CMS Manual System

Pub 100-08 Medicare Program Integrity

Transmittal 167

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: October 27, 2006

Change Request 4296

NOTE: Transmitta1 159, Change Request 4296, dated September 22, 2006, is rescinded and replaced with Transmittal 167. This replacement clarifies the transition period to include dates of service and to establish the timeframe as October 1, 2006 through December 31, 2006. In addition, the Provider Education requirements have been renumbered to 4296. 15, 16, 17 and 18 to avoid duplication from the Business Requirements. All other information remains the same.

SUBJECT: New DMEPOS Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFS) for Claims Processing.

I. SUMMARY OF CHANGES: The CMS has developed improved CMNs and DIFs that are consistent with current medical practices and conform with Medicare guidelines. Through this process, CMS revised several CMNs and replaced three CMNs with two DIFs. As a result of these revisions, a revision to the IOM, Pub.100-08, Program Integrity Manual, chapter 5 is being made. In addition, a revision to the IOM, Pub.100-08, Program Integrity Manual, chapter 3, section 3.4.1.1, is being made to permit the use of a signature and date stamp. These forms have been approved by the Office of Management and Budget (OMB). The OMB approved form number for the CMS-484 form is #0938-0534. The OMB approved form number for the CMS-846, 847, 848, 849, 854, 10125, and 10126 forms is OMB #0938-0679.

NEW/REVISED MATERIAL :

EFFECTIVE DATE : October 1, 2006
ANALYSIS AND CODING DATE: July 1, 2006

IMPLEMENTATION DATE : October 2, 2006
TRANSITION PERIOD: October 1, 2006 – December 31, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3/3.4.1.1/ Documentation Specifications for Areas Selected for Prepayment or Postpayment MR
R	5/Table of Contents
R	5/5.1/ Home Use of DME
D	5/5.1.1/Physicians Orders
D	5/5.l.l.l/Verbal Orders
D	5/5.1.1.2/Written Orders
D	5/5.1.1.2.1/Written Orders Prior to Delivery
D	5/5.1.1.3/Requirements of New Orders
D	5/5.1.1.4/CMN as the Written Order
D	5/5.1.1.4.1/Cover Letters for CMNs
D	5/5.1.1.4.2/Completing a CMN
D	5/5.1.1.4.3/DMERC's and DMERC PSC's Authority to and/Assess an Overapyment or CMP When Invalid CMNs are Identified
D	5/5.1.1.5/Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders
D	5/5.1.1.6/Physician Assistant Rules Concerning Orders and CMNs
R	5/5.2/Rules Concerning Prescriptions (Orders)
R	5/5.2.1/Physician Orders
N	5/5.2.2/Verbal Orders
N	5/5.2.3/Written Orders
N	5/5.2.3.1/Written Orders Prior to Delivery
N	5/5.2.4/Requirement of New Orders
R	5/5.3/Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)
R	5/5.3.1/Completing a CMN or DIF
R	5/5.3.2/Cover Letters for CMNs
D	5/5.3.2.1/Guidance on Safeguards in Making Monthly Payments
D	5/5.3.2.1.1/Pick-up Slips

R	5/5.3.3/Acceptability of Faxed Orders and Facsimile or Electronic CMNs and DIFs
D	5/5.3.3.1/Acceptability of Faxed Orders and Facsimile or Electronic Certificates of Medical Necessity
R	5/5.4/DME MACs and DME PSC's Authority to Initiate an Overpayment or CMP When Invalid CMNs Are Identified
R	5/5.5/Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders and CMNs
R	5/5.6/Physician Assistant Rules Concerning Orders and CMNs
R	5/5.7/Documentation in the Patient's Medical Record
D	5/5.7.1/Definitions
D	5/5.7.1.1/Definitions of Customized DME
D	5/5.7.2/Items Eligible for ADMC
D	5/5.7.3/Instructions for Submitting ADMC Requests
D	5/5.7.4/Instructions for Processing ADMC Requests
D	5/5.7.5//Affirmative ADMC Decisions
D	5/5.7.6/Negative ADMC Decisions
D	5/5.7.7/DMERC and DMERC PSC Tracing
R	5/5.8/Supplier Documentation
N	5/5.9/Evidence of Medical Necessity
N	5/5.9.1/Evidence of Medical Necessity for the Oxygen CMN
N	5/5.9.2/Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims
N	5/5.10/Period of Medical Necessity - Home Dialysis Equipment
N	5/5.11/Safeguards in Making Monthly Payments
R	5/5.11.1/Guidance on Safeguards in Making Monthly Payments
R	5/5.12/Pick-up slips
N	5/5.13/Incurred Expenses for DME and Orthotic and Prosthetic Devices
N	5/5.14/ Patient Equipment Payments Exceed Deductible and Coinsurance on Assigned Claims
N	5/5.15/Definitions of Customized DME
N	5/5.16/Advance Determination of Medicare Coverage (ADMC) of Customized DME

N	5/5.16.1/Items Eligible for ADMC
N	5/5.16.2/Instructions for Submitting ADMC Requests
N	5/5.16.3/Instructions for Processing ADMC Requests
N	5/5.16.4/Affirmative ADMC Decisions
N	5/5.16.5/Negative ADMC Decisions
N	5/5.17/DME PSC Tracking

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-08	Transmittal: 167	Date: October , 2006	Change Request 4296

NOTE: Transmitta1 159, Change Request 4296, dated September 22, 2006, is rescinded and replaced with Transmittal 167. This replacement clarifies the transition period to include dates of service and to establish the timeframe as October 1, 2006 through December 31, 2006. In addition, the Provider Education requirements have been renumbered to 4296. 15, 16, 17 and 18 to avoid duplication from the Business Requirements. All other information remains the same.

SUBJECT: New DMEPOS Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFS) for Claims Processing

I. GENERAL INFORMATION

A. Background: The Certificates of Medical Necessity (CMNs) provide 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. CMNs contain section A through D. Section A and C are completed by the supplier and Section B and D are completed by the physician. A DME Information Form (DIF) is completed and signed by the supplier. It does not require a narrative description of equipment and cost or a physician signature. Contractors review the documentation provided on the CMNs and DIFs and determine if the medical necessity and applicable coverage criteria for DMEPOS have been met.

B. Policy: The CMS has developed improved CMNs and DIFs that are consistent with current medical practices and conform with Medicare guidelines. Through this process, CMS revised several CMNs and replaced three CMNs with two DIFs. As a result of these revisions, a revision to the IOM, Pub. 100-08, Program Integrity Manual, chapter 5 is being made. In addition, a revision to the IOM, Pub. 100-08, Program Integrity Manual, chapter 3, section 3.4.1.1 is being made to permit the use of a signature and date stamp.

These forms have been approved by the Office of Management and Budget (OMB). The OMB approved form number for the CMS-484 form is #0938-0534. The OMB approved form number for the CMS-846, 847, 848, 849, 854, 10125 and 10126 forms is OMB# 0938-0679.

Contractors shall allow a transition period for CMNs or DIFs with dates of service (DOS) from October 01, 2006 through December 31, 2006. Claims tied to a CMN/DIF will be accepted and processed based on the format of the CMN/DIF.

Contractors shall no longer accept old CMN/DIF forms for claims with DOS on or after January 01, 2007.

Use of the new CMNs and DIFs will become effective for claims tied to a CMN or DIF with DOS on or after January 01, 2007. Claims for items requiring a CMN or DIF shall be submitted and processed using the revised CMNs and DIFs (CMS-484, 846, 847, 848, 849, 854, 10125 and 10126).

Table 1 identifies the CMNs submitted and entered during the transition period from October 01, 2006 through December 31, 2006.

(As of January 01, 2007, these forms will no longer be accepted.)

DMERC FORM	CMS FORM	ITEMS ADDRESSED
484.2	484	Home Oxygen Therapy
01.02A	841	Hospital Beds
01.02B	842	Support Surfaces
04.03B	846	Lymphedema Pumps (Pneumatic Compression Devices)
04.03C	847	Osteogenesis Stimulators
06.02B	848	Transcutaneous Electrical Nerve Stimulators (TENS)
07.02A	849	Seat Lift Mechanisms
09.02	851	External Infusion Pumps
10.02A	852	Parenteral Nutrition
10.02B	853	Enteral Nutrition
11.01	854	Section C Continuation Form

Table 1

Table 2 identifies the revised CMNs that will be submitted and entered during the transition period from October 01, 2006 through December 31, 2006.

As of January 01, 2007, the new forms will be the only valid versions of the CMNs/DIFs.

Note that the title of the CMS-484 form changed from Home Oxygen Therapy to Oxygen and the title of the CMS-846 form changed from Lymphedema Pumps to Pneumatic Compression Devices.

DME FORM	CMS FORM	ITEMS ADDRESSED The forms below can be accessed at: http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage
484.03	484	Oxygen
04.04B	846	Pneumatic Compression Devices
04.04C	847	Osteogenesis Stimulators
06.03B	848	Transcutaneous Electrical Nerve Stimulators (TENS)
07.03A	849	Seat Lift Mechanisms
11.02	854	Section C Continuation Form

Table 2

Table 3 identifies the DIFs that will be submitted and entered during the transition period from October 01, 2006 through December 31, 2006.

As of January 01, 2007, the new forms will be the only valid versions of the CMNs/DIFs.

Note that the CMN for Infusion Pumps (CMS-851) was replaced with a DIF for External Infusion Pump (CMS-10125). The CMNs for Parenteral Nutrition (CMS-852) and Enteral Nutrition (CMS-853) were replaced with a DIF for Enteral and Parenteral Nutrition (CMS-10126).

DME FORM	CMS FORM	ITEMS ADDRESSED The forms below can be accessed at: http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage
09.03	10125	External Infusion Pumps
10.03	10126	Enteral and Parenteral Nutrition

Table 3

Contractors shall cease requiring CMNs for hospital beds and support surfaces for claims with DOS effective October 01, 2006.

Table 4 identifies the CMNs that will be eliminated for claims with DOS on or after October 01, 2006.

DMERC FORM	CMS FORM	ITEMS

		ADDRESSED
01.02A	841	Hospital Beds
01.02B	842	Support Surfaces

Table 4

Signature and date stamps will be accepted for DMEPOS items that require a CMN/DIF with DOS on or after October 01, 2006.

As defined in chapter 3, of the Program Integrity Manual (PIM), if data analysis indicates potentially aberrant billing, contractors shall continue to follow the guidance as defined in this chapter when performing medical review on claims with dates of service during and after the transition to the new forms**.**

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	**Requirements**	**Responsibility ("X" indicates the columns that apply)**								
		FI	RHHI	CARRIER	DMERC / DME MAC	Shared System Maintainers				Other-DME PSC
						FISS	MCS	VMS	CWF	
4296.1	Contractors shall implement new versions of CMN forms that have been developed and approved.				X			X		X
4296.2	Contractors shall implement new DIFs that have been developed and approved.				X			X		X
4296.3	Contractors shall adjust all locally controlled tables and edits so they relate to the newly revised CMNs and the new DIFs.				X			X	X	X

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	CARRIER	DMERC / DME MAC	Shared System Maintainers				Other-DME PSC
						FISS	MCS	VMS	CWF	
4296.4	Contractors shall continue to process claims according to current instructions for claims tied to a CMN on file prior to October 01, 2006.				X			X	X	X
4296.5	Contractors shall cease requiring CMNs for hospital beds and support surfaces for claims with DOS effective October 01, 2006.				X			X	X	X
4296. 6	CWF shall remove hospital bed codes and support surface codes from CWF Category 59. The HCPCS codes for Hospital Beds are: E0250-E0251; E0255-E0256; E0260-E0261; E0265-E0266; E0290-E0297; E0301-E0304. The HCPCS code for Support Surfaces is: E0194.								X	
4296.7	Contractors shall implement new, improved CMN forms: 484, 846, 847, 848, 849 and 854.				X			X		X
4296.8	Contractors shall implement new DIFs: 10125-External Infusion Pumps and 10126-External and Parenteral Nutrition. NOTE: The CMNs for these services have been eliminated.				X			X		X
4296.9	Contractors shall allow a transition period from October 01, 2006 through December 31, 2006 when both the old CMN and the new CMN/DIFs will be accepted.				X			X		X
4296.9.1	Contractors shall no longer accept the old CMN forms for claims with DOS on or after January 01, 2007.				X			X		X
4296.9.1.1	For claims currently stopped because of the above inconsistency, contractors shall create a skeleton CMN and forward to CWF for those claims to process.				X				X	

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	CARRIER	DME RC / DME MAC	Shared System Maintainers				Other-DME PSC
						FISS	MCS	VMS	CWF	
4296.9.2	Contractors shall reject claims with the old CMN forms after the transition period ends.				X			X		X
4296.10	The system shall not accept only a NPI number until the NPI crosswalk is in place.				X			X		X
4296.10.1	Contractors shall require <u>both</u> a Legacy supplier number and an NPI number OR only a legacy supplier number on CMNs/DIFs until the NPI-crosswalk is up and running.				X			X		X
4296.10.2	Contractors shall require both the legacy number (UPIN) and the NPI OR the legacy number only for referring physicians on the CMNs/DIFs until the NPI-crosswalk is up and running.				X			X		X
4296.11	Contractors shall accept signature and date stamps on CMNs and DIFs.				X			X		X
4296.12	Contractors shall ensure Physicians are accurately indicating their treating physician's Unique Physician Identification Number (UPIN) <u>and</u> applicable National Provider Identifier (NPI) until the NPI cross-walk is up and running.				X			X		X
4296.12.1	When inserting the NPI number, the physician shall indicate this by using the qualifier XX followed by the 10-digit number.				X			X		X
4296.12.2	When inserting the UPIN number, use the qualifier 1G followed by the 6-digit number. (For example, 1Gxxxxxx).				X			X		X
4296.13	Contractors shall ensure suppliers are accurately indicating their Medicare Supplier Number assigned to them by the National Supplier Clearinghouse (NSC) <u>and</u> applicable National Provider Identifier (NPI) until the NPI cross-walk is up and running.				X			X		X

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	CARRIER	DME RC / DME MAC	Shared System Maintainers				Other-DME PSC
						FISS	MCS	VMS	CWF	
4296.13.1	When inserting the NPI Number, the supplier shall indicate this by using the qualifier XX followed by the 10-digit number.				X			X		X
4296.13.2	When inserting the legacy supplier number (NSC number), the supplier shall indicate this by using the qualifier 1C followed by the 10-digit number (for example 1Cxxxxxxxxxx).				X			X		X
4296.14	Contractors shall update free software to conform with the new/revised/deleted CMNs and DIFs.				X			X		X

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DME RC/DME MAC	Shared System Maintainers				Other-DME PSC
						FISS	MCS	VMS	CWF	
4296.15	Contractors shall provide their suppliers and providers very specific guidance on changes in the old CMNs versus new CMNs; deleted CMNs, and new DIFs.				X					X
4296.16	Contractors shall instruct their suppliers and providers on how to fill out the new CMNs and DIFs.				X					X
4296.17	Contractors shall update all supplier manuals, bulletins, articles, and other educational documents to reflect the new changes contained in this CR.				X					X
4296.18	A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.				X					X

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: October 1, 2006 **Analysis and Coding Date:** July 1, 2006 **Implementation Date:** October 2, 2006 **Transition Period:** October 1, 2006 – December 31, 2006 **Pre-Implementation Contact(s):** **For non-system changes:** Camille Soondar Camille.soondar@cms.hhs.gov **For system changes**: Joanne Spalding Joanne.spalding@cms.hhs.gov **Post-Implementation Contact(s)** **For non-system changes:** Camille Soondar Camille.soondar@cms.hhs.gov **For system changes**: Joanne Spalding Joanne.spalding@cms.hhs.gov	**Medicare contractors shall implement these instructions within their FY 2006 operating budgets.**

***Unless otherwise specified, the effective date is the date of service.**

3.4.1.1 - Documentation Specifications for Areas Selected for Prepayment or Postpayment MR

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

The contractor may use any information they deem necessary to make a prepayment or postpayment claim review determination. This includes reviewing any documentation submitted with the claim as well as soliciting documentation from the provider or other entity when the contractor deems it necessary and in accordance with PIM, chapter 3, §3.4.1.2.

A. Review of Documentation Submitted with the Claim

If a claim is targeted based on data for prepayment or postpayment medical review (including automated, routine, or complex) contractors may review unsolicited supporting documentation accompanying the claim, but are not required to do so.

There are two exceptions to this rule. Contractors may deny without reviewing attached or simultaneously submitted documentation (1) when clear policy serves as the basis for denial, and (2) in instances of medical impossibility (see PIM, chapter 3, §3.5.1).

NOTE: The term "clear policy" means a statute, regulation, NCD, coverage provision in an interpretive manual, or LCD that specifies the circumstances under which a service will always be considered non-covered or incorrectly coded. Clear policy that will be used as the basis for frequency denials must contain utilization guidelines that the contractor considers acceptable for coverage.

If a contractor chooses to allow supporting paper documentation to be submitted with the claim for medical review purposes the contractor shall inform providers in their jurisdiction of that fact (see PIM, chapter 3, §3.5).

B. Signature Requirements

Medicare requires a legible identifier for services provided/ordered. The method used (e.g., hand written, electronic, or signature stamp) to sign an order or other medical record documentation for medical review purposes in determining coverage is not a relevant factor. Rather, an indication of a signature in some form needs to be present. Do not deny a claim on the sole basis of type of signature submitted.

Providers using alternative signature methods (e.g., a signature stamp) should recognize that there is a potential for misuse or abuse with a signature stamp or other alternate signature methods. For example, a rubber stamped signature is must less secure than other modes of signature identification. The individual whose name is on the alternate signature method bears the responsibility for the authenticity of the information being attested to. Physicians should check with their attorneys and malpractice insurers in regard to the use of alternative signature methods.

All State licensure and State practice regulations continue to apply. Where State law is more restrictive than Medicare, the contractor needs to apply the State law standard. The signature requirements described here do not assure compliance with Medicare conditions of participation.

Note that this instruction *also applies to Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs). CMNs and DIFs are forms used to determine if the medical necessity and applicable coverage criteria for Durable Medical Equipment, Prosthetic, and Orthotic Supplies (DMEPOS) have been met.*

C. Review of Documentation Solicited After Claim Receipt

The process whereby a contractor requests additional documentation after claim receipt is known as "development." Providers selected for review are responsible for submitting medical records requested of them by the contractor within established timeframes. Development requirements are listed below in section 3.4.2.1.

D. Requirements That Certain Tests Must Be Ordered By The Treating Physician

Effective November 25, 2002, 42 CFR 410.32(a) requires that when billed to any contractor, all diagnostic x-ray services, diagnostic laboratory services, and other diagnostic services must be ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.

E. Diagnosis Requirements

Section 1833(e) of the Act provides that no payment may be made "under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person . . ."Contractors may require information, in accordance with the requirements below whenever they deem necessary to make a determination listed in section 3.4.1 and thus to determine appropriate payment.

Some provider types are required to submit diagnosis codes on all claims while other provider types are required to submit diagnosis codes only if such information is required by an LMRP.

- Claims Submitted by Physicians or **§1842(b)(18)(C) of the Act** Practitioners Must Contain Diagnosis Codes.

Section 1842 (p)(1) of the Act states that each claim submitted by a physician or §1842(b)(18)(C) of the Act practitioner "shall include the appropriate diagnosis code (or codes)…". For services from physicians and §1842(b)(18)(C) of the Act practitioners submitted with an ICD-9 code that is missing, invalid, or truncated, contractors must return the billed service to the provider as unprocessable in accordance with MCM §3005.4(p) or MIM §3605.3.

- Claims Submitted By All Other Provider Types Must Contain Diagnosis Codes If Such Codes Are Required By An LMRP (effective 7/1/02).

In order to address potential abuse or overutilization, contractors can require that ICD-9 diagnosis codes be submitted with each claim for the targeted service. This information is used in determining whether the services are covered and correctly coded. Effective April 1, 2002, contractors may require ICD-9 diagnosis codes to be submitted by all non-physician billers with every claim for a targeted service only if such a requirement appears in an LMRP for that service. Contractors must educate providers about this requirement beginning no later than January 1, 2002. This outreach should occur via Web site bulletin articles, etc.

For individual non-physician providers who are identified due to unusual billing practices, fraud referrals, etc., contractors may also require ICD-9 diagnosis codes to support the medical necessity of all or some claims submitted by the targeted entities, even if no LMRP exists requiring such codes.

For services submitted with an ICD-9 diagnosis code that is missing, incorrect or truncated as indicated above, contractors must return the billed service to the provider as unprocessable.

F. Requirements for Lab Claims

The American Medical Association's (AMA) 1998 edition of the Current Procedural Terminology (CPT) established three new and one revised Organ or Disease Oriented laboratory panels. Since these panels are composed of clinically relevant groupings of automated multichannel tests there is a general presumption of medical necessity. If there is data or reason to suspect abuse of the new panel codes, contractors may review these claims. Should contractors determine the need to develop a LMRP for laboratory panel codes, develop these policies at the panel code level. In some instances of perceived abuse of the new panel codes, you may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test.

Medicare Program Integrity Manual

Chapter 5 – Items and Services Having Special DME Review Considerations

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(Rev. 167, 10-27-06)

5.1 – Home Use of DME

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Medicare law limits Part B payment for DME to items/supplies used (delivered) in the patient's home. For claims that show a nursing home or hospital address as the beneficiary's residence, or if the place of service code indicates that the beneficiary is an inpatient of a hospital or nursing home, *durable medical equipment medicare administrative contractors (DME MACs)* and DME program safeguard contractors (PSCs) develop for the date of admission and determine whether payment is possible. (chapter 5, section 5.13) If a hospital is a participating hospital, an emergency hospital, or a hospital which meets the requirements of §1861(e)(l) of the Act, it does not qualify as the patient's home.

The following screening guides apply when the individual is in a *skilled nursing facility* (SNF):

- Where an institution is classified as a participating SNF, an §1819(a)(1) institution, or where a SNF has a part classified as participating and a part classified as meeting §1819(a)(1) of the Act, it cannot be considered the individual's home;

- If an institution has a part which is participating or a part which meets §1819(a)(l), and a remaining part which does not meet §1819(a)(l), identify the part in which the patient was physically located during the use period. The institution may be considered the individual's home only if he/she was in the part which does not meet §1819(a)(l). See Pub.100-2, chapter 16, §60 if an item of equipment is furnished or used outside the U.S.; or,

- If a DME rental start date coincides with the patient's discharge date from an institution not classified as a "home", *DME MACs* pay for medically necessary DME.

These rules apply only to DME claims. Orthotic and prosthetic devices are not subject to the "home use" requirement for coverage and payment purposes.

5.2 - Rules Concerning Prescriptions (Orders)

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

5.2.1 - Physician Orders

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

The supplier for all Durable Medical Equipment, Prosthetic, and Orthotic Supplies (DMEPOS) is required to keep on file a physician prescription (order). The treating physician must sign and date the order. A supplier must have an order from the treating physician before dispensing any DMEPOS item to a beneficiary.

5.2.2 - Verbal Orders

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Except as noted in chapter 5 section *5.2.3.1* suppliers may dispense most items of DMEPOS based on a verbal order. This verbal dispensing order must include: a

description of the item, the beneficiary's name, the physician's name and the start date of the order. Suppliers must maintain written documentation of the verbal order and this documentation must be available to the *DME MACs* or *DME PSCs* upon request. If the supplier does not have an order from the treating physician before dispensing an item, the item is noncovered, and the supplier must not submit a claim for the item to the *DME MACs.*

For items that are dispensed based on a verbal order, the supplier must obtain a written order that meets the requirements of this section.

5.2.3 - Written Orders

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Written orders are acceptable for all transactions involving DMEPOS. Written orders may take the form of a photocopy, facsimile image, electronically maintained, or original "pen-and-ink" document. (See chapter 3, section 3.4.1.1.B.)

All orders must clearly specify the start date of the order.

For items that are dispensed based on a verbal order, the supplier must obtain a written order that meets the requirements of this section.

If the written order is for supplies that will be provided on a periodic basis, the written order should include appropriate information on the quantity used, frequency of change, and duration of need. (For example, an order for surgical dressings might specify one 4 x 4 hydrocolloid dressing that is changed 1-2 times per week for 1 month or until the ulcer heals.)

The written order must be sufficiently detailed, including all options or additional features that will be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number.

If the order is for a rented item or if the coverage criteria in a policy specify length of need, the order must include the length of need.

If the supply is a drug, the order must specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable).

Someone other than the physician may complete the detailed description of the item. However, the treating physician must review the detailed description and personally sign and date the order to indicate agreement.

If a supplier does not have a faxed, photocopied, electronic or pen and ink signed order in their records before they submit a claim to Medicare (i.e., if there is no order or only a verbal order), the claim will be denied. If the claim is for an item for which an order is required by statute (e.g., therapeutic shoes for diabetics, oral anticancer drugs, oral

antiemetic drugs which are a replacement for intravenous antiemetic drugs), the claim will be denied as not meeting the benefit category and is therefore not appealable by the supplier (see Pub.. 100-4, chapter 29, §10, 30.3, 60 for more information on appeals). For all other items, if the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary.

Medical necessity information (e.g., an ICD-9-CM diagnosis code, narrative description of the patient's condition, abilities, limitations) is NOT in itself considered to be part of the order although it may be put on the same document as the order.

5.2.3.1- Written Orders Prior to Delivery

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

A written order prior to delivery is required for: pressure reducing pads, mattress overlays, mattresses, and beds; seat lift mechanisms; TENS units; power operated vehicles and power wheelchairs. *DME MACs and DME PSCs* may identify other items for which they will require a written order prior to delivery.

For these items, the supplier must have received a written order that has been both signed and dated by the treating physician and meets the requirements of section *5.2.3* before dispensing the item.

If a supplier bills for an item without a written order, when the supplier is required to have a written order prior to delivery, the item will be denied as not meeting the benefit category (see *Pub. 100-04, chapter 29, §10, 30.3, 60* for more information on appeals).

5.2.4 – Requirement of New Orders

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

A new order is required in the following situations:

- There is a change in the order for the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy;
- When an item is replaced; and
- When there is a change in the supplier.

5.3 - Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

A Certificate of Medical Necessity (CMN) (see table 1) or a DME Information Form (DIF) (see table 2) is a form required to help document the medical necessity and other coverage criteria for selected *DMEPOS* items. CMNs contain sections A through D.

Section A and C are completed by the supplier and Section B and D are completed by the physician**.** A DIF is completed and signed by the supplier. It does not require a narrative description of equipment and cost or a physician signature.

The following forms below have been approved by the Office of Management and Budget (OMB). For the CMS- 484 form, the OMB# is 0938-0534. For the CMS forms- 846, 847, 848, 849, 854, 10125 and 10126, the OMB# is 0938-0679.

Table 1 identifies the CMNs:

DME FORM	**CMS FORM**	**ITEMS ADDRESSED** The forms below can be accessed at: http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage
484.03	484	Oxygen
04.04B	846	Pneumatic Compression Devices
04.04C	847	Osteogenesis Stimulators
06.03B	848	Transcutaneous Electrical Nerve Stimulators
07.03A	849	Seat Lift Mechanisms
11.02	854	Section C Continuation Form

Table 1

Table 2 identifies the DIFs:

DME FORM	**CMS FORM**	**ITEMS ADDRESSED** The forms below can be accessed at: http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage
09.03	10125	External Infusion Pumps
10.03	10126	Enteral and Parenteral Nutrition

Table 2

For certain items or services billed to a *DME MAC*, the supplier must receive a signed CMN from the treating physician or a signed DIF from the supplier. A supplier must have a faxed, photocopied, an original signed order or an electronic CMN or DIF in their records before they can submit a claim for payment to Medicare. CMNs or DIFs have a *DME* form number (e.g., 01, 02, 03) and a revision number (e.g., .01, .02). Some forms also have an alpha suffix (e.g., A, B, C).

All CMNs and DIFs have a CMS form number in addition to the *DME* form number. (See the following listing of form numbers.) The CMS form number is in the bottom left corner of the form. CMNs and DIFs are referred to by their CMS form numbers. *DME* form numbers identify the CMN on electronic claims submitted to the *DME MAC* in the

National Standard Format (NSF). For example, CMS Form 484 serves as the CMN for oxygen; CMS Form 10125 serves as the DIF for External Infusion Pump.

A faxed, photocopied, an original signed order, or an electronic signed CMN or DIF must be maintained by the supplier and be available to the *DME MAC or DME PSC* on request. When hardcopy CMNs or DIFs are submitted to the *DME MAC or DME PSC,* the supplier must include a copy of only the front side. *When CMNs are submitted electronically to the DME MAC or DME PSC, information from sections A and B are required.*

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 supplier's interest to maintain a copy of what they faxed to the physician. Suppliers must maintain a copy of the completed CMN or DIF 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. The DIF must be two-sided with instructions on the back and completed by the supplier. Because these forms have been approved by the Office of Management and Budget (OMB), when a CMN or DIF is submitted with a paper claim, the hard copy must be an exact reproduction of the CMS form.

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

- Pitch may vary from 10 characters per inch (cpi) to 17.7 cpi;
- Line spacing must be 6 lines per inch;
- Each form 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 in section C 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 (pressure reducing pads, mattress overlays, mattresses, and beds; seat lift mechanisms; TENS units; *and power operated vehicles*) 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 (for *DME PSCs*, refer the supplier to the primary GTL or associate GTL and SME) as a potential civil monetary penalty case.

The 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 (for *DME PSCs*, refer the supplier to the primary GTL or associate GTL and SME) as a potential civil monetary penalty case.

Do not modify the language or content when reprinted. Also, do not accept any CMN or DIF 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-CMNs) or electronic DIFs (e-DIFs). E-CMNs or e-DIFS must adhere to all privacy, security, and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMNs or e-DIFs 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.

If an item requires a CMN or a DIF and the supplier does not have a faxed, photocopied, an original hardcopy, or an electronic signed CMN or DIF in their records before they submit a claim to Medicare, the claim will be denied. If the CMN or DIF is used to verify that statutory benefit requirements have been met, then the claim will be denied as not meeting the benefit category.

In cases where two or more suppliers merge, the resultant supplier should make all reasonable attempts to secure copies of all active CMNs or DIFs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the *DME MAC or DME PSC.*

When reviewing claims where the medical record contains a copied, faxed or electronically maintained CMN or DIF (any CMN or DIF created, modified, and stored via electronic means such as commercially available software packages and servers), the *DME MAC* and *DME PSC* must accept the copied, faxed or electronic document as fulfilling the requirements for these documents.

When a *DME PSC* is investigating potentially fraudulent behavior by a supplier, it will be the supplier's responsibility to prove the authenticity/validity of the claim(s) under investigation. A *DME PSC* may require the supplier to prove the authenticity/validity of the signature on the CMN, DIF, order, or any other questionable portion of the claim(s) under investigation.

Upon request by the *DME MAC and DME PSC*, suppliers must provide the CMN or DIF, in a format that the *DME MAC and DME PSC* can accept, in a timely manner. Upon medical review, the *DME MAC and DME PSC* should not deny claims solely because the CMN or DIF is faxed, copied, or electronic. The *DME MAC or DME PSC* may request the supplier to download and print a hard copy of an electronic order, CMN or DIF if the *DME MAC or DME PSC* cannot access it electronically.

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 written order if the narrative description in Section C is sufficiently detailed (as described above). This applies to both hard copy and electronic orders or CMNs. A DIF does not contain a section for a narrative description and is not applicable.

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

The *DME MACs or DME PSCs* need not make any shared system changes to electronically accept e-CMNs or DIFS as CMS views e-CMNs or DIFs as a transaction between the physician and suppliers. Suppliers must continue to use current systems for transmitting claim information to the *DME MAC or DME PSC.*

5.3.1 – Completing a CMN or DIF

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

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. Medicare requires a legible identifier for services provided/ordered. The method used (e.g., hand written, electronic, or signature stamp) to sign an order or other medical record documentation for medical review purposes in determining coverage is not a relevant factor. Rather, an indication of a signature in some form needs to be present. Do not deny a claim on the sole basis of type of signature submitted. Signature and date stamps are acceptable for use on CMNs and DIFs.

The "Delivery Date/Date of Service" on the claim must not precede the "Initial Date" on the CMN or DIF or the 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 DIF or 3 months from the date of the physician's signature.

The *DME MAC and DME PSCs* have the authority to request to verify the information on a CMN or DIF 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 DIF, or if it appears that the CMN or DIF has been altered, the *DME MAC and DME PSC* should deny the service and initiate the appropriate administrative or corrective actions.

In the event of a post pay audit, the supplier must be able to produce the CMN or DIF and, if requested by the *DME MAC or DME PSC* produce information to substantiate the information on the CMN or DIF. If the supplier cannot produce this information, the *DME MAC and DME PSCs* should deny the service and initiate the appropriate administrative or corrective actions.

If there is a change made to any section of the CMN after the physician has signed 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.

5.3.2 - Cover Letters for CMNs

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

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 *DME MACs and DME PSCs* should not take adverse action against suppliers that solely involve cover letters.

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

5.3.3 - Acceptability of Faxed Orders and Facsimile or Electronic CMNs or DIFs)

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

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

The *DME MACs and DME PSCs* retain the authority to request additional documentation to support the claim. If a *DME MAC or DME PSC* finds indications of potential fraud or misrepresentation of these documents, or the claims submitted, they should refer the matter to the *DME PSC* for development.

For additional information when reviewing documentation during medical review, refer to the Program Integrity Manual (PIM), chapter 3, section 3.4.1.1 on “Documentation Specifications for Areas Selected for Prepayment or Postpayment Medical Review.”

5.4 – DME MACs and DME PSCs Authority to Initiate an Overpayment and/or Civil Monetary Penalty (CMP) When Invalid CMNs or DIFs Are Identified

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Section 1862(a)(1)(A) 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 or DIF on file or to submit a valid CMN or DIF to the *DME MAC or DME PSC* 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. A valid DIF is one in which the supplier has attested to and signed supporting the medical need for the item. When the *DME MACs and DME PSCs* identify a claim for which a CMN or DIF is not valid, they may deny the claim and/or initiate overpayment action.

If a *DME MAC or DME PSC* identifies a supplier that has a pattern of improperly completing the CMN or DIF, the *DME MAC or DME PSC* may choose to initiate 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.

5.5 - Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders and CMNs

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

A nurse practitioner or clinical nurse specialist may give the dispensing order and sign the written order in the following situations:

- They are treating the beneficiary for the condition for which the item is needed;
- They are practicing independently of a physician;
- They bill Medicare for other covered services using their own provider number; and

- They are permitted to do all of the above in the State in which the services are rendered.

A nurse practitioner or clinical nurse specialist may complete Section B and sign Section D of a CMN if they meet all the criteria described above for signing orders.

5.6 - Physician Assistant Rules Concerning Orders and CMNs

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Physician assistants may provide the dispensing order and write and sign the written order if they satisfy all the following requirements:

- They meet the definition of physician assistant found in §1861(aa)(5)(A) of the Act;

- They are treating the beneficiary for the condition for which the item is needed;

- They are practicing under the supervision of a Doctor of Medicine or Doctor of Osteopathy;

- They have their own UPIN; and

- They are permitted to perform services in accordance with State law.

Physician assistants may complete section b and sign section D of a CMN if they meet all the criteria described above for signing orders.

5.7 – Documentation in the Patient's Medical Record

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. If an item requires a CMN or DIF, it is recommended that a copy of the completed CMN or DIF be kept in the patient's record. However, neither a physician's order nor a CMN nor a DIF nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable).

See PIM, chapter 3, section 3.4.1.1, for additional instructions regarding review of documentation during pre- and post-payment review.

The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other professionals including, but not limited to, nurses, physical or occupational therapists, prosthetists, and orthotists.

The documentation in the patient's medical record does not have to be routinely sent to the supplier or to the *DME MAC or DME PSC*. However, the *DME MAC or DME PSC* may request this information in selected cases. If the *DME MAC or DME PSC* does not receive the information when requested or if the information in the patient's medical record does not adequately support the medical necessity for the item, then on assigned claims the supplier is liable for the dollar amount involved unless a properly executed advance beneficiary notice (ABN) of possible denial has been obtained.

5.8 - Supplier Documentation

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Before submitting a claim to the *DME MAC* the supplier must have on file a dispensing order, the written order, the CMN (if applicable), the DIF (if applicable), information from the treating physician concerning the patient's diagnosis (if an ICD-9-CM code is required on the claim), and any information required for the use of specific modifiers or attestation statements as defined in certain *DME PSC* policies. The supplier should also obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criterion for an item has been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed ABN of possible denial has been obtained.

Documentation must be maintained in the supplier's files for seven (7) years.

Suppliers are required to maintain proof of delivery documentation in their files. The proof of delivery requirements are outlined below according to the method of delivery. The three methods of delivery are:

- Supplier delivering directly to the beneficiary or authorized representative;
- Supplier utilizing a delivery/shipping service to deliver items; and
- Delivery of items to a nursing facility on behalf of the beneficiary.

Proof of delivery documentation must be available to the *DME PSC* on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently do not provide documentation to support their services may be referred to the OIG for imposition of CMPs or Administrative Sanctions.

5.9 – Evidence of Medical Necessity

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)
If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating physician must specify on the prescription, or on the CMN, the type of supplies needed and the frequency with which they must be replaced, used, or consumed. *DME PSCs* evaluate supply utilization information as part of the medical necessity determination for DMEPOS. They do not accept "PRN" or "as needed" utilization estimates for supply replacement, use, or consumption.

Absent a State law to the contrary or a supply utilization problem, the prescription or physician's certification submitted for the DMEPOS may also serve as medical evidence for supply replacement claims. However, when a prescription for DMEPOS is renewed or revised, supply utilization information must be specified or updated by the physician on the CMN. *DME PSCs* assess the continuing medical necessity.

The *DME MACs and DME PSCs* must establish procedures for monitoring the utilization of replacement supplies. *DME MACs and DME PSCs* must inform suppliers of the need to submit updated medical information if the patient's condition materially changes the equipment, device, or supply utilization requirements. Absent such notification, *DME MACs and DME PSCs* do not allow claims for unexplained increases in supply utilization above the usage level they previously determined as medically necessary. Suppliers *shall* provide this information with the claim where indicated in published policy or to make it available to the *DME MACs or DME PSC* on request.

If necessary or appropriate for a medical necessity determination, the *DME PSC* must ask the supplier to obtain documentation from the treating physician, establishing the severity of the patient's condition and the immediate and long term need for the equipment and the therapeutic benefits the patient is expected to realize from its use. A claim of therapeutic effectiveness or benefit based on speculation or theory alone cannot be accepted. When restoration of function is cited as a reason for use of DMEPOS, the exact nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in which the equipment or device will restore or improve the bodily function should be explained by the treating physician.

If the *DME PSC* is unsuccessful in obtaining medical information from the supplier for non-assigned claims, it gives the beneficiary the opportunity to obtain the desired information from the supplier. If, after obtaining the requested information, a question of medical necessity remains, the *DME PSC* medical staff must resolve the issue.

5.9.1 - Evidence of Medical Necessity for the Oxygen CMN

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)
If *DME PSCs* learn that the physician of record is no longer the treating physician, the supplier *shall* obtain from the physician currently responsible for the patient's pulmonary condition a current fully-completed *oxygen* CMN. After review of this *oxygen* CMN, *DME MACs* continue monthly payments if the evidence establishes medical necessity. Their records must be updated to identify the new treating physician

5.9.2 - Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

The use of the Certificates of Medical Necessity (CMNs) for motorized wheelchairs, manual wheelchairs and power operated vehicles will be phased out for claims with Dates of Service (DOS) on or after May 5, 2005.

For claims with dates of service before May 5, 2005, claims shall be submitted and processed using the fully completed and signed CMNs (CMS-843 for motorized wheelchairs, CMS-844 for manual wheelchairs, CMS-850 for power operated vehicles, and CMS-854, Section C Continuation Form).

Since MMA §302 allows physicians, physician assistants, nurse practitioners, or clinical nurse specialists to prescribe power mobility devices, it is no longer necessary to require a specialist in physical medicine, orthopedic surgery, neurology or rheumatology to provide a written prescription for POVs.

The physician or treating practitioner (a physician assistant, nurse practitioner or clinical nurse specialist) must conduct a face-to-face examination of the beneficiary and write a written prescription for the *power mobility device (PMD).*

The written prescription must include the beneficiary's name; the date of the face-to-face examination; the diagnoses and conditions that the PMD is expected to modify; a description of the item; the length of need; the physician or treating practitioner's signature; and the date the prescription is written.

The written prescription for the PMD must be in writing and signed and dated by the physician or treating practitioner (a physician assistant, nurse practitioner or clinical nurse specialist) who performed the face-to-face examination. The face-to-face examination requirement does not apply when only accessories for power mobility devices are being ordered.

The physician or treating practitioner must submit a written prescription for the PMD to the supplier. This written prescription for the PMD must be received by the supplier within 30 days after the face-to-face examination. For those instances of a recently hospitalized beneficiary, the written prescription must be received by the supplier within 30 days after the date of discharge from the hospital.

Prior to dispensing a PMD, the DME supplier must obtain from the physician or treating practitioner who performed the face-to-face examination the written prescription accompanied by supporting documentation of the beneficiary's need for the PMD in the home. Pertinent parts from the documentation of the beneficiary's PMD evaluation may include the history, physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans. The physician or treating practitioner should select only those parts of the medical record that clearly demonstrate medically necessity for the

PMD. The parts of the medical record selected should be sufficient to delineate the history of events that led to the request for the PMD; identify the mobility deficits to be corrected by the PMD; and document that other treatments do not obviate the need for the PMD, that the beneficiary lives in an environment that supports the use of the PMD and that the beneficiary or caregiver is capable of operating the PMD. In most cases, the information recorded at the face-to-face examination will be sufficient. However, there may be some cases where the physician or treating practitioner has treated a patient for an extended period of time and the information recorded at the face-to-face examination refers to previous notes in the medical record. In this instance, those previous notes would also be needed. The physician, treating practitioner or supplier that is a HIPAA covered entity should make sure to remove or edit any materials that may be contained within the medical record that are not necessary to support the prescription. For example, a gynecologic report would not be needed in the records submitted for a beneficiary whose clinical need for a PMD is based solely on disability secondary to a stroke.

As defined in the PIM, chapter 3, if data analysis indicates potentially aberrant billing, contractors shall continue to follow the guidance as defined when performing medical review on claims with dates of service on or after May 5, 2005.

5.10 - Period of Medical Necessity - Home Dialysis Equipment

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

The period of medical necessity for home dialysis equipment must be specified, e.g., "at least x months." Situations may occur causing temporary non-use of equipment:

- Beneficiary requires in-facility treatment for re-stabilization or as a result of some acute condition. The beneficiary is expected to return to home dialysis;

- Beneficiary is temporarily without a suitable home dialysis assistant;

- Beneficiary is away from home but expects to return; or

- Beneficiary is a transplant candidate and is taken off home dialysis preparatory to transplant. (If the transplant cannot occur, or if the transplant is not successful, the patient will very likely resume home dialysis and an evaluation can be made whether it will be within the immediate or foreseeable future.)

Under such circumstances, *DME PSCs* determine that medical necessity exists and pay for a period of up to 3 months after the month home dialysis equipment was last used. This does not eliminate the necessity for periodic reevaluation of medical necessity. It provides a tolerance to avoid frequent reevaluation in renal dialysis situations and provides for continuity of payments where economically advantageous.

5.11 - Safeguards in Making Monthly Payments

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

The *DME MACs and DME PSCs* shall establish appropriate safeguards to assure that payments are not made beyond the last month of medical necessity. They must develop appropriate safeguards to identify and investigate the following:

Multiple claims for rental of the same or similar equipment from the same supplier within the same rental month (e.g., rental claims with different start dates but within the same rental period); *Pub.100-04, chapter 20, §30.5* specifically forbids payments for multiple claims for rental of the same or similar equipment from either the same or a different supplier during the same rental month.

- Contraindicated items of rented or purchased equipment;

- Incompatible claims information (e.g., liquid oxygen contents billed for a purchased gas delivery system);

- Medical equipment rentals or purchases after a beneficiary's death;

- Rental start dates on or after the purchase of the same or comparable equipment (absent evidence that the beneficiary has disposed of purchased equipment);

- Rental claims for the same or similar equipment from different suppliers for the same or overlapping rental months; and

- Equipment rental start dates within periods of confinement in an institution that cannot be considered a patient's home.

The *DME MACs and DME PSCs* shall resolve these situations on a prepayment basis. Development, if necessary, may be via written or telephone contact per *Pub. 100-08* subject to any other documentation or development guidelines specified in *Pub. 100-02, chapter 15, §100-01, Pub. 100-04, chapter 20, §10.1.1 and Pub. 100-04, chapter 20, §100.2.3.*

To the extent possible, *DME MACs and DME PSCs* give beneficiaries and supplier-assignees advance notice of the date and reason that payments are scheduled to stop. (See *Pub. 100-04, chapter 21 for EOMB language.)*

5.11.1 – Guidance on Safeguards in Making Monthly Payments

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

It is appropriate to develop safeguards against improper payment of claims. This section provides *DME MACs and DME PSCs* with additional guidance in creating and applying these safeguards to DME claims.

5.12 – Pick-up Slips

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

For purposes of this section, a pick-up slip is written confirmation, provided by a supplier, that the supplier has removed an item of DME from the beneficiary’s home.

When making determinations, *DME PSCs* must ascertain not only whether equipment is present in the home, but must determine which equipment is actually being used by the patient. Therefore, it is inappropriate to determine, solely based on lack of a pick up slip that a piece of equipment may still be in use. Likewise, it is inappropriate for *DME PSCs* to deny claims solely based on lack of a pick up slip. *DME PSCs* should develop these claims to determine which piece of equipment is medically necessary.

5.13 - Incurred Expenses for DME and Orthotic and Prosthetic Devices

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

The first month's expense for rental is incurred on the date of delivery of the equipment. Expenses for subsequent months are incurred on the same date of the month. Where equipment is purchased, benefits are payable on the same basis. Suppliers may submit claims as of the date expenses are incurred. If the date of delivery is not specified on the claim, reviewers assume, in the absence of evidence to the contrary, that the date of purchase or rental was the date of delivery.

Generally, for all DMEPOS, the supplier's date of service (DOS) is the date of delivery to a beneficiary's home. For DMEPOS provided to a beneficiary immediately following a hospital inpatient stay and/or DME immediately following a nursing home stay, the DOS is the date of final discharge to the beneficiary's home. For mail order DMEPOS provided immediately subsequent to a hospital inpatient stay and/or DME immediately following a nursing home stay, the DOS is the latter of the actual delivery date or the date of the discharge. Under no circumstances can the DOS be earlier than the date of delivery.

No payment may be made for rental for any month throughout which the patient is in an institution that does not qualify as his or her home (see *Pub. 100-02, chapter 15, §110.3)* or is outside the U.S. (See *Pub. 100-02, chapter 16, §60.)* If the patient is at home as of the first day of a rental month and, for part of the same rental month, is in an institution which cannot qualify as his or her home, or is outside the U.S., payment may be made for the entire rental month. Similarly, if an item of rental equipment is returned to the supplier before the end of a payment month because the beneficiary died in that rental month or because the equipment became unnecessary in that month, payment may be made for the entire rental month. However, if the supplier charges for only part of a month, or the *DME MAC* is aware that the supplier customarily follows such a practice, it pays on a prorated basis. If the individual is outside the U.S. for more than 30 days and returns to the U.S. (before resuming payments), it determines medical necessity as in an initial case.

Note that in the case of purchased equipment, *Pub. 100-02, chapter 16, §60* requires that the beneficiary must have been in the United States when the item was delivered, and *Pub. 100-01, chapter 2, §40.1* requires that the individual must have had Supplementary Medical Insurance (SMI) coverage at the time the item was delivered. Therefore, where a purchased item of equipment was delivered to an individual outside the United States or before his/her coverage period began (i.e., the effective date of his/her enrollment), the entire expense of the item is excluded from coverage whether it was paid for in its

entirety at purchase or on a deferred or installment basis. Payment cannot be made in such cases even though the individual uses the item inside the United States or after his/her coverage begins.

Contractor systems must maintain the outcome (e.g., audit trail) of prepayment decisions such as approved, denied, or partially denied.

5.14 – Patient Equipment Payments Exceed Deductible and Coinsurance on Assigned Claims

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

The DME MACs pay the patient under the procedure described in *Pub. 100-04, chapter 29* where the patient's payments on an assigned claim exceed the deductible and coinsurance applicable to the allowed charges.

They pay benefits to the supplier first. After the supplier has been paid, *DME MACs* pay the beneficiary so that the payments to the supplier plus the amount paid by the beneficiary equal the fee schedule for the purchase of the equipment. The patient is paid according to the amount by which the deductible and coinsurance were overpaid.

The supplier may prefer to delay charging the beneficiary until the amount of deductible and coinsurance are known. Any payments which have been made, however, should be shown in Item 29 of the Form CMS-1500 or Item 10 of the Form CMS-1490.

5.15 – Definition of Customized DME

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Section 1834(a)(4) of the Act and 42 CFR 414.224 define customized DME as being items of DME which have been uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of the beneficiary's treating physician.

For instance, a wheelchair which has been; (1) measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, (2) assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs, and (3) is intended for an individual patient's use in accordance with instructions from the patient's physician would be considered “customized".

5.16 – Advance Determination of Medicare Coverage (ADMC) of Customized DME

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Section 1834(a)(15)(C) of the Act provides that carriers shall, at the request of a supplier or beneficiary, determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered if:

- The item is a customized item,

- The patient to whom the item is to be furnished, or the supplier, requests that such advance determination be made, and

- The item is not an inexpensive item as specified by the Secretary.

This section provides for direction in implementing §1834 (a)(15)(C) of the Act.
It is important to note that ADMCs are not initial determinations as defined at 42 CFR 405.801(a), because no request for payment is being made. As such, an ADMC cannot be appealed.

This is a voluntary program. Beneficiaries and suppliers are not required to submit ADMC requests in order to submit claims for items. Additionally, *DME PSCs* may not require an ADMC request as a prerequisite for submitting a claim.

5.16.1 – Items Eligible for ADMCs

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Effective September 1, 2001, the *DME PSCs* will no longer provide prior authorization for transcutaneous electrical nerve stimulators, seat lift mechanisms or power operated vehicles.

The *DME PSCs* shall publish examples of the types of items for which ADMCs are available. These examples shall be published yearly in the *DME PSC's* Suppliers' Bulletin. Examples will be published in the form of HCPCS codes eligible for this program. Because HCPCS codes describe general "categories" of equipment, this list is not a list of specific items, but rather a general list of the categories of types of items eligible for this program.

5.16.2 – Instructions for Submitting ADMC Requests

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Beginning October 1, 2001, at their option, suppliers or beneficiaries may submit, in hard copy, requests for ADMC. Requests must contain adequate information from the patient's medical record to identify the patient for whom the item is intended, the intended use of the item, and the medical condition of the patient that necessitates the use of a customized item.

Each *DME PSC* shall publish the mailing address to which requests should be sent.

5.16.3 – Instructions for Processing ADMC Requests

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Once a request is received, the *DME PSC shall* determine if there is sufficient medical documentation that supports whether the item is reasonable and necessary. In addition, a review of the beneficiary's claims' history should be conducted in order to determine whether any other reason exists to cause the claim to be denied, e.g., whether the same or similar equipment has already been provided.

Upon receipt of a request, the *DME PSC* shall render an advance determination of Medicare coverage within 30 calendar days. *DME PSCs* shall provide the requestor with their decision, be it affirmative or negative, in writing.

If requests are received for the wrong item(s), the request will be rejected. Rejected requests should not be counted as workload.

Requests for appropriate items received without documentation to support coverage will be denied as not meeting the medical necessity requirements Medicare has established for the item.

5.16.4 – Affirmative ADMC Decisions

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

When making an ADMC, the *DME PSC* should review the information submitted with the request to determine; 1) if a benefit category exists, 2) if a statutory exclusion exists, and 3) if the item is reasonable and necessary.

An affirmative ADMC decision will provide the supplier and the beneficiary assurance that the beneficiary, based on the information submitted with the request, will meet the medical necessity requirements Medicare has established for the item. An affirmative ADMC decision does not provide assurance that the beneficiary meets Medicare eligibility requirements nor does it assure that any other Medicare requirements (MSP, etc.) have been met. Only upon submission of a complete claim, can the *DME PSC* make a full and complete determination.

An affirmative ADMC decision does not extend to the price that Medicare will pay for the item.

An affirmative ADMC decision is valid for a period of 6 months from the date the decision is rendered. Oftentimes, beneficiaries who require customized DME are subject to rapid changes in medical condition. These changes may obviate the need for a particular item, either because the beneficiary's condition improved or deteriorated. For this reason, the date the item was provided to the beneficiary cannot be more than 6 months after the date the ADMC decision was made.

The *DME PSCs* reserve the right to review claims on a pre- or post-payment basis and, notwithstanding the requirements of this section, may deny claims and take appropriate remedy if they determine that an affirmative ADMC decision was made based on incorrect information.

5.16.5 – Negative ADMC Decisions

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

A negative ADMC decision communicates to the supplier and the beneficiary that, based on the information submitted with the request, the beneficiary does not meet the medical

necessity requirements Medicare has established for the item. The negative ADMC decision should indicate why the request was denied.

A beneficiary or a supplier can resubmit an ADMC request if additional medical documentation is obtained that could affect the prior negative ADMC decision. However, requests may only be submitted once during a 6-month period.

5.17 - DME PSC Tracking

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

The DME PSCs shall develop the capability to track ADMC requests in order to assure that decisions are rendered in a timely and appropriate fashion. *DME PSCs* shall also develop the capability to ensure that: 1) items for which an affirmative ADMC decision was made are not denied as not meeting the medical necessary requirements of the policy, and 2) claims for item that received a negative ADMC decision are denied as not covered, unless additional medical documentation submitted with the claims supports coverage.