

Supporting Statement for Paperwork Reduction Act Submission

***Durable Medical Equipment Medicare Administrative Contractor (MACs),
Certificate of Medical Necessity and Supporting Documentation Requirements
CMS-484, 846, 847, 848, 849, 854, 10125, and 10126/OMB Control Number: 0938-0679***

A. EXECUTIVE SUMMARY

CMS is submitting this request as a revision to an existing information collection request (ICR). In an effort to maintain related information collection requirements under the same control number, CMS is merging OMB Control No.: 0938-0534 (Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy) into this information collection request (OMB Control No.: 0938-0679). As a result of the merge, there is an overall burden increase of 326,400 hours. CMS is requesting a three year approval as all forms are currently in-use.

B. BACKGROUND

Medicare serves over 50 million beneficiaries and processes over 1.3 billion claims per year. In order to process and pay such a large number of claims, Medicare has Medicare Administrative Contractors (MACs) to process Part A and Part B claims, and Durable Medical Equipment Medicare Administrative Contractors (DME MACs) to process claims for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS).

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 reengineering 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 believed 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 Regional 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 DME MACs, CMS 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 DME MAC's reviews 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 MAC's, 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.

Currently, there are a total of 8 CMNs that have a unique OMB control number 0938-0679. The current CMS form numbers are represented below:

1. CMS-484 Oxygen and supplies (formerly OMB control number 0938-0534 which is being combined with this OMB control number 0938-0679).
2. CMS-846: Pneumatic Compression Devices
3. CMS-847: Osteogenesis Stimulators
4. CMS-848: Transcutaneous Electrical Nerve Stimulators (TENS)
5. CMS-849: Seat Lift Mechanisms
6. CMS-854: Section C Continuation Form
7. CMS-10125: External Infusion Pumps
8. 8. CMS-10126: Enteral and Parenteral Nutrition.

This clearance request is for CMS all the form numbers listed above.

C. 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)).

Under Section 42 C.F.R §410.38 and §424.5, Medicare has the legal authority to collect sufficient information to determine payment for oxygen, and oxygen equipment.

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 is used to collect information required to help determine the medical necessity of certain items and subsequent payment of a claim. 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 staff of 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 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 the Background 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

The DME MACs processed approximately a total of 21 million claims for oxygen and 3.5 million claims for all other CMNs annually that had CMS form numbers 484, 846, 847, 848, 849, 854, 10125, and 10126 for beneficiaries. 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 a 60-day notice in the Federal Register on February 19, 2016 (81 FR 8498). No comments were received. A 30-day FR Notice published on May 11, 2016 (81 FR 29269).

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 uses multiple CMN forms to determine eligibility:

1. CMS-484 Oxygen and Supplies
2. CMS-846: Pneumatic Compression Devices
3. CMS-847: Ostogenesis Stimulators
4. CMS-848: Transcutaneous Electric Nerve Stimulator
5. CMS-849: Seat Lift Mechanisms
6. CMS-854: Continuation Form
7. CMS-10125: External Infusion Pumps
8. CMS-10126: Enteral and Parenteral Nutrition

Total Volume

We estimate that suppliers will submit 1,632,000 of the oxygen CMN form CMS 484 each year. We estimate that suppliers will submit 460,817 of all other CMN forms each year. This includes forms CMS 846, 847, 848, 849, 10125, and 10126. (The CMN Continuation Form CMS 854 is seldom used and so the burden is not counted separately instead it is part of the average for the other forms.) 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.

Total Hours

CMS estimates that it takes approximately 12 minutes to complete the CMN form, whether it is electronic (online fillable form) or paper. Both forms require the same data and information whether it is filled out in paper or online.

- Physician’s time is approximately 2 minutes to sign/authorize and review the form,
- Medical Office staff time is approximately 10 minutes to complete the form.

CMS estimates that the total annual hour burden for completing ALL CMN forms is over 400,000 hours. Forms CMS 846, 847, 848, 849, 854, 10125, and 10126 are estimated at 92,163 hours and CMS form 484 (oxygen) is estimated at 326,000 hours. The estimate of annual hour burden is based on the 8,880 respondents as identified on Form 83 Part II.

Total time burden ALL CMNs	Hours
Non oxygen	92,163
Oxygen	326,400
Total time burden ALL CMNs	418,563

Cost to Respondents

The total cost to the respondents for completing ALL CMN forms is \$15,301,534.

The average cost to complete a CMN is \$12.97¹ per form and can be broken down as:

- Physician loaded hourly wage is \$194.66 by hour or \$3.24 per minute
 - Medical Office staff loaded wage is \$38.88 per hour or \$0.65 per minute

CMS Form Number	Total Volume	Annual cost burden per form @ \$12.97 per CMN
484	1,632,000	\$ 21,164,864
846	31020	\$ 402,288
847	31510	\$ 408,643
848	90362	\$ 1,171,875
849	44179	\$ 572,943
10125	73325	\$ 950,927
10126	190421	\$ 2,469,506
total cost for all CMNs	2,092,817	\$ 27,141,046

¹ Bureau of Labor Statistics’ May 2015 National Occupational Employment. Hourly wage rates include the costs of fringe benefits (calculated at 100 percent of salary) and the adjusted hourly wage. https://www.bls.gov/oes/current/oes_nat.htm#31-0000

Cost to the respondents is calculated as the volume of CMNs multiplied by the cost per CMN.

13. Capital Costs

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

14. Cost to Federal Government Federal Cost

MAC data entry clerks require approximately 1 minute in processing the CMN. Their average hourly salary is \$15 or \$0.25 a minute. We receive approximately 2,092,817 CMNs annually. Therefore, contractor costs to handle the CMNs are approximately \$523,204.

15. Changes in Burden/Policy

CMS is increasing the burden from 92,400 hours to 418,800 hours to account for merging CMS-484, into this collection; therefore there is a total burden hour increase of 326,400.

16. Publication/Tabulation

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

17. Expiration Date

The expiration date will be displayed on all instruments.