Medicare Program Integrity Manual
Chapter 5 – Items and Services Having Special *DME* Review Considerations

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(Rev. 71, 04-09-04)

*5.*1 – Home Use of DME

(Rev. 71, 04-09-04)

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, DMERCs *and DMERC PSCs* develop for the date of admission and determine whether payment is possible. (See PIM Chapter 5, §5.4.) 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 an 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 MCM §2312.l 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", DMERCs *and DMERC PSCs* 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.*1.1 – Physician Orders

(Rev. 71, 04-09-04)

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.*1.1.1 - Verbal Orders

(Rev. 71, 04-09-04)

Except as noted in Chapter 5 Section *5.*1.1.2.1, 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 DMERC *or DMERC PSC* 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 DMERC *or DMERC PSC*.

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.*1.1.2 -Written Orders

(Rev. 71, 04-09-04)

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 & ink signed order in their records before they can submit a claim to Medicare (i.e., if there is no order or only a verbal order), the claim will be denied. If the item is one that requires a written order prior to delivery (see Section *5.*1.1.2.1), the claim will be denied as not meeting the benefit category. 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 MCM Section 12000 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

If an item requires a *Certificate of Medical Necessity (*CMN*)* and the supplier does not have a faxed, photocopied, electronic, or pen & ink signed CMN in their records before they submit a claim to Medicare, the claim will be denied. If the CMN is used to verify that statutory benefit requirements have been met, then the claim will be denied as not meeting the benefit category. If the CMN is used to verify that medical necessity criteria have been met, the claim 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, etc.) is NOT in itself considered to be part of the order although it may be put on the same document as the order.

*5.*1.1.2.1 - Written Orders Prior to Delivery

(Rev. 71, 04-09-04)

A written order prior to delivery is required for: pressure reducing pads, mattress overlays, mattresses, and beds; seat lift mechanisms; TENS units; and power operated vehicles. DMERCs *and DMERC 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.*1.1.2 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 the MCM, Section 12000 for more information on appeals).

*5.*1.1.3 – Requirement of New Orders

(Rev. 71, 04-09-04)

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

*5.*1.1.4 - CMN as the Written Order

(Rev. 71, 04-09-04)

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 *and DMERC PSC* must accept the copied, faxed or electronic document as fulfilling the requirements for these documents.

When a DMERC *or DMERC 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 DMERC *or DMERC PSC* may require the supplier to prove the authenticity/validity of the signature on the CMN or order, or any other questionable portion of the claim(s) under investigation.

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

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

*5.*1.1.4.1 - Cover Letters for CMNs

(Rev. 71, 04-09-04)

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

The DMERC *and DMERC PSCs* 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 *and DMERC PSCs* should encourage suppliers to include language in their cover letters to remind physicians of their responsibilities.

*5.*1.1.4.2 – Completing a CMN

(Rev. 71, 04-09-04)

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 *and DMERC PSCs* 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 *and DMERC PSCs* 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 *or DMERC PSC*, produce information to substantiate the information on the CMN. If the supplier cannot produce this information, the DMERCs *and DMERC PSCs* 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.

*5.*1.1.4.3– DMERCs' *and DMERC PSCs'* Authority to Assess an Overpayment and/or CMP When Invalid CMNs Are Identified *(Rev. 71, 04-09-04)*

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 on file or to submit a valid CMN to the DMERC *or DMERC 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. When the DMERCs *and DMERC PSCs* identify a claim for which a CMN is not valid, they may deny the claim and/or initiate overpayment action.

If a DMERC or *DMERC PSC* identifies a supplier that has a pattern of improperly completing the CMN, the DMERC *or DMERC PSC* 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.

*5.*1.1.5 - Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders

(Rev. 71, 04-09-04)

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.*1.1.6 - Physician Assistant Rules Concerning Orders and CMNs

(Rev. 71, 04-09-04)

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 and §2156(A) of the Medicare Carriers Manual;
- 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.*2 – Documentation in the Patient's Medical Record

(Rev. 71, 04-09-04)

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, it is recommended that a copy of the completed CMN be kept in the patient's record. However, neither a physician's order nor a CMN 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. There must be clinical 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 information on a supplier prepared statement or physician attestation (if applicable).

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 DMERC *or DMERC PSC*. However, the DMERC *or DMERC PSC* may request this information in selected cases. If the DMERC *or DMERC 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.*2.1 - Supplier Documentation

(Rev. 71, 04-09-04)

Before submitting a claim to the DMERC *or DMERC PSC*, the supplier must have on file a dispensing order, the written order, the CMN (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 DMERC *and DMERC 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 DMERC *or DMERC 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.*3 – Evidence of Medical Necessity

(Rev. 71, 04-09-04)

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. DMERCs *and DMERC 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. DMERCs *and DMERC PSCs* assess the continuing medical necessity.

DMERCs *and DMERC PSCs* must establish procedures for monitoring the utilization of replacement supplies. DMERCs *and DMERC 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, DMERCs *and DMERC PSCs* do not allow claims for unexplained increases in supply utilization above the usage level they previously determined as medically necessary. Suppliers must provide this information with the claim where indicated in published policy or to make it available to the DMERC *or DMERC PSC* on request.

If necessary or appropriate for a medical necessity determination, the DMERC *or DMERC 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 DMERC *or DMERC 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 DMERC *or DMERC PSC* medical staff must resolve the issue.

*5.*3.1 – Period of Medical Necessity--Home Dialysis Equipment

(Rev. 71, 04-09-04)

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, DMERCs *and DMERC 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.*3.2 – Safeguards in Making Monthly Payments

(Rev. 71, 04-09-04)

DMERCs *and DMERC PSCs* must 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);
- 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.

DMERCs *and DMERC PSCs* must resolve these situations on a prepayment basis. Development, if necessary, may be via written or telephone contact per MCM §3311, subject to any other documentation or development guidelines specified in MCM §§4105ff.

To the extent possible, DMERCs *and DMERC PSCs* give beneficiaries and supplier-assignees advance notice of the date and reason that payments are scheduled to stop. (See MCM §§7012ff. for EOMB language.)

*5.*3.2.1 – Guidance on Safeguards in Making Monthly Payments

(Rev. 71, 04-09-04)

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

*5.*3.2.1.1 – Pick-up Slips

(Rev. 71, 04-09-04)

MCM §4105.2(B) 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.

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, DMERCs *and DMERC 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 DMERCs *and DMERC PSCs* to deny claims solely based on lack of a pick up slip. DMERCs *and DMERC PSCs* should develop these claims to determine which piece of equipment is medically necessary.

*5.*3.3 - Certificates of Medical Necessity

(Rev. 71, 04-09-04)

For certain items or services billed to a DMERC *or DMERC PSC*, the supplier must receive a signed 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 *or DMERC PSC* form number (e.g., 01, 02, 03) and a revision number (e.g., .01, .02). Some DMERC *and DMERC PSC* forms also have an alpha suffix (e.g., A, B, C).

All CMNs have a *CMS* form number in addition to the DMERC *or DMERC PSC* form number. (See the following listing of CMN form numbers.) The *CMS* form number is in the bottom left corner of the form. CMNs are referred to by their *CMS* form numbers. DMERC *and DMERC PSC* form numbers identify the CMN on electronic claims submitted to the DMERC *and DMERC PSC* in the National Standard Format (NSF). *CMS* 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 *and DMERC PSCs* on request. When hardcopy CMNs are submitted to the DMERC *or DMERC PSC*, the supplier must include a copy of only the front side. When CMNs are submitted electronically to the DMERC *or DMERC PSC*, only information from sections A, B, and D are required since section C cannot 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:

DMERC FORM	*CMS* FORM	ITEMS ADDRESSED
484.2	484	Home oxygen therapy
01.02A	841	Hospital beds
01.02B	842	Support surfaces
02.03A	843	Motorized wheelchairs

02.03B	844	Manual wheelchairs
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
07.02B	850	Power operated vehicles
09.02	851	External Infusion Pumps
10.02A	852	Parenteral nutrition
10.02B	853	Enteral nutrition
11.01	854	Section C continuation (manual and motorized wheelchairs - ONLY)

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:

- *P*itch may vary from 10 characters per inch (cpi) to 17.7 cpi;
- Line spacing must be 6 lines per inch;
- 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 *(for PSCs, the GTL, Co-GTL, and SME)* 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 *(for PSCs, the GTL, Co-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 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.

*5.*3.3.1 – Acceptability of Faxed Orders and Facsimile or Electronic Certificates of Medical Necessity

(Rev. 71, 04-09-04)

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

The DMERCs *and DMERC PSCs* retain the authority to request additional documentation to support the claim. If a DMERC *or DMERC PSC* 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.

*5.*4 – Incurred Expenses for DME and Orthotic and Prosthetic Devices

(Rev. 71, 04-09-04)

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 MCM §2100.3) or is outside the U.S. (See MCM §2312.) 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 DMERC *or DMERC PSC* 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, MCM §2312 requires that the beneficiary must have been in the United States when the item was delivered, and MCM §1050 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.*5 – Patient Equipment Payments Exceed Deductible and Coinsurance on Assigned Claims

(Rev. 71, 04-09-04)

DMERCs *and DMERC PSC* pay the patient under the procedure described in MCM §7057 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, DMERCs *and DMERC PSCs* 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.*6 – Evidence of Medical Necessity - Oxygen Claims

(Rev. 71, 04-09-04)

If DMERCs *and DMERC PSCs* learn that the physician of record is no longer the treating physician, the supplier must be directed to obtain from the physician currently responsible for the patient's pulmonary condition a current, fully completed CMN. After review of this CMN, DMERCs *and DMERC PSCs* continue monthly payments if the evidence establishes medical necessity. Their records must be updated to identify the new treating physician and, if necessary, adjust the schedule for further re-certifications.

*5.*7 – Advance Determination of Medicare Coverage (ADMC) of Customized DME

(Rev. 71, 04-09-04)

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, DMERCs *and DMERC PSCs* may not require an ADMC request as a prerequisite for submitting a claim.

*5.*7.1 – Definitions

(Rev. 71, 04-09-04)

*5.*7.1.1 – Definitions of Customized DME

(Rev. 71, 04-09-04)

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.*7.2 – Items Eligible for ADMCs

(Rev. 71, 04-09-04)

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

The DMERCs *and DMERC PSCs* shall publish examples of the types of items for which ADMCs are available. These examples shall be published yearly in the DMERC's *and DMERC 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.*7.3 – Instructions for Submitting ADMC Requests

(Rev. 71, 04-09-04)

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 DMERC *and DMERC PSC* shall publish the mailing address to which requests should be sent.

*5.*7.4 – Instructions for Processing ADMC Requests

(Rev. 71, 04-09-04)

Once a requst is received, the DMERC *or DMERC 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 DMERC *or DMERC PSC* shall render an advance determination of Medicare coverage within 30 calendar days. DMERCs *and DMERC 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.*7.5 – Affirmative ADMC Decisions

(Rev. 71, 04-09-04)

When making an ADMC, the DMERC *or DMERC 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 DMERC *or DMERC 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 DMERCs *and DMERC 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.*7.6 – Negative ADMC Decisions

(Rev. 71, 04-09-04)

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.*7.7 – DMERC *and DMERC PSC* Tracking

(Rev. 71, 04-09-04)

DMERCs *and DMERC PSCs* shall develop the capability to track ADMC requests in order to assure that decisions are rendered in a timely and appropriate fashion. DMERCs *and DMERC 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.