Supporting Statement for Paperwork Reduction Act Submissions

Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Supporting Regulations in 42 C.F.R. § 424.57
CMS-R-263/OMB Control Number: 0938-0749)

A. BACKGROUND

CMS enrolls suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) into the Medicare program via a uniform application, the CMS-855S. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process as well as identified and prevented fraudulent DMEPOS suppliers from entering the Medicare program. As part of this process, verification of compliance with supplier standards is necessary. The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR § 424.57(c)) and where it practices or renders its services. This site investigation form also aides the Medicare contractors (the National Provider Enrollment DMEPOS Contractors (NPEs)) in verifying compliance with the required supplier standards found in 42 CFR § 424.57(c). CMS is making revisions to the currently approved information collection. The revisions to the form include the following:

- General Revisions
    - Reorganized order of sections to: Facility Information, Interview of Individuals Present, Licensure/Certification, Inventory, Records & Telephone, Contact with Beneficiary
- Reason For Visit Section
    - Changed "Ad-Hoc Request" to "Non-Application Based"
    - Changed "Please obtain copies of the following documents if checked:" to "For Non-Application based requests, please obtain copies of the following documents if applicable"
- Facility Information Section
    - Under, "Is access to facility restricted (gated community, call box, etc.)?" added sub-question that states: "If yes, how is access granted?"
    - Removed, "If a home-based business, are all local zoning requirements met?"
    - Removed, "If no, how does the supplier accommodate disabled persons?"
    - Added comment space under, "Is there a permanent, visible sign with the supplier's business name posted on the facility?"
    - Under, "Are hours of operation posted?" added sub-question that states, "If yes, where are hours of operation posted?" options will are: Main entrance of building, Entrance of supplier, Both
    - Moved this question up to first page, above "Please obtain copies of the following documents if checked:" Was the site visit completed? If unable to conduct site visit for any reason (supplier not operational or inspection refused), please explain in the Additional Comments section at the end of this form.
        - Added comment section below this question and changed wording to, "Was the site visit completed? If unable to conduct site visit for any reason (supplier not

operational or inspection refused), please explain in the Comments section below."

- Interview of Individual(s) Present Section:
  - Removed, "The supplier must provide a list of all owners and management with day-to-day control, including name and title."
  - For this question, "Does the supplier have other locations that service Medicare beneficiaries? If additional space is needed, please use the Additional Comments section at the end of this form" added comment section below and changed wording to, "Does the supplier have other locations that service Medicare beneficiaries? If additional space is needed, please use the Comments section below."
  - For this question, "Does the owner or any relatives own(ed) any other medical entities? If additional space is needed, please use the Additional Comments section at the end of this form." added comment section below and changed wording to, "Does the owner or any relatives own(ed) any other medical entities? If additional space is needed, please use the Comments section below."
  - Moved this question under "Facility Information Section": Does the supplier share office space with other DME suppliers or other medical businesses?
  - Removed options of Office personnel, EIN, and Telephone and added option for Patient Exam Rooms for this question, "Do the co-located businesses share any of the following items?"
- Records and Telephone Section:
  - Changed, "Are the patient records maintained (check all that apply)" to "Where are the patient records maintained (check all that apply)" and added these options: no patient records, supplier refusal/not permitted to view
  - Changed, "If "No" to any of the above, please explain" to "If, "No," or supplier refused any of the above, please explain:"
  - Split question into 2 yes or no questions with option to attach copy:
    - Does the supplier have a written/electronic complaint policy/procedure established? If yes, please attach a copy of their complaint policy/procedure.
    - Does the supplier have a written/electronic document for logging complaints? If yes, please attach a copy of their complaint log.
  - Added option for "Search Engine" to this question: "How was the phone number verified (check all that apply)?"
- Licensing/Certification Section:
  - Changed options to yes, no, and N/A Application Based for this question: "Are the supplier's business, customers, and employees covered by comprehensive liability insurance? (Obtain current certificate of insurance with NSC as the certificate holder.)"
    - Also changed question to, "For Non-application based requests, are the supplier's business..."
    - Also changed NSC to NPE
  - Changed options to yes, no, and N/A Application Based for this question: "Does the supplier have valid state and federal licenses applicable to their business?"
- Inventory Section:
  - For this question: "Briefly provide description of inventory present:"
    - Changed to "If yes, briefly provide description…"
    - Added: "If no, briefly describe why:"

    - Removed: “Does the inventory present support the supplier's billing history?”
    - Removed: “If “No”, please obtain invoices and/or contracts to verify the purchase of DME supplies.”
    - Changed options to yes, no, and N/A Application Based and made these stand-alone questions, as opposed to sub-questions:
        - “Does the supplier maintain an off-site storage facility?”
        - “Does the supplier accept other types of health insurance? If yes, please list:”
- Contact with Beneficiary Section:
    - Added question with options for yes, no, and attach copy: “Does the supplier maintain proof of delivery of items furnished to beneficiaries?"
    - Moved this question to Inventory Section: “Does the supplier accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries? If “No” explain the reasons why:”
- Signature and Declaration Section:
    - Added, “In taking pictures, I am attesting that no PII was captured in the photographs.”

JUSTIFICATION

1. *Need and Legal Basis*

42 CFR § 424.57 outlines special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier Medicare billing numbers. Section 424.57 states that Medicare does not issue a billing number to a supplier unless it meets all 30 standards outlined in that subpart. The site inspection verifies that the standards are met by the supplier. The site inspection form allows inspectors to verify the information in a concise, uniform manner.

42 CFR § 424.57(d) states that CMS will revoke a supplier's billing privileges if the supplier is found not to meet the standards in paragraphs (b) and (c) of this section.

42 CFR § 424.57(e) states a supplier must renew its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last renewal of Medicare billing privileges.)

Sections 1814(a) and 1833(e) of the Act require the submission of information necessary to determine the amounts due to a provider or other person. To fulfill this requirement, CMS must collect information on any DMEPOS supplier who submits a claim to Medicare or who applies for a Medicare billing number before allowing the supplier to enroll. This information must, minimally, clearly identify the provider and its' place of business as required by the Budget Reconciliation Act of 1985 (P.L. 99-272) [42 U.S.C. § 9202(g)] and provide all necessary documentation to show they are qualified to perform the services for which they are billing. The site inspection form allows inspectors to verify the information using a standardized information collection methodology.

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 CMS may require, a billing number. In order to issue or renew a billing

number, CMS needs to verify, via a site inspection, the information collected from the supplier on the initial application for enrollment and the application for revalidation.

2. *Purpose and users of the information*

The C.F.R. § 424.500 states 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 except for physicians and practitioners who have entered into a private contract with a beneficiary as described in part 405, subpart D of this chapter. Providers and suppliers must meet and maintain these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies.

This form is used by the two National Site Visit Contractors (NSVCs) Eastern and Western Regions to conduct site visits for DMEPOS suppliers to verify compliance with required DMEPOS supplier standards. The contractor collects the information from the supplier during the site visit and forwards it to the NPEs for evaluation. Once accepted, the results are entered into the Provider Enrollment Chain and Ownership System (PECOS) to show the DMEPOS' compliance with the supplier standards found in 42 C.F.R. section 424.57(c).

The collection and verification of this information defends and protects our beneficiaries from illegitimate DMEPOS suppliers. These procedures also protect the Medicare Trust Fund against fraud. It gathers information that allows the NPEs to ensure that the applicant or enrolled DMEPOS supplier (in revalidation status) has the necessary credentials and inventory, as well as compliance with the DMEPOS supplier standards, to provide the DMEPOS equipment and supplies for which the suppliers intend to bill Medicare. This is the sole instrument implemented for this purpose.

3. *Improved Information Techniques*

This form does not lend itself to the use of improved information technology, as all the site inspections must be individually performed. However, improved information techniques allow the site investigators to upload the completed site visits and any relevant documentation to their systems, rather than mailing them to the NPEs.

4. *Duplication and Similar Information*

The site visit form is intended to validate the information provided by a DMEPOS supplier on the CMS-855S application. The DMEPOS supplier does not have to duplicate the information already provided on the application. The DMEPOS supplier is only required to allow the site inspector to verify the information already provided on the CMS-855S.

5. *Small Business*

This form will affect small businesses; however, DMEPOS suppliers have always been required to provide CMS with documentation to verify information collected on the CMS-855S application,

including site investigations, as a condition of enrollment. Accordingly, the impact is minimal – CMS carries the burden of the cost; the supplier must allocate a small amount of time to this effort to answer any questions the site visit investigator might have.

6. *Less Frequent Collections*

   This information is collected only as needed. It is necessary for verification of enrollment information. It will be collected upon initial enrollment revalidation (currently every three years) and when the NSVCs conduct unannounced site visits in accordance with special fraud initiatives. If it were collected less frequently, CMS would not be able to determine the legitimacy of the DMEPOS suppliers in the Medicare program.

7. *Special Circumstances*

   There are no special circumstances associated with this collection.

8. *Federal Register Notice/Outside Consultation*

   A 60-day Notice will publish in the Federal Register on May 16, 3024. .

   No outside consultation was sought.

9. *Payments/Gifts 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 and cost)*

For this proposed renewal of the site investigation form, CMS has recalculated the burden amounts using data compiled from the Provider Enrollment, Chain and Ownership System (PECOS) and the

National Site Visit Contractors (NSVCs). The new estimates for completing the site investigations are taken directly from the actual site visits performed in fiscal year 2023. The new figures of processed site visits are exact and therefore more accurate than the prior estimates.

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

- The site investigation form is completed by the NSVCs.
- The NSVCs currently receive and process approximately 16,029 site investigation forms per year (as seen in Table 1).
- Hour burden of the respondents is calculated as follows based on the following assumptions:
    - The CMS-R-263 will be completed by the NSVC site inspectors;
    - The record keeping burden is included in the time determined for completion by the NSVCs;
    - The NSVC reported that each site visit takes one hour to complete; and

There is no monetary cost to the suppliers, as the NSVCs complete the site visit form.

The annual and three-year summary of all burden hours and costs are reflected in Table 1 (below).

Table 1

Type of Respondents	OMB Control No.	Number of Respondents	Number of Responses	Average Burden per Response (hours)	Total Annual Burden (hours)	Cost Per Site Visit	Total Cost ($)
Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)	0938-0749	16,029	16,029	1 hour for each site visit by the NSVC	16,029 hours	$175.00 average for observational/ detailed 30-day site visit	$2,805,075
3-year total	0938-0749	48,087 Respondents	48,087 Responses	1 hour for each site visit by the NSVC	48,087	$175.00 average for observational/ detailed 30-day site visit	$8,415,225

13. *Cost to Respondents (Capital)*

There are no capital costs associated with this collection.

14. *Cost to Federal Government*

The estimated annualized cost to the government is **$2,805,075.** The table below describes itemized cost components.

$175 per site investigation multiplied by 16,029 site investigations = $2,805,075.

Item	Estimated Annualized Cost
National Site Visit Contractor	$175[1] per site visit
Number of DME Site Investigations per year	16,029 site visits
Total	$2,805,075

15. *Changes in Burden/Program Changes*

The prior renewal of the CMS-R-263 estimated approximately 8,255 DMEPOS suppliers were visited per year. Updated information shows 16,029 suppliers received site visits for fiscal year 2023. The difference in respondents is 7,774 (16,029 minus 8,255). These are exact figures from the NSVC's systems and are taken directly from the actual site visits processed for calendar year 2023. The increase of 7,774 burden hours is the difference in the DMEPOS enrollment population requiring a site visit in 2019 compared to fiscal year 2023.

The prior renewal of the CMS-R-263 estimated $200.00 per site visit, which totaled $1,651,000.00 annually. Updated information shows a site investigation costs on average $175.00 per site visit, which totaled $2,805,075. This number was derived by taking the average cost of performing a 30-day observational/detailed site visit as reported by the 2 National Site Visit Contractors (NSVCs) Eastern and Western Regions. The difference is an increase in cost burden of $1,154,075 ($2,805,075 minus $1,651,000.00).

16. *Publication/Tabulation*

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

17. *Expiration Date*

The expiration date will be displayed on the top, right-hand corner of page 1 of the site visit form.

1 Cost figure for site visit ($175) derived from the National Site Visit Contractors Data and is the average cost of performing a 30-day observational/detailed site visit.