

Medicare Program Integrity Manual

Department of Health and
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 11

Date: SEPTEMBER 18, 2001

CHANGE REQUEST 1773

CHAPTER NUMBERS	NEW SECTIONS	REVISED SECTIONS	DELETED SECTIONS
Chapter 5		1.1.4	
Chapter 5	1.1.4.1		
Chapter 5	1.1.4.2		
Chapter 5	1.1.4.3		
Chapter 5	3.3		
Chapter 5	3.3.1		

**NEW/REVISED MATERIAL--EFFECTIVE: September 24, 2001
IMPLEMENTATION DATE: September 24, 2001**

Section 1.1.4, CMN as the Written Order, is being revised to provide instructions on how DMERCs should handle electronic CMNs upon review.

Section 1.1.4.1, Cover Letters for CMNs, is being added to change the section number to be more consistent throughout the manual.

Section 1.1.4.2, Completing a CMN, is being added to change the section number to be more consistent throughout the manual.

Section 1.1.4.3, DMERC's Authority to Assess an Overpayment and/or CMP When Invalid CMNs are Identified, is being added to change the section number to be more consistent throughout the manual.

Section 3.3, Certificates of Medical Necessity, is being added to provide a description of certificates of medical necessity (CMNs) and how the DMERCs use CMNs as evidence for medical necessity. Section 3312 of the MCM was deleted and moved into this section.

Section 3.3.1, Acceptability of Faxed Orders and Facsimile or Electronic CMNs, is being added to clarify that DMERCs should accept faxed, copied, and electronic orders and CMNs on review of DMEPOS claims as being accurate unless indications of potential fraud or misrepresentation exist.

These instructions should be implemented within your current operating budget.

NOTE: Red italicized font identifies new material.

Medicare Program Integrity Manual

Chapter 5 – Items and Services Having Special DMERC Review Considerations

Table of Contents (Rev. 11, 09-18-01)

- 1 – Home Use of DME
 - 1.1 – Physician Orders
 - 1.1.1 – Dispensing Orders
 - 1.1.2 – Detailed Written Orders
 - 1.1.3 – Requirement of New Orders
 - 1.1.4 – CMN as the Written Order
 - 1.1.4.1 - Cover Letters for CMNs*
 - 1.1.4.2 - Completing a CMN*
 - 1.1.4.3 - DMERC's Authority to Assess an Overpayment and/or CMP When Invalid CMNs are Identified*
 - 1.1.5 – Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders
- 2 – Documentation in the Patient’s Medical Record
 - 2.1 – Supplier Documentation
 - 2.1.1 – Delivery Method 1 - Supplier Delivers Items Directly to the Beneficiary or Authorized Representative
 - 2.1.2 – Delivery Method 2 - Supplier Utilizes a Delivery/Shipping Service
 - 2.1.3 – Delivery Method 3 - Delivery of Items to a Nursing Facility on Behalf of the Beneficiary
- 3 – Evidence of Medical Necessity
 - 3.1 – Period of Medical Necessity--Home Dialysis Equipment
 - 3.2 – Safeguards in Making Monthly Payments
 - 3.2.1 - Guidance on Safeguards in Making Monthly Payments
 - 3.2.1.1 - Pick-up Slips
 - 3.3 - Certificates of Medical Necessity*
 - 3.3.1 - Acceptability of Faxed Orders and Facsimile or Electronic Certificates of Medical Necessity*
- 4 – Incurred Expenses for DME and Orthotic and Prosthetic Devices
- 5 – Patient Equipment Payments Exceed Deductible and Coinsurance on Assigned Claims
- 6 – Evidence of Medical Necessity - Oxygen Claims
- 7 - Advance Determination of Medicare Coverage (ADMC) of Customized DME
 - 7.1 - Definitions
 - 7.1.1 - Definitions of Customized DME
 - 7.2 - Items Eligible for ADMC
 - 7.3 - Instructions for Submitting ADMC Requests
 - 7.4 - Instructions for Processing ADMC Requests

- 7.5 - Affirmative ADMC Decisions
- 7.6 - Negative ADMC Decisions
- 7.7 - DMERC Tracking

1.1.4 – CMN as the Written Order -- (Rev. 11, 09-18-01){tc "1.1.4 – Certificate of Medical Necessity (CMN) as the Written Order" \1 3}

When reviewing claims where the medical record contains a copied, faxed or electronically maintained CMN (any CMN created, modified, and stored via electronic means such as commercially available software packages and servers), the DMERC should accept where feasible, the copied, faxed or electronic document as fulfilling the requirements for these documents. If evidence indicates that the CMN being reviewed has been falsified, or the supplier is unable to provide adequate assurance of the medical necessity of the items or services, the DMERC can request additional information, including an original signature, in order to obtain that assurance.

*For items that require a CMN, and for accessories, supplies, and drugs related to an item requiring a CMN, the CMN may serve as the detailed written order **IF** the narrative description in Section C is sufficiently detailed (as described above). This applies to both hard copy and electronic orders and CMNs.*

A supplier must have a hard copied, faxed or electronic order or CMN in their records before they can submit a claim for payment to Medicare. Suppliers must ensure the security and integrity of electronically maintained CMNs are in accordance with any regulations published by CMS.

Upon request by the DMERCs, suppliers must provide the CMN, in a format that the DMERCs can accept, in a timely manner. Upon medical review, the DMERCs should not deny claims because of the existence of a faxed, copied or electronic order or CMN, unless the document is unreadable or otherwise violates instructions found in Chapter 1 §3.3 of the Program Integrity Manual or violates any regulations published by the CMS. DMERCs need not make any standard system changes to electronically accept e-CMNs as CMS views e-CMNs as a transaction between the physician and suppliers. The DMERC may request the supplier to download and print a hard copy of an electronic order or CMN if the DMERC can not access it electronically. Suppliers must continue to use current systems for transmitting claim information to the DMERC.

1.1.4.1 - Cover Letters for CMNs -- (Rev.11, 09-18-01)

Cover letters can be used by a supplier as a method of communication between the supplier and the physician. It is not CMS's intent to restrict necessary communication between the supplier and the physician. CMS does not require nor regulate the cover letter. The DMERCs should not take adverse action against suppliers that solely involve cover letters.

The DMERC should regularly publish an article in their bulletins asking suppliers to remind physicians of their responsibility in completing and signing the CMN. It is the physician's responsibility to determine both the medical need for, and the utilization of, all health care services. The physician should ensure that information relating to the beneficiary's condition is correct. The DMERC should encourage suppliers to include language in their cover letters to remind physicians of their responsibilities.

1.1.4.2 – Completing a CMN -- (Rev. 11, 09-18-01)

The “Initial Date” found in Section A of the CMN, should be either the specific date that the physician gives as the start of the medical necessity or, if the physician does not give a specific start date, the “Initial Date” would be the date of the order.

The “Signature Date” is the date the physician signed and dated Section D of the CMN. This date might not be the same as the “Initial Date”, since the “Signature Date” must indicate when the physician signed Section D of the CMN.

The “Delivery Date/Date of Service” on the claim must not precede the “Initial Date” on the CMN or start date on the written order. To ensure that an item is still medically necessary, the delivery date/date of service must be within 3 months from the “Initial Date” of the CMN or 3 months from the date of the physician's signature.

The DMERCs have the authority to request to verify the information on a CMN at any time. If the information contained either in the supplier’s records or in the patient’s medical record maintained by the ordering physician fails to substantiate the CMN, or if it appears that the CMN has been altered, the DMERCs should consider the service not reasonable and necessary and initiate the appropriate administrative actions.

In the event of a post pay audit, the supplier must be able to produce the CMN and, if requested by the DMERC, produce information to substantiate the information on the CMN. If the supplier cannot produce this information, the DMERCs should consider the service not reasonable and necessary, and initiate a denial or an overpayment action.

If there is a change made to any section of the CMN after the physician has completed Section B and signed Section D of the CMN, the physician must line through the correction, initial and date the correction; or the supplier may choose to have the physician complete a new CMN.

1.1.4.3– DMERCs’ Authority to Assess an Overpayment and/or CMP When Invalid CMNs Are Identified -- (Rev. 11, 09-18-01)

Section 1862(a)(1) of the Act prohibits Medicare payment for services that are not reasonable and necessary. Section 1833(e) of the Act requires that Medicare be furnished by providers and suppliers “such information as may be necessary in order to determine the amount due....” These sections provide support that a failure to have a valid CMN on file or to submit a valid CMN to the DMERC makes the underlying claim improper because Medicare does not have sufficient information to determine whether the claim is reasonable and necessary. A valid CMN is one in which the treating physician has attested to and signed supporting the medical need for the item, and the appropriate individuals have completed the medical portion of the CMN. When the DMERCs identify a claim for which a CMN is not valid, they may deny the claim and/or initiate overpayment action.

If a DMERC identifies a supplier that has a pattern of improperly completing the CMN, the DMERC may choose to develop a potential Civil Monetary Penalty (CMP) case against the supplier. The authority for such action is found in §1834(j)(2)(A)(iii) of the Act which states that “any supplier of medical equipment and supplies who knowingly and willfully distributes a CMN in violation of clause (I) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed \$1,000 for each such certificate of medical necessity so distributed.” The provisions of §1128A of the Act (other than subsections (a) and (b) shall apply to CMPs penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under §1128(A)(a)) of the Act.

3.3 - Certificates of Medical Necessity - - (Rev. 11, 09-18-01)

For certain items or services billed to a DME Regional Carrier (DMERC), the supplier must receive a signed Certificate of Medical Necessity (CMN) from the treating physician. A supplier must have a faxed or copied, original signed order or CMN in their records before they can submit a claim for payment to Medicare. CMNs communicate, either on paper or in an electronic record, required medical necessity information and have a DMERC form number (e.g., 01, 02, 03) and a revision number (e.g., .01, .02). Some DMERC forms also have an alpha suffix (e.g., A, B, C).

All CMNs have a HCFA form number in addition to the DMERC form number. (See the following listing of CMN form numbers.) The HCFA form number is in the bottom left corner of the form. CMNs are referred to by their HCFA form numbers. DMERC form numbers identify the CMN on electronic claims submitted to the DMERC in the National Standard Format (NSF). HCFA Form 484 serves as the CMN for home oxygen therapy.

A faxed, copied, an original hardcopy, or an electronic CMN must be maintained by the supplier and be available to the DMERCs on request. When hardcopy CMNs are submitted to the DMERC, the supplier must include a copy of only the front side. When CMNs are submitted electronically to the DMERC, only information from sections A, B, and D are required since section C can not be transmitted electronically. However, suppliers who bill electronically are not exempt from having section C completed on the original CMN.

The following is a list of the currently approved CMNs:

<i>{PRIVATE}</i> <i>DMERC</i> <i>FORM</i>	<i>HCFA</i> <i>FORM</i>	<i>ITEMS ADDRESSED</i>
<i>484.2</i>	<i>484</i>	<i>Home oxygen therapy</i>
<i>01.02A</i>	<i>841</i>	<i>Hospital beds</i>
<i>01.02B</i>	<i>842</i>	<i>Support surfaces</i>
<i>02.03A</i>	<i>843</i>	<i>Motorized wheelchairs</i>
<i>02.03B</i>	<i>844</i>	<i>Manual wheelchairs</i>
<i>03.02</i>	<i>845</i>	<i>Continuous positive airway pressure (CPAP) devices</i>
<i>04.03B</i>	<i>846</i>	<i>Lymphedema pumps (pneumatic compression devices)</i>
<i>04.03C</i>	<i>847</i>	<i>Osteogenesis stimulators</i>
<i>06.02B</i>	<i>848</i>	<i>Transcutaneous electrical nerve stimulators (TENS)</i>
<i>07.02A</i>	<i>849</i>	<i>Seat lift mechanisms</i>
<i>07.02B</i>	<i>850</i>	<i>Power operated vehicles 09.02851 Infusion pumps</i>
<i>09.02</i>	<i>851</i>	<i>External Infusion Pumps</i>
<i>10.02A</i>	<i>852</i>	<i>Parenteral nutrition</i>
<i>10.02B</i>	<i>853</i>	<i>Enteral nutrition</i>
<i>11.01</i>	<i>854</i>	<i>Section C continuation (manual and motorized wheelchairs - ONLY)</i>

The CMN sent to the physician must be two-sided with instructions on the back. If the CMN is mailed to the physician, the supplier must send the two-sided form. If the CMN is faxed, the supplier must fax both the front and back of the form. It is in the suppliers' interest to maintain a copy of what they faxed to the physician. Suppliers must maintain a copy of the completed CMN in their records. However, if the physician only faxes the front of the completed CMN then the supplier is only

*required to maintain the front portion of the CMN. Because these forms have been approved by the Office of Management and Budget (OMB), when a CMN is submitted with a paper claim, the hard copy must be an **exact** reproduction of the CMS form.*

However, when the CMN is submitted electronically and the supplier chooses to maintain a hard copy CMN, the font may be modified as follows:

o Pitch may vary from 10 characters per inch (cpi) to 17.7 cpi;

o Line spacing must be 6 lines per inch;

o Each CMN must have a minimum 1/4 inch margin on all four sides;

Without exception, these modified hard copy forms must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions printed on the back; and

CMN question sets may not be combined.

The CMN can serve as the physician's order if the narrative description is sufficiently detailed. This would include quantities needed and frequency of replacement on accessories, supplies, nutrients, and drugs. For items requiring a written order prior to delivery (decubitis care items, TENS, POVs, seat lift mechanisms), suppliers may utilize a completed and physician-signed CMN for this purpose. Otherwise, a separate order in addition to a subsequently completed and signed CMN is necessary.

The supplier may not complete the information in section B of the CMN. A supplier who knowingly and willfully completes section B of the form is subject to a civil monetary penalty up to \$1,000 for each form or document so distributed. Any supplier who remains in non-compliance after repeated attempts by the contractor to get the supplier into compliance, refer to your RO as a potential civil monetary penalty case.

The information in section C of the CMN (fee schedule amount, narrative description of the items furnished and the supplier's charge for the medical equipment or supplies being furnished) must be completed on the form by the supplier prior to it being furnished to the physician. A supplier who knowingly and willfully fails to include this information may be subject to a civil monetary penalty up to \$1,000 for each form or document so distributed. Any supplier who remains in non-compliance, after repeated attempts by the contractor to get the supplier into compliance, refer to your RO as a potential civil monetary penalty case.

Do not modify the language or content when reprinted. Also, do not accept any CMN that has been modified in any way by any other party. In addition, do not accept any other certifications of medical necessity by other insurers or government agencies.

Suppliers and physician may choose to utilize electronic CMNs (e-CMN). E-CMNs must adhere to all privacy, security, and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMNs must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions as printed on the back of the hardcopy form.

3.3.1 – Acceptability of Faxed Orders and Facsimile or Electronic Certificates of Medical Necessity – (Rev. 11, 09-18-01)

When reviewing claims and orders or auditing CMNs for DMEPOS, DMERCs may encounter faxed, copied, or electronic orders and CMNs in supplier files. Generally, DMERCs should accept these documents as fulfilling the requirements for these documents.

The DMERCs retain the authority to request additional documentation to support the claim. If a DMERC finds indications of potential fraud or misrepresentation of these documents, or the claims submitted, they should refer the matter to the Benefit Integrity unit for development.