law 104-134) amended 31 U.S.C. 7701 by adding paragraph (c) to require that any person or entity doing business with the Federal Government provide their Tax Identification Number (TIN).
- The Internal Revenue (IRS) Code, section 3402(t) requires us to collect additional information about the proprietary/non-profit structure of a Medicare provider/supplier to allow exclusion of non-profit organization from the mandatory 3% tax withholding.
- The IRS section 501(c) requires each Medicare provider/supplier to report information about its proprietary/non-profit structure to the IRS for tax withholding determination.
- Under section 1834(a)(20) of the Act:
 - Section 1834(a)(20)(A) requires DMEPOS suppliers to comply with the DMEPOS quality standards in order to bill Medicare.
 - Section 1834(a)(20)(B) requires the Secretary to designate and approve one or more independent accreditation organizations for the purpose of confirming DMEPOS suppliers' adherence to the DMEPOS quality standards.
 - Section 1834(a)(20)(G)(i) allows certain Medicare supplier types to be exempt from the accreditation requirement.
- Section 1834(a)(20)(G)(i) of the Act allows certain Medicare supplier types to be exempt from the accreditation requirement.
- 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.
- 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(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 § 424.57 requires DMEPOS suppliers comply with 30 specific standards in order to receive and maintain Medicare billing privileges.
- 42 CFR § 424.58 requires accreditation in order for a DMEPOS supplier to enroll in Medicare.

- 5 U.S.C. 522(b)(4) requires privileged or confidential commercial or financial information be protected from public disclosure.

2. Information Users

The Form CMS-855S is submitted by DMEPOS suppliers to initially apply for a Medicare billing number, revalidate Medicare enrollment, reactivate Medicare enrollment, report a change to current Medicare enrollment information, and to voluntarily terminate the supplier's Medicare enrollment, as applicable. The collection and verification of the information provided on the Form CMS-855S application protects Medicare beneficiaries and the Medicare Trust Funds from unqualified DMEPOS suppliers. This is sole instrument used for this purpose.

Form CMS-855S applications are processed by one of two Medicare Administrative Contractors (MACs): (1) National Provider Enrollment (NPE) West (Palmetto Government Benefits Administrators); and (2) NPE East (Novitas Solutions).

3. Improved Information Techniques

This collection lends itself to electronic collection methods. The Provider Enrollment, Chain and Ownership System (PECOS) (SORN number 09-70-0532) 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 PECOS data is restricted to CMS and the MACs. Providers/suppliers can submit a Form CMS-855S (i) electronically via PECOS or (ii) via paper.

4. Duplication and Similar Information

The data captured on this form is not duplicated through any other public information collection. No similar data can be modified to capture the information on this form.

5. Small Business

A Medicare billing number is required of all health care suppliers/providers that wish to submit claims for payment to the Medicare Trust Funds; the enrollment process therefore affects small businesses that seek a Medicare billing number. However, these businesses have always been required to provide CMS with provider enrollment information to help ensure the provider/supplier is legitimate and to collect information to successfully process their Medicare claims.

6. Less Frequent Collections

This information is collected on an as needed basis. The information provided on Form CMS-855S is necessary for initial enrollment in the Medicare program. It is essential to collect this information the first time a DMEPOS supplier enrolls with a Medicare contractor, so that CMS' contractors can: (1) uniquely identify the supplier; (2) confirm the supplier's eligibility and legitimacy; and (3) collect relevant information to process the supplier's claims in a timely and accurate manner.

After the DMEPOS supplier's initial enrollment, the information is collected less frequently and often initiated by the supplier for reasons such as a change of information or to voluntarily withdraw from the Medicare program. It is also be collected as part of the enrollment revalidation process every three years.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published in the Federal Register on 08/18/2025 (90 FR 40073). No comments were received during the comment period.

The 30-day Federal Register notice published in the Federal Register on 11/20/2025 (90 FR 52406) No outside consultation was sought.

9. Payment/Gift to Respondents

No payments and/or gifts will be provided to respondents.

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.

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

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimate (hours)

12.1 – Background Information

12.1.1 – Wage Estimates

This Section 12 outlines the estimated hour and cost burdens associated with the requested Form CMS-855S application and burden changes associated with this ICR. As a baseline for calculating the cost burden, we will use the following median wage categories from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates for all salary estimates (<https://data.bls.gov/oes/#/industry/000000>).

Table 1: May 2024 BLS National Occupational Employment and Wage Estimates

| Occupation Title | Occupation Code | Median Hourly Wage (\$/hr) | Fringe Benefits and Overhead (\$/hr) | Adjusted Hourly Wage (\$/hr) |
|--|-----------------|----------------------------|--------------------------------------|------------------------------|
| Physicians | 29-1210 | 115.00 | 115.00 | 230.00 |
| General and Operations Managers | 11-1021 | 49.50 | 49.50 | 99.00 |
| Office and Administrative Support Workers, All Other | 43-0000 | 22.27 | 22.27 | 44.54 |

12.1.2 - Current Burden Estimates for the Form CMS-855S

Table 2 below outlines the current OMB-approved Form CMS-855S annual hour and cost burdens. These are based on the following data and assumptions:

- There are five categories of Form CMS-855S applications:
 - Initial Enrollments (which includes adding a new practice location because each individual location must be separately enrolled)
 - Revalidations
 - Reactivations
 - Change of Information
 - Voluntary Terminations
- For our existing OMB-approved Form CMS-855S burdens, we estimated that:
 - 50% of these applications are submitted by large organizations, 25% by retail store managers, and 25% by physicians. This means that 25% of all Form CMS-855S applications (regardless of transaction type) are submitted by physicians and the remaining 75% by organizations.
 - Each application (regardless of transaction or submitter type) is completed by office staff under the BLS “Office and Administrative Support Workers, All Other” category.
 - Signers of organizational applications fall within the BLS “General and Operations Managers” BLS wage category.
 - Physician applications are signed by physicians.
- The “Hourly Labor Cost of Reporting” Category below outlines the amount of time that: (1) office personnel spend completing each application; and (2) the physician or managerial personnel (as applicable) spends reviewing and signing the application.

Table 2: Current OMB-Approved Form CMS-855S Total Annual Burden

| Regulation Section(s) | Number of Respondents | Number of Responses | Burden per Response (hours) | Total Annual Burden (hours) | Total Cost |
|---------------------------------------|-----------------------|---------------------|-----------------------------|-----------------------------|-------------------|
| Initial Enrollment | 6,716 | 6,716 | 4 | 26,864 | 1,445,233 |
| Reactivation | 2,508 | 2,508 | 4 | 10,032 | 539,703 |
| Revalidation | 8,099 | 8,099 | 2 | 16,198 | 871,502 |
| Reporting a Change of Information | 14,117 | 14,117 | 1 | 14,117 | 868,295 |
| Voluntarily Withdrawing from Medicare | 1,350 | 1,350 | 0.5 | 675 | 41,560 |
| Annual Total | 32,790 | 32,790 | Varies | 67,886 | 3,766,293 |
| 3-year total | 98,370 | 98,370 | Varies | 203,658 | 11,298,879 |

12.2. Specific Form Changes:

This Section 12.2 et seq. addresses the changes we are proposing to the Form CMS-855S application. Note that:

- We do not believe that any of these revisions would involve the submission of data on voluntary termination applications.
- Except as otherwise noted, there would be no alteration in the number of respondents or responses for the initial enrollment, reactivation, and revalidation categories. This is because the number of submissions of these three application types would not increase. Only the particular data elements on the form would change. This also means that the only applicable wage estimate would be that for office personnel (\$44.54) since they would be furnishing the new data.

12.2.1 Enrollment for Medicaid Purposes (Section 1A)

We are adding the following reason for the supplier’s submission of the application: “You are solely enrolling in Medicare to participate in Medicaid or another health care program and will not be billing

Medicare.” We anticipate no burden changes from this addition. It merely gives the supplier another option for identifying the submission reason.

12.2.2 Previous TIN (Section 1A)

One of the reasons for a supplier’s application submission is to report a change in TIN. We are adding a line under this reason checkbox via which the supplier can report its previous TIN. This will help CMS and the NPEs identify the supplier. Changes in TIN typically involve the completion of an initial Form CMS-855S and enrollment as a new supplier. As such, we do not expect any alteration in burden for the “Initial Applications” category, for, again, it already includes TIN changes.

12.2.3 Beneficiary Records Address (Section 1B)

We are adding a checkbox via which the supplier can indicate that it is changing its Medicare beneficiary medical records storage address. This will not cause additional supplier burden, for it simply gives the supplier an additional option for indicating its submission reason.

12.2.4 Section 6 for Signatories (Section 1B)

When changing an authorized or delegated official, the supplier must complete certain sections of the Form CMS-855S. These sections are listed in Section 1B of the application next to the authorized official and delegated official checkboxes. We are adding Section 6 to this list. However, this is simply a technical edit because Section 6 must already be completed in such situations. No new burden is thus implicated.

12.2.5 Organizational/Business Structure (Section 2C)

We are adding “General Partnership”, “Limited Partnership”, and “Sole Owner” to the list of available checkboxes via which the supplier identifies its business structure. This will not involve new supplier burden. General partnerships, limited partnerships, and sole owners will simply check one of these three boxes instead of the current “Other” box.

12.2.6 Government Type (Section 2C)

We are adding checkboxes via which the supplier can identify whether it is a government entity and, if so, its government entity type. These checkboxes mirror those on the Form CMS-855A application. As this data has not previously been requested on the Form CMS-855S, it will constitute new supplier burden.

There are roughly 216 enrolled government-owned DMEPOS suppliers. We project that it would take a government-owned supplier approximately 2 minutes (0.0333 hours) to complete the checkboxes. In terms of impacted applications, we estimate that annually the following number of government-owned suppliers would provide this data:

- Initial Enrollments – 5
- Revalidations – 60
- Reactivations – 17

(The change of information category would not be impacted, for we do not believe there would be changes from government-owned to non-government-owned supplier types and vice versa.)

Using a \$44.54 wage figure, we project the following burden increase associated with this new data element:

Table 3: Annual Burden from New Government-Owned Checkbox

| Application Category | Total Additional Hour Burden | Total Addition Cost Burden (\$) |
|-----------------------------|-------------------------------------|--|
| Initial Applications | 0.167 (.0333 x 5) | 7 (0.167 x \$44.54) |
| Revalidations | 2 (.0333 x 60) | 89 (2 x \$44.54) |
| Reactivations | 1 (.0333 x 17) | 45 (1 x \$44.54) |

Since total hour burdens are typically rounded to the nearest whole dollar figure, the annual hour burden for initial applications will be zero. Only the cost burden will change.

12.2.7 Physician Specialty (Section 2E1)

Existing Section 2E1 of the Form CMS-855S requires the supplier to identify its supplier type by checking the appropriate box. One such box is “Physician”. We are adding a space underneath this box via which the physician DMEPOS supplier can indicate the physician specialty. Since this is a new data element, new burden will be involved.

We estimate that completing this data element would take 1 minute (.0167 hours). We also project that the following numbers of physician Form CMS-855S applications would submit this data:

- Initial Enrollments – 445
- Revalidations – 5,118
- Reactivations – 1,445

(The change of information category would not be impacted because we do not believe there would be changes in physician specialties.)

Applying a \$44.54 wage figure, we estimate the following annual burden increase associated with this data element:

Table 4: Annual Burden from New Physician Specialty Element

| Application Category | Total Additional Hour Burden | Total Addition Cost Burden (\$) |
|-----------------------------|-------------------------------------|--|
| Initial Applications | 7 (.0167 x 445) | 312 |
| Revalidations | 85 (.0167 x 5,118) | 3,786 |
| Reactivations | 24 (.0167 x 1,445) | 1,069 |

12.2.8 Non-Accredited Products (Section 2E3)

Current Section 2E3 of the Form CMS-855A lists several DMEPOS items that are not subject to accreditation under § 424.58. If the supplier furnishes one of these items, it must check the box next to the applicable item. We are adding a new checkbox for suppliers of Oral HIV PrEP Drugs. Since these suppliers have not previously had to identify themselves in Section 2E3 as suppliers of said drugs, this will constitute new burden that will only impact the initial, revalidation, and revalidation categories. (It is possible that changes of information may be submitted to report the new furnishing

or terminated furnishing of these drugs, but we have no information on which we can form an estimate. We therefore request public comments on the potential burden regarding changes of information.)

We estimate that completing this checkbox would take 1 minute (.0167 hours) and that the following annual numbers of Form CMS-855S applications would check the new box:

- Initial Enrollments – 29
- Revalidations – 334
- Reactivations – 94

Applying a \$44.54 wage figure, we estimate the following annual burden increase associated with this data element:

Table 5: Annual Burden from New Oral HIV PrEP Drugs

| Application Category | Total Additional Hour Burden | Total Addition Cost Burden (\$) |
|-----------------------------|-------------------------------------|--|
| Initial Applications | 1 (.0167 x 29) | 45 |
| Revalidations | 6 (.0167 x 334) | 267 |
| Reactivations | 2 (.0167 x 94) | 89 |

12.2.9 Furnished Products and Services (Section 2E4)

Existing Section 2E4 contains an extensive list of DMEPOS items and services that DMEPOS suppliers provide. The supplier must check which items and services it furnishes. In addition, two columns next to each service/item require the supplier to check whether it:

- Fills orders, fabricates, or fits items from its own inventory
- Contracts with another company for the purchase of items necessary to fill orders

We are adding a third column via which the supplier can check whether the item is furnished by mail order. As this is new data, new burden will be implicated.

a. Initial Enrollments/Revalidations/Reactivations - We estimate that completing this checkbox would take 2 minutes (.0167 hours) at a \$44.54 hourly wage and that the following numbers of DMEPOS suppliers each year would submit this data:

- Initial Enrollments – 540
- Revalidations – 6,215
- Reactivations – 1,754

This results in the following annual burden:

Table 6: Annual Burden for Main-Order Checkbox

| Application Category | Total Additional Hour Burden | Total Additional Cost Burden (\$) |
|-----------------------------|-------------------------------------|--|
| Initial Applications | 9 (.0167 x 540) | 401 |
| Revalidations | 104 (.0167 x 6,215) | 4,632 |

| | | |
|---------------|--------------------|-------|
| Reactivations | 29 (.0167 x 1,754) | 1,292 |
|---------------|--------------------|-------|

b. Change of Information

We do not have concrete data to help us estimate the number of changes of information that would be submitted to report that the supplier now furnishes a particular product via mail order. Solely for purposes of this ICR and to propose a basis for which we can solicit public comment, we project that 100 such applications would be submitted each year. Consistent with the previously noted 75/25 ratio for organization versus physician applications, we project that 25 physicians and 75 entities would submit these changes of information. Per Table 2 above, the time burden for each submission would be 1 hour. Applying the wage estimates in Table 1 to this figure results in the following annual cost projections:

Table 7: Annual Burden for Change of Information Submissions Involving Completion of New Mail-Order Checkbox

| Submitter | Respondents | Responses | Total Hour Burden Based on 1 Hour Burden Per Submission | Hourly Wage Based on 0.8 Hour Time Burden for Office Staff (\$44.54) and 0.2 Hour Burden for Physician (\$230.00) or Entity General Manager (\$99.00) | Total Burden (\$) |
|---------------|-------------|------------|---|---|-------------------|
| Physician | 25 | 25 | 25 | 82 (36 (Office Staff) + 46 (Physician)) | 2,050 |
| Entity | 75 | 75 | 75 | 56 (36 (Office Staff) + 20 (Manager)) | 4,200 |
| Totals | 100 | 100 | 100 | Varies | 6,250 |

12.2.10 *Deletion and Addition of Products/Services*

In Section 2E4’s list of products/services, we are removing Cochlear Implants and adding:

- Cognitive Behavioral Therapy Devices (CBTDs)
- External Electrical Stimulation Devices (Not Otherwise Classified)
- Multi-Function Respiratory Devices (Excluding Ventilators)
- Urinary Suction Pumps

Since these suppliers have not previously had to identify themselves as suppliers of one of these four products/items, this will constitute new burden. We project that the following numbers of applications would be submitted by suppliers furnishing at least one of these four items:

- Initial Enrollments – 68
- Revalidations – 778
- Reactivations – 220

At a \$44.54 hour wage and a per response estimate of 2 minutes (.0333 hours), this results in the

following yearly burdens:

Table 8: Annual Burden for Deletion/Addition of Product/Services for Initial, Revalidation, and Reactivation

| Application Category | Total Additional Hour Burden * | Total Additional Cost Burden (\$) * |
|-----------------------------|---------------------------------------|--|
| Initial Applications | 2 (.0333 x 68) | 89 |
| Revalidations | 26 (.0333 x 778) | 1,158 |
| Reactivations | 7 (.0333 x 220) | 312 |

* This constitutes the net burden increase of the 4 new supplier types and the removal of an existing one.

As for changes of information (e.g., the supplier reports it is now furnishing CBTDs in addition to its other product(s)), we project the following totals:

Table 9: Annual Burden for Change of Information Submissions Involving Product/Services Checkbox

| Submitter | Respondents | Responses | Total Hour Burden Based on 1 Hour Burden Per Submission | Hourly Wage Based on 0.8 Hour Time Burden for Office Staff (\$44.54) and 0.2 Hour Burden for Physician (\$230.00) or Entity General Manager (\$99.00) | Total Burden (\$) |
|------------------|--------------------|------------------|--|--|--------------------------|
| Physician | 110 | 110 | 110 | 82 (36 (Office Staff) + 46 (Physician)) | 9,020 |
| Entity | 328 | 328 | 328 | 56 (36 (Office Staff) + 20 (Manager)) | 18,368 |
| Totals | 438 | 438 | 438 | Varies | 27,388 |

12.2.11 Adverse Legal Actions (Section 3)

The supplier is required under Sections 3, 5, and 6 of the Form CMS-855S to report whether it or any party identified in Section 5 or 6 has one of adverse actions described in Section 3. We are adding the following adverse actions to the Section 3 list of actions:

- Any federal or state felony conviction(s) of any owner, managing employee, managing organization, officer or director of the supplier.
- Any crime, under federal or state law, where an individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld, or the criminal conduct has been expunged or otherwise removed, or there is a post-trial motion or appeal pending, or the court has made a finding of guilt or accepted a plea of guilty or nolo contendere.
- Any misdemeanor conviction, under federal or state law, related to sexual abuse, sexual misconduct, inappropriate physical contact of another, or child pornography.

- Excluding Medicaid, any current or past federal health care program exclusion, revocation, or termination of any billing number

Since these will be new actions that DMEPOS suppliers must report, we do not have historical data on which we can establish a clear estimate. Solely for purposes of soliciting comments on the possible burden, we will tentatively project the following:

a. Initial Enrollments/Revalidations/Reactivations – We believe it would take the supplier 30 minutes (0.5 hours) to report one of these actions on the application and the following numbers of applications would be submitted each year disclosing this data:

- Initial Enrollments – 2
- Revalidations – 5
- Reactivations – 3

Using a \$44.54 wage estimate, this results in the following burden:

Table 10: Annual Burden for Reporting Adverse Legal Actions

| Application Category | Total Additional Hour Burden * | Total Additional Cost Burden (\$) |
|-----------------------------|---------------------------------------|--|
| Initial Applications | 1 (0.5 x 2) | 45 |
| Revalidations | 3 (0.5 x 5) | 134 |
| Reactivations | 2 (0.5 x 3) | 89 |

b. Changes of Information

We also have no data to help us project the number of changes of information that would report this data (e.g., disclosing that an owner has recently been convicted of a felony). For purposes, again, of soliciting comments to establish a clearer estimate, we tentatively project the following submissions:

Table 11: Annual Burden for Reporting Adverse Legal Actions

| Submitter | Respondents | Responses | Total Hour Burden Based on 1 Hour Burden Per Submission | Hourly Wage Based on 0.8 Hour Time Burden for Office Staff (\$44.54) and 0.2 Hour Burden for Physician (\$230.00) or Entity General Manager (\$99.00) | Total Burden (\$) |
|------------------|--------------------|------------------|--|--|--------------------------|
| Physician | 1 | 1 | 1 | 82 (36 (Office Staff) + 46 (Physician)) | 82 |
| Entity | 1 | 1 | 1 | 56 (36 (Office Staff) + 20 (Manager)) | 56 |
| Totals | 2 | 2 | 2 | Varies | 138 |

Existing Section 4E2 of the Form CMS-855S asks the supplier whether it stores its patient medical records electronically. If the supplier checks “Yes”, it must identify where/how these records are stored; this can be a website, URL, in-house software program, online service, vendor, etc. but must be a site that can be accessed by the contractor if needed. We are proposing to remove this data element and instead require the supplier to list the name and address of the company it uses for electronic storage. However, we do not believe there would be a burden increase, for only the type of data will be changing and not the relative volume.

12.2.13 – Owning/Managing Organization Type (Section 5)

We are adding “General Partnership”, “Limited Partnership”, “5 Percent or More Direct Ownership Interest” and “5 Percent or More Indirect Ownership Interest” to the list of checkboxes via which the supplier can identify the listed owning/managing entity’s business structure. This will not involve new supplier burden. It will merely give suppliers more options via which to identify said entity’s business type.

12.2.14 – Additional Owning/Managing Individual Information (Section 6A)

We are adding three new data elements to Section 6(A) via which the supplier would have to report its owning/managing individuals’ telephone numbers, e-mail addresses, and fax number. As this is new information on the Form CMS-855S, we are unable to conclusively ascertain the additional burden that would be involved. To solicit comments on this issue, however, we will project that providing this data would take 15 minutes (0.25 hours) and that the following annual application submissions would include this information:

- Initial Applications – 1,780
- Revalidations – 20,470
- Reactivations – 5,778

Insofar as changes of information, the current number of OMB-approved respondents and responses already take into account the number of CMS-855S changes of information that report a new or changed owning/managing individual – which, in turn, would require completion of the telephone and fax numbers as well as the e-mail address. We thus do not anticipate an increase in the number of respondents and responses. The only additional burden would be in total hours and costs. To calculate this, we will project that 3,836 suppliers would submit this data as part of a change of information that reports a new or changed owner or managing employee.

Using a \$44.54 wage estimate, this results in the following additional burdens:

Table 12: Annual Burden for Section 6 Telephone/Fax Number and E-mail Address – Initials, Revalidations, and Reactivations

| Application Category | Total Additional Hour Burden * | Total Additional Cost Burden (\$)* |
|-----------------------------|---------------------------------------|---|
| Initial Applications | 445 (0.25 x 1,780) | 19,820 |
| Revalidations | 5,118 (0.25 x 20,470) | 227,956 |
| Reactivations | 1,445 (0.25 x 5,778) | 64,360 |
| Changes of Information | 959 (0.25 x 3,836) | 42,714 |

12.2.15 – Partnership Checkboxes (Section 6)

Section 6 contains several checkboxes via which an owning individual can identify the type of interest the person has in the supplier. One such box is “Partner”. We are proposing to replace this box with two new boxes: “General Partner” and “Limited Partner”. This will not involve any increased burden, for the individual will simply be identifying the type of partnership interest.

12.2.16 – Supporting Documentation (Section 12)

Section 12 lists various documents the supplier must submit with its application. One such document is the Form CMS-588 (Electronic Funds Transfer Authorization Agreement - OMB Control No.: 0938-0626), which must be accompanied by a voided check. We are proposing to change the voided check requirement to the submission of either such a check or a letter from the bank verifying the supplier’s account information. We do not believe this change will impact existing burden because the supplier can still submit a voided check.

12.3 – DMEPOS Supplier Change in Majority Ownership (CIMO)

As already noted, CMS on July 2, 2025, published in the Federal Register the CY 2026 HH PPS proposed rule. Among the DMEPOS supplier-related proposals in this proposed rule is a requirement in new § 424.551 that a DMEPOS supplier undergoing a CIMO must enroll as a new DMEPOS supplier, undergo a survey by a DMEPOS AO, and be newly accredited by a DMEPOS AO. This would require the DMEPOS supplier’s completion of an initial Form CMS-855S as a new supplier.

In the proposed rule, we projected that an average of 3,768 DMEPOS suppliers each year have a CIMO. We currently require any DMEPOS supplier undergoing a change of ownership involving a new tax identification number to enroll in Medicare as a new supplier. Since these suppliers already have to complete a new enrollment application, there would be no change in their Form CMS-855S information collection burden. Although we do not have concrete estimates as to what portion of the above 3,768 suppliers fall into this category, we believe it is roughly 400-500. We will therefore base our Form CMS-855S burden projections on an estimated 3,300 affected suppliers.

Per the figures in Table 2 above, completion of an initial Form CMS-855S application takes approximately 4 hours, resulting in an annual time burden of 13,200 hours (3,300 hours x 4). In terms of costs, office and administrative support workers (BLS median wage of \$44.28) complete the application for a 3.5-hour burden, and a general and operations manager (\$99.00 wage) takes approximately 0.5 hours to review and sign the form. This results in an annual cost burden of \$674,784 ((3.5 hours x 3,300 x \$44.28) + (0.5 hours x 3,300 x \$99.00)).

Since this provision would only impact initial applications, there will be no change to the revalidation, reactivation, and change of information burdens.

12.4 – Total Burden Increase

Table 13 identifies the projected hour and cost burden increase associated with our information collection request. It totals the figures from the proposed provisions addressed in Sections 12.2 et seq.

and 12.3 and is broken down by application type. (For instance, the total annual hour burden and total annual cost categories for initial enrollments combines the totals from Section 12.3 for CIMOs (e.g., 13,200 hours) and Tables 3-6, 8, 10, and 12 in Sections 12.2 et al. (e.g., 465 hours)).

We also note the following:

- The initial enrollment category will have an increase in the number of respondents and responses due to suppliers submitting an application for a CIMO.
- The change of information category will retain its existing 1 hour per submission burden but will have increased total burden and cost due to: (1) the additional changes of information that – per the above tables – would be submitted; and (2) additional data that must be furnished as part of a change of information involving data presently on the form (e.g., telephone numbers for new managing employee).
- There will be no respondent/response changes for the revalidation and reactivation categories.

Table 14 will contain our new requested burden estimates. It combines the totals in Table 2 (the current OMB-approved burden) with the additional burden outlined in Table 13.

Table 13: Additional Burden Associated with this ICR

| Regulation Section(s) | Additional Number of Respondents | Additional Number of Responses | Burden per Response (hours) | Hour Breakdown Per Personnel Category | Additional Total Annual Burden (hours) | Additional Total Annual Cost (\$) |
|-----------------------------------|---|---------------------------------------|------------------------------------|---|---|--|
| Initial Enrollment | 3,300 | 3,300 | 4 | Office and Administrative Support Workers (3.5 hours) Physician or Managerial Personnel (0.5 hour) | 13,665 | 695,503 |
| Reactivation | 0 | 0 | 4 | Office and Administrative Support Workers (3.5 hours) Physician or Managerial Personnel (0.5 hour) | 1,510 | 67,256 |
| Revalidation | 0 | 0 | 2 | Office and Administrative Support Workers (1.75 hours) Physician or Managerial Personnel (0.25 hour) | 5,344 | 238,022 |
| Reporting a Change of Information | 540 | 540 | 1 | Office and Administrative Support Workers (0.8 hours) Physician or Managerial Personnel (0.2 hour) | 1,499 | 76,490 |
| Annual Total | 3,840 | 3,840 | Varies | N/A | 22,018 | 1,077,271 |
| 3-year total | 11,520 | 11,520 | Varies | N/A | 66,054 | 3,231,813 |

Table 15: Total Requested Burden in this ICR

| Regulation Section(s) | Number of Respondents | Number of Responses | Burden per Response (hours) | Total Annual Burden (hours) | Total Cost |
|-----------------------------------|------------------------------|----------------------------|------------------------------------|------------------------------------|-------------------|
| Initial Enrollment | 10,016 | 10,016 | 4 | 40,064 | 2,140,736 |
| Reactivation | 2,508 | 2,508 | 4 | 10,032 | 606,959 |
| Revalidation | 8,099 | 8,099 | 2 | 16,198 | 1,109,524 |
| Reporting a Change of Information | 14,657 | 14,657 | 1 | 14,657 | 1,340,433 |
| Annual Total | 35,280 | 35,280 | Varies | 89,229 | 5,197,652 |
| 3-year total | 105,840 | 105,840 | Varies | 267,687 | 15,592,956 |

13. Cost to Respondents (Capital)

There are no capital costs associated with this collection.

14. Cost to Federal Government

14.1 NPEs

We anticipate additional costs to the NPEs with respect to processing the aforementioned new data and, for CIMOs, new CMS-855S applications. We estimated in Table 13 an additional annual hour burden pursuant to this ICR of 66,054. Given our experience, we estimate it will take the NPEs a similar amount of time to process this data.

The applicable NPE hourly wage is equivalent to a GS-9, Step 5 (Washington/Baltimore/Arlington

locality), which is \$37.97. (See <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/>.) This results in an annual NPE cost of \$2,508,070.

14.2 Federal Government

The cost to the Federal government will mostly involve: (1) the PRA process (e.g., preparing the PRA package); (2) posting the revised form documents to CMS.gov; and (3) performing outreach as needed. CMS employees will perform these tasks. The hourly wage of said employee is at a GS-13, Step 5 level (Washington/Baltimore/Arlington locality), or \$65.48. (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/>). We estimate that the foregoing tasks will take a total of 60 hours. This results in a total cost of \$3,929.

15. Changes in Burden/Program Changes

This section 15 outlines the burden changes from this ICR:

The changes include adding additional documents in Section 12 as mandatory documents to be included with the application (e.g., maintenance documentation, capped rental or routinely purchased DME agreement, product warranty). These changes have not resulted in a change in burden.

15.1 Hour Burden Changes

Table 16: Change in Form CMS-855S Hour Burden

| Regulation Section(s) | Currently Approved Estimates | Revised Estimates | Net Change |
|-----------------------------------|------------------------------|-------------------|------------|
| Initial Enrollment | 26,864 | 40,529 | +13,665 |
| Reactivation | 10,032 | 11,542 | + 1,510 |
| Revalidation | 16,198 | 21,542 | + 5,344 |
| Reporting a Change of Information | 14,117 | 15,616 | + 1,499 |

15.2 Cost Burden Changes

Table 8: Change in Form CMS-855S Cost Burden

| Regulation Section(s) | Currently Approved Estimates | Revised Estimates | Net Change |
|-----------------------|------------------------------|-------------------|------------|
| Initial Enrollment | 1,445,233 | 2,140,736 | + 695,503 |
| Reactivation | 539,703 | 606,959 | + 67,256 |
| Revalidation | 871,502 | 1,109,524 | + 238,022 |
| Reporting a Change of | 868,295 | 1,340,433 | + 76,490 |

16. Publication/Tabulation

There are no plans to publish the outcome of the data collection.

17. Expiration Date

The expiration date will be displayed on the top, right-hand corner of page 1 of the Form CMS-855S application.