Supporting Statement for Paperwork Reduction Act Submission

Durable Medical Equipment Regional Carrier, Certificate of Medical Necessity and Supporting Documentation Requirements –Oxygen
CMS-484

A. BACKGROUND

Medicare serves over 43 million beneficiaries and processes over 950 million claims per year. 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 oxygen and oxygen equipment. 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 these 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 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 in March 2008, CMS began consolidating processing for DMEPOS claims at four Medicare Administrative Contractors (MACs). This consolidation 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 DME MACs, 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 for items that present an increased risk to the Medicare program. The CMNs are consistent across the regional carriers, and suppliers are familiar with both the forms and the process of submitting them. Currently, CMS form number 484 has a unique OMB control number (0938-0534).

Through such action, 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.

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

being provided meets the 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 for every claim they submit for payment.

Under Section 1834(j)(2) of the Act, 42 U.S.C. §1395m(j)(2), suppliers of DME items are prohibited from providing medical information to physicians when a CMN is being completed 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 and the supplier shall also list on the CMN the fee schedule amount and the suppliers charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician. 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)).

Under Section 42 Code of Federal Regulations §410.38 and §424.5, Medicare has the legal authority to collect sufficient information to determine payment for oxygen, and oxygen equipment.

Oxygen and oxygen equipment is by far the largest single total charge of all items paid under durable medical equipment coverage authority. Detailed criteria concerning coverage of home oxygen therapy are found in Medicare Carriers Manual Chapter II-Coverage Issues Appendix, Section 60-4.

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 must be available to the DMERC upon request.

2. Information Users

The CMN collects information required to help determine the medical necessity of certain items. CMS requires CMNs where items may present a vulnerability to the Medicare program. Each 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.

In order to determine if a beneficiary needs home oxygen therapy, a qualifying blood gas study must be performed and it must comply with the DME MACs Oxygen Medical Policy on the standards for conducting the test and also be covered under Medicare Part B. A beneficiary must be seen and evaluated by the treating physician within specific timeframes as indicated by the Oxygen Medical Policy in order to complete an Initial CMN Certification, a Recertification CMN and a Revised CMN Certification.

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, the 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 DME MACs were created since the. CMS, in order to lessen the burden on these 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 MACs 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 DMERCs processed approximately 11 million claims for oxygen for approximately 1.5million beneficiaries. There were approximately 15,000 unique supplier numbers with a submitted charge for oxygen. The CMN currently in place has provided protection to the Trust Fund by ensuring only reasonable and necessary claims are paid. Additionally, the CMNs actually cut the paper work burden associated with filing a Medicare claim by allowing the supplier to submit just this one form.

8. ***Federal Register Notice/Outside Consultation***

CMS published The Federal Register notice for this collection of information on **July 18, 2008,** attached**.**

Since March, 1994, the American Medical Association, Practicing Physicians' Advisory Council, National Association of Medical Equipment Suppliers, Health Industry Distributors Association, and several other national and local supplier organizations (e.g. National Association For Medical Direction of Respiratory Care) expressed concerns that the existing CMNs were not user-friendly, and were burdensome. In order to accommodate the suggestions of some of the national supplier organizations, CMS and its contractors developed a revised CMN that is clearer and easier to complete. The current version took effect on 08/01/96 and all suppliers of durable

medical equipment and supplies continue to use this version.

In 2004, there were several CMN process studies and workgroups that reviewed the oxygen CMN with the DME MACs and CMS. These studies were aimed to gather information on the contents of the CMNs and determine if they are consistent with current medical practices, Medicare, and DMERC guidelines. The CMN process was also looked at to see how it could be improved. As a result, the DME MACs and CMS collaborated to help revise individual questions. Comments were considered as we revised this CMN. This new oxygen CMN captures the current approach to determining coverage, and encourages thoughtful consideration of all treatments and dialogue between physicians, beneficiaries and suppliers

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***

CMS estimates the total annual hour burden for completing the CMN form is 326,000 hours. CMS estimated that respondents could complete the form in 12 minutes. We estimate that 15,000 suppliers will submit a total of 1,630,000 CMN forms each year. This requirement has and will continue to be a cost of doing business with Medicare. A DMERC 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 326,000 hours.

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 at the most.

Adding copying, postage, and other administrative costs, we estimate the total cost per CMN to be between $5.25 - $8.75.

13. ***Capital Costs***

There are no capital costs, as the electronic software is provided free.

14. ***Cost to Federal Government***

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 1,630,000 million CMNs costs approximately $294,000. Other than the initial infrastructure and front-end software for electronic claims, the federal cost for the average electronic claim would be much cheaper than for paper processing.

15. ***Changes in Burden***

The change in burden is due to an increase in the number of respondents. The last approved version of this information collection request (ICR) had calculations based on 11,000 respondents. In this resubmission of the ICR, the number of respondents increased from 11,000 to 15,000. The total number of burden hours has been adjusted accordingly.

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