

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 documentation solely for the purpose of renewing the Paper Work Reduction Act (PRA) time limit for all CMNs currently in use. These CMNs are due to expire on February 29, 2020 and since CMS still uses all these forms and there are no changes to the forms or process, we seek to extend them through to February 28, 2023 or for approval not to include an expiration date since these forms remain in active use. There is no additional burden or cost for this action.

The following narrative gives a background on the history of the CMN at CMS and estimated costs and burden.

B. BACKGROUND

Medicare serves over 50 million beneficiaries and processes over one 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 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 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
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. 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 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 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 electronically 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 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 12 million claims for oxygen and approximately 2 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 notice in the Federal Register on October 28, 2019 (84 FR 57734). Comments have been addressed in Appendix A. A 30-day notice published in the Federal Register on February 24, 2020 (85 FR 10442).

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 1,076,061 of the oxygen CMN form CMS 484 each year.

We estimate that suppliers will submit 259,597 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 receives 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.

- 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 267,131 hours. Forms CMS 846, 847, 848, 849, 854, 10125, and 10126 are estimated at 51,919 hours and CMS form 484 (oxygen) is estimated at 215,212 hours.

Total time burden ALL CMNs	Hour
Non oxygen	51,919
Oxygen	215,212
Total time burden ALL CMNs	267,131

Cost to Respondents

The total cost to the respondents for completing ALL CMN forms is \$10,979,108.

The average cost to complete a CMN is \$8.22 per form and can be broken down

as:

- Physician loaded hourly wage is \$135.42 by hour or \$2.26 per minute
- Medical Office staff loaded wage is \$22.09 per hour or \$0.37 per minute

CMS Form Number	Total Volume	Annual cost burden per form @\$8.22 per CMN
484	1,076,061	\$8,845,221
846	50738	\$417,066
847	40308	\$331,332
848	5698	\$46,838
849	7496	\$61,617
10125	31855	\$261,848
10126	123502	\$1,015,186
total cost for all CMNs	1,335,658	\$10,979,108

Cost to the respondents is calculated as the volume multiplied by the loaded per minute wage multiplied by the number of minutes:

Total Time Burden non oxygen		non oxygen minutes	non oxygen hours
Physicians	Ave. 2 minutes per CMN	519,194.00	8,653.23
Office staff	Ave. 10 minutes per CMN	2,595,970.00	43,266.17
total Hours			51,919.40

Total Time Burden oxygen		oxygen minutes	oxygen hours
Physicians	Ave. 2 minutes CMN per	2,152,122.00	35,868.70
Office staff	Ave. 10 minutes CMN per	10,760,610.00	179,343.50
total Hours			215,212.20

Total time burden ALL CMNs	
Non oxygen	51,919.40
Oxygen	215,212.20
Total time burden ALL CMNs	267,131.60

13. Capital Costs

There are no capital costs associated with this information collection.

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 1,335,658 CMNs annually. Therefore, contractor costs to handle the CMNs are approximately \$333,915.

15. Changes in Burden/Policy

As a result in decreasing the annual number of CMN submissions, CMS is decreasing the burden from 418,800 hours to 267,131 hours. Therefore, there is a total burden hour decrease of 151,669.

16. Publication/Tabulation

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

17. Expiration Date

The expiration date and OMB control number are displayed on each instrument.