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

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 contractor (the National Supplier Clearinghouse Medicare Administrative Contractor (NSC MAC) and/or its subcontractors) in verifying compliance with the required supplier standards found in 42 CFR § 424.57(c). This site investigation form collects the same information as its predecessor, with no exceptions. All information collected on this site investigation remains unchanged.

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 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 we may require, a billing number. In order to issue or renew a billing number, we need to verify, via a site inspection, the information collected from the supplier on the initial application for enrollment and the application for revalidation.

Section 1833(q) of the Social Security Act requires that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) be uniquely identified for all claims for services that are ordered or referred.

2. Information Users

This form is used by the NSC MAC and its subcontractor on site visits to verify compliance with required DMEPOS supplier standards. The subcontractor collects the information from the supplier through an interview and forwards it to the NSC MAC for evaluation.

3. Use of Information Technology

This form does not lend itself to the use of improved information technology, as all the site inspections must be individually performed.

4. Duplication of Efforts

The site visit form is intended to validate the information provided by a DMEPOS supplier on the CMS 855S application.

5. Small Businesses

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.

6. Less Frequent Collection

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 NSC MAC conducts 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 Federal Register notice was published on January 16, 2015 (80 FR 2430). No comments were received.

9. Payments/Gifts to Respondents

There are no payments or gifts 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.

11. Sensitive Questions

There are no questions of a sensitive nature associated with these requirements.

12. Burden Estimates (Hours & Wages)

The total annual hour burden for DMEPOS suppliers is 15,000 hours. This is based on an estimate of 30 minutes to complete the interview for the approximately 30,000 DMEPOS suppliers visited per year.

There is no monetary cost to the suppliers, as the NSC MAC or its subcontractor completes the form.

13. Capital Costs

There are no capital costs to the respondents.

14. Cost to Federal Government

There is no additional cost to the Federal government. Site investigations will be completed in the normal course of Federal duties. Currently, the cost is approximately $225 per site investigation.

15. Changes to Burden

This notification maintains the current burden of 15,000 hours annually.

16. Publication/Tabulation Dates

There are no plans to publish or tabulate the information collected.

17. Expiration Date

We are planning on displaying the revision approval date and the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

N/A

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Site Investigation – Durable Medical Equipment (DME) Supplier Location and Supporting Regulations in 42 C.F.R. § 424.57

ATTACHMENT A

Below is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.

2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.

3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.

4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.

5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.

6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.

7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.

8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.

9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of

a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.

10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.

11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.

12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.

13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.

14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.

15. A supplier must 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.

16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.

17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.

18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.

19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.

20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.

21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.

22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific

products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). *Implementation Date - October 1, 2009*

23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.

24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.

25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.

26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). *Implementation date- May 4, 2009*

27. A supplier must obtain oxygen from a state- licensed oxygen supplier.

28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).

29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.

30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.