Supporting Statement for Paperwork Reduction Act Submission

Durable Medical Equipment Medicare Administrative Contractor (MACs), Certificate of Medical Necessity and Supporting Documentation Requirements
CMS-846-849, 10125, 10126, and 10269

A. BACKGROUND

Medicare serves over 43 million beneficiaries and processes over 950 million claims per year. In order to process and pay such a large number of claims, Medicare has 23 fiscal intermediaries to process Part A claims, and 18 carriers to process Part B claims including those for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Using past experience and listening to the needs of Medicare providers, suppliers, and beneficiaries, CMS (formerly known as HCFA) identified problems associated with processing claims for DMEPOS. Those same sources have helped to provide successful solutions.

In 1991, we began looking at the way we process claims for durable medical equipment, prosthetics, orthotics and supplies. In consultation with our customers and our partners, we heard that we needed to focus more on customer service, to establish more uniform requirements for claims submission and adjudication, and to do a better job of preventing improper payments.

Prior to 1993, suppliers of DMEPOS submitted their claims to one of 33 different carriers for processing and payment. The biggest portion of these carriers' workload was physician submitted claims and this is where their efforts were concentrated. DMEPOS suppliers and beneficiaries often complained of slow claims payment and poor service on their inquiries. Carrier coverage policies for DMEPOS items were not consistent and often varied considerably among carriers across the country. National supplier chains submitted claims to several carriers, often with differing results. In a number of instances suppliers sought out the carriers with the least restrictive coverage policies (carrier shopping) and submitted their claims there. Electronic claims submission requirements differed between carriers, requiring suppliers to submit their claims in different formats. In addition, CMS had no single focus to accumulate and analyze DMEPOS claims information for program management.

In partnership with suppliers, providers, and Medicare beneficiaries, CMS sought to design solutions through consistent administrative actions to utilize current technology while re-engineering the processes then in place. For example, to achieve more sophisticated and uniform coverage policy, to improve claims processing and to help prevent fraud and abuse, we concluded that we should concentrate all processing for equipment and supplies in a small number of specialized carriers. We believe that the use of a few administrative carriers would greatly reduce the variance in coverage policy and utilization parameters among carriers. Greater efficiency would be achieved because each carrier would have a trained pool of experienced personnel who would be able to handle DMEPOS claims more effectively and process claims more quickly and accurately.

Starting March 1, 2008 CMS began consolidating processing for DMEPOS claims at four Durable Medical Equipment Medicare Administrative Contractors (MACs) that replaced the

Durable Medical Equipment Carriers (DMERCs). This consolidation of the DME MACs also allowed for standardized submission of electronic claims. All suppliers were now able to use a single format to submit their claims to Medicare. This was a major redesign of the previous process that had well over 30 different electronic formats, a major deterrent to electronic billing.

Through these four carriers, we have achieved greater efficiency not only in the processing of claims but in the development and application of coverage policy and medical review. Each of the four DME MACs review Certificates of Medical Necessity (CMNs). Suppliers submit CMNs for items that present an increased risk to the Medicare program. The CMNs are consistent across the DME MACs, and suppliers are familiar with both the forms and the process of submitting them.

Through the use of the DME MACs, CMS has been able to ensure more appropriate and consistent payment of DMEPOS claims nationwide. The data has shown savings due to lower administrative costs and cost-effective pre-screening edits. By consolidating our operations, utilizing knowledgeable personnel and using cost effective technology we have created a more efficient and manageable claims processing system that better serves Medicare beneficiaries, providers and suppliers.

We learned that our customers have expectations and are a valuable resource when identifying areas where an organization needs improvement. By taking actions to meet those expectations current processes are improved and CMS discovered new and different perspectives on old systems. We look forward to employing these newly practiced skills in the future.

The CMS has been involved in a series of continuing meetings with the OMB in regards to the status of these forms. In addition, CMS contracted to evaluate the overall efficiency and effectiveness of individual CMNs.

Currently, there are a total of 6 CMNs with individual CMS form numbers (841, 842, 844-854, 101269) and 2 DME Information Forms (10125-10126) that have a unique OMB control number (0938-0679). The current CMS form numbers are represented below:

- CMS-846: Lymphedema Pumps (Pneumatic Compression Devices) (OMB Control Number: 0938-0679)
- CMS-847: Osteogenesis Stimulators (OMB Control Number: 0938-0679)
- CMS-848: Transcutaneous Electrical Nerve Stimulators (TENS) (OMB Control Number: 0938-0679)
- CMS-849: Seat Lift Mechanisms (OMB Control Number: 0938-0679)
- CMS-854: Section C Continuation Form (OMB Control Number: 0938-0679)
- CMS-10269: Positive Airway Pressure (PAP) Devices for Obstructive Sleep Apnea (OMB Control Number: 0938-0679)
- CMS-10125: External Infusion Pumps (OMB Control Number: 0938-0679)
- CMS-10126: Enteral and Parenteral Nutrition (OMB Control Number: 0938-0679).

CMS-845 for Continuous Positive Airway Pressure (CPAP) was eliminated but it is being reinstated as a newly revised form CMS-10269. CPAP has a national coverage decision (NCD) that was broadened to allow for the test to be performed in the Medicare beneficiary's home. The home use of CPAP has opened the Medicare program up to increased billing which causes a vulnerability to the Medicare program. CMS-10269 for CPAP will be used to make sure physicians are ordering the test and that the CPAP test is medically necessary.

This clearance request is for CMS form numbers 846-849, 10125, 10126, and 10269.

B. JUSTIFICATION

1. Need and Legal Basis

Under Section 1862 (a)(1)(A) of the Social Security Act (the Act), 42 U.S.C. §1395y(a), the Secretary may only pay for items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." In order to assure this, CMS and its contractors develop Medical policies that specify the circumstances under which an item or service can be covered. The CMN provides a mechanism for suppliers of Durable Medical Equipment, defined in 42 U.S.C. §1395x(n), and Medical Equipment and Supplies defined in 42 U.S.C. §1395j(5), to demonstrate that the item they provide meets the minimal criteria for Medicare coverage.

Section 1833(e), 42 U.S.C. §1395l(e), provides that no payment can be made to any provider of services, or other person, unless that person has furnished the information necessary for Medicare or its contractor to determine the amounts due to be paid. Certain individuals can use a CMN to furnish this information, rather than having to produce large quantities of medical records.

Under Section 1834(j)(2) of the Act, 42 U.S.C. §1395m(j)(2), suppliers of DME items may not provide medical information to physicians on a CMN used to document medical necessity. The physician who orders the item is responsible for providing the information necessary to demonstrate that the item provided is reasonable and necessary. Any supplier of medical equipment who knowingly and willfully distributes a CMN in violation of this restriction is subject to penalties, including civil money penalties (42 U.S.C. §1395m(j)(2)(A)(iii)).

For Medicare to consider any item for coverage and payment, the information submitted by the supplier (e.g., claims and CMNs), including documentation in the patient's medical records, must corroborate that the patient meets Medicare coverage criteria. The patient's medical records may include: physician's office records; hospital records; nursing home records; home health agency records; records from other healthcare professionals or test reports. This documentation does not need to be submitted with every claim, but must be available to the DME MAC upon request.

2. Information Users

The CMN collects information required to help determine the medical necessity of certain items. CMS requires CMNs where there may be a vulnerability to the Medicare program. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those who bill for the items) complete the administrative information (e.g., patient's name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinicians (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the beneficiary's medical condition and signs the CMN. The physician or other clinician returns the CMN to the supplier who has the option to maintain a copy and then submits the CMN (paper or electronic) to CMS, along with a claim for reimbursement.

3. Improved Information Techniques

Collection of this information involves the use of automated, electronic, mechanical or other technology. The use of standard forms facilitates review by CMS. Additionally, the standard form defines necessary documentation and information clearly -- eliminating the possibility of submitting unnecessary documentation, such forms make suppliers more efficient. Further, suppliers can submit the CMNs to the DME MACs in electronic format.

4. Duplication and Similar Information

The required medical information is not available outside the individual beneficiary's medical chart/file kept by the physician. The CMN collects certain pieces of information regarding the patient, their condition, and the item of DME without having to individually request and review medical records for each claim.

The DME MACs use the patient's name, address and Health Insurance Claim Number, though collected on the claim, to "match" a claim to a CMN.

Further, the law specifies that suppliers list charge information and the Medicare fee schedule amount (where applicable) on the CMN "prior to distribution of the CMN to the physician."

5. Small Business

These forms will affect small businesses; however, these businesses have created, completed and processed CMNs since the DME MAC regionalization. CMS, in order to lessen the burden on the small businesses has provided free software to facilitate electronic billing. Further, we provide training throughout the country on how to file both claims and the associated CMNs. These standardized forms will only collect pertinent information to make a medical necessity determination. Without the forms, small businesses would be required to submit more individualized documentation to support their claims.

6. Less Frequent Collections

As discussed in item #1 above, CMNs are used by Medicare and its contractors to help verify that items and services provided are reasonable and necessary as required by Section 1862(a)(1)(A) of the Act, 42 U.S.C. §1395y(a)(1)(A). CMNs have provided suppliers a means of furnishing information to the DME MAC without having to produce large quantities of medical records. Without use of these forms, a substantial increased burden would occur for CMS as well as for certain providers and suppliers.

7. Special Circumstances

More often than quarterly
Last year, the DME MACs processed approximately a total of 5.4 million claims for CMS form numbers 841, 842, and 846-849, 10125, 10126 and 854 for approximately 1.2 million beneficiaries. There were approximately 51,000 unique supplier numbers with a submitted charge for the above CMS form numbers. The CMNs currently in place have provided protection to the Trust Fund by helping to ensure only reasonable and necessary claims are paid. Additionally, the CMNs actually cut the paperwork burden associated with filing a Medicare claim by allowing the supplier to submit one form.

8. Federal Register Notice/Outside Consultation

CMS published The Federal Register notice for this collection of information on **June 26, 2009.**

9. Payment/Gift to Respondents

No payment or gifts will be provided to respondents.

10. Confidentiality

There is no confidentiality concern associated with this request.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this request.

12. Burden Estimate (Total Hours and Wages)

CMS estimates the total annual hour burden for completing the CMN form is 1,296,000 hours. CMS estimated that respondents could complete the form in 12 minutes. We estimate that

suppliers will submit 6,480,000 of these CMN forms each year. This requirement has and will continue to be a cost of doing business with Medicare. A DME MAC can receive a CMN electronically. Billers obtain electronic software free of charge to promote electronic billing. CMS feels strongly that if the CMNs were not in place, the expense to the government would increase dramatically through substantial increases in medical review activities both in staffing and full-scale claim development.

The total burden associated with this collection is 1,296,000 hours.

CMN Burden

CMS Forms
CMS-846: Pneumatic Compression Devices
CMS-847: Ostogenesis Stimulators
CMS-848: Transcutaneous Electric Nerve Stimulator
CMS-849: Seat Lift Mechanisms
CMS-854: Continuation Form
CMS-10125: External Infusion Pumps
CMS-10126: Enteral and Parenteral Nutrition
CMS-10269: Positive Airway Pressure (PAP)

Cost to Respondents

Respondent Cost

Cost to the respondents is as follows: $12.86 per hour times 10 minutes for clerical work (it should take the clerk no more than 10 minutes per CMN to fill out the information on the form) and a maximum of 2 minutes for the physician. The clerical cost is $12.86 divided by 6 or $2.14 per CMN. It should take the physician no longer than 1 to 2 minutes to complete, review and sign the form. If the physician's time is valued at $85 per hour, 1 to 2 minutes is worth $1.42 to $2.84. The total cost per CMN is 2.14 + 1.42 = $3.56 or 2.14 + 2.84 = $4.98 in most cases. Adding copying, postage and other administrative cost, we estimate the total cost per CMN to be between $5.25 - $8.75.

13. Capital Costs

There are no capital costs, as the billers obtain electronic software free.

14. Cost to Federal Government

Federal Cost

Carrier data entry clerks require approximately 1 minute to enter the CMN. Their average annual salary in 2008 is $26,750. Their hourly wage is $12.86 (26,750 divided by 2080 hours).

To handle the 6,480,000 CMNs cost approximately $1,166,000. Other than the initial infrastructure and front-end software for electronic claims, the federal cost for the average electronic claim is much cheaper than for paper processing.

15. Changes in Burden/Policy

In February 2009 this form was approved by OMB. CMS is resubmitting CMN Form 10269 (OMB Control Number: 0938-0679) to include a question to meet coverage and medical necessity criteria.

Due to a technical oversight on the part of CMS an important question was missing that would allow claims with an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 5 without symptoms for Criterion 2 be paid for by the Medicare program. The omission of the following question "Does the patient have documented evidence of at least one of the following: Excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease or history of stroke" could cause improper payment of claims without regards as to whether the patient has signs or symptoms in support of meeting the applicable coverage criteria for PAP devices.

16. Publication/Tabulation

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

17. Expiration Date

We are seeking approval to not display the expiration date. These forms are used on a continuous basis; to include an expiration date could result in the needless destruction of many forms.

18. Certification Statement

There are no exceptions to the certification statement. This collection of information complies with 5 CFR 1220.9.