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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-08 Medicare Program Integrity | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 168 | Date: OCTOBER 31, 2006 |
| | Change Request 5107 |

NOTE: Transmittal 166, dated October 6, 2006, is rescinded and replaced with Transmittal 168, dated October 31, 2006. This replacement clarifies the transition period. All other information remains the same.

SUBJECT: DMEPOS Transcutaneous Electrical Nerve Stimulators (TENS) Certificate of Medical Necessity (CMN) for Purchases: Form CMS-848

I. SUMMARY OF CHANGES: The CMS has recently developed improved certificates of medical necessity (CMNs) approved by the Office of Management and Budget (OMB). The OMB approved form number for Form CMS-848 is OMB #0938-0679. The revised Transcutaneous Electrical Nerve Stimulators (TENS) CMN will only apply to purchases. As of January 1, 2007, contractors shall not require a CMN for TENSs rentals.

New/Revised Material

Effective Date: October 2, 2006

Implementation Date: January 2, 2007

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: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|--|
| R | 5/5/5.3/ Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs) |

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 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: 166 | Date: October 31, 2006 | Change Request 5107 |
|-------------|------------------|------------------------|---------------------|

NOTE: *Transmittal 166, dated October 6, 2006 is rescinded and replaced with Transmittal 168, dated October 31, 2006. This replacement clarifies the transition period. All other information remains the same.*

SUBJECT: DMEPOS Transcutaneous Electrical Nerve Stimulators (TENS) Certificate of Medical Necessity (CMN) for Purchases Only: Form CMS-848

I. GENERAL INFORMATION

A. Background: The CMS has recently developed improved certificates of medical necessity (CMNs) approved by the Office of Management and Budget (OMB). The OMB approved form number for Form CMS-848 is OMB# 0938-0679.

B. Policy: The revised Transcutaneous Electrical Nerve Stimulators (TENS) CMN will only apply to purchases.

As of January 1, 2007, contractors shall not require a CMN for TENS rentals.

For rentals, contractors shall allow a transition period for the TENS CMNs with dates of service (DOS) on or after October 1, 2006 through December 31, 2006. Suppliers shall submit a partially-completed unsigned TENS CMN. Contractors shall not edit on this partially- complete TENS CMN. Claims tied to a TENS CMN will be accepted and processed based on the format of the CMN.

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement

“Should” denotes an optional requirement

| Requirement Number | Requirements | Responsibility (“X” indicates the columns that apply) | | | | | | | | |
|--------------------|--|---|------------------|---------------------------------|-----------------------|---------------------------|-------------|-------------|-------------|--------------------------------------|
| | | F I | R H H I | C a r r i e r | D M E R C | Shared System Maintainers | | | | Other: DME PSC and DME MACs |
| | | | | | | F I S S | M C S | V M S | C W F | |
| 5107.1 | For rentals, contractors shall allow suppliers to submit a partially-completed unsigned TENS CMN for claims with DOS <u>on or after October 1, 2006, and ending on December 31, 2006</u> . | | | | X | | | | | X |

| Requirement Number | Requirements | Responsibility (“X” indicates the columns that apply) | | | | | | | | |
|--------------------|--|---|-------------|---------------------------------|-----------------------|---------------------------|-------------|---|---|-----------------------------|
| | | F I | R H I | C a r r i e r | D M E R C | Shared System Maintainers | | | | Other: DME PSC and DME MACs |
| F I S S | M C S | | | | | V M S | C W F | | | |
| 5107.1.1 | Contractors shall notify suppliers that the old TENS CMNs forms must be used during this transition period. | | | | X | | | | | X |
| 5107.2 | Contractors and shared systems shall not edit on any information contained on the partially-completed, unsigned TENS CMNs for rentals. | | | | X | | | X | | X |
| 5107.3 | As of January 1, 2007, contractors shall not require a CMN for TENS rentals. | | | | X | | | | | X |
| 5107.4 | Contractors will accept and process claims tied to a TENS CMN based on the format of the CMN. | | | | X | | | | | X |
| 5107.5 | Beginning with DOS January 1, 2007, contractors <u>shall not</u> require a CMN for TENS rentals (RR). | | | | X | | | X | X | |

III. PROVIDER EDUCATION

| Requirement Number | Requirements | Responsibility (“X” indicates the columns that apply) | | | | | | | | |
|--------------------|--|---|-------------|---------------------------------|-----------------------|---------------------------|-------------|--|--|-----------------------------|
| | | F I | R H I | C a r r i e r | D M E R C | Shared System Maintainers | | | | Other- DME- PSC and DME MAC |
| F I S S | M C S | | | | | V M S | C W F | | | |
| 5107.6 | <p>Contractors shall provide very specific guidance to providers and suppliers on how to partially-complete the unsigned TENS for rentals during the transition period <u>on or after October 1, 2006, and ending on December 31, 2006</u> as follows. (NOTE: Suppliers <u>must use</u> the old CMN forms for this transition period.)</p> <p>Section A of the CMN – Enter the date of service (i.e., the delivery date) in the “Initial” date field;</p> <p>Section A of the CMN – Enter all information</p> | | | | X | | | | | X |

| Requirement Number | Requirements | Responsibility (“X” indicates the columns that apply) | | | | | | | |
|--------------------|---|---|-------------|---------------------------------|-----------------------|---------------------------|-------------|--|---|
| | | F I | R H I | C a r r i e r | D M E R C | Shared System Maintainers | | | |
| F I S S | M C S | | | | | V M S | C W F | | |
| | <p>in required fields as is currently being done; Section B of the CMN – Enter 99 in the “Est. Length of Need” field; Section B of the CMN – Enter the primary diagnosis in the “diagnosis Codes” field; Section B of the CMN – Enter “D” as the answer to questions 1,3, and 6. Enter “5” as the answer to question 5. You may leave the answer to questions 2 and 4 blank. Section C of the CMN – May leave blank, Section D of the CMN – Enter a “yes” in the “Physician’s Signature” field. Enter the delivery date in the “Signature Date” field. Paper CMNs – For hard copy CMNS, only complete section A. All other sections of the CMN should be left blank.</p> | | | | | | | | |
| 5107.7 | <p>A 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 "MLN 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 MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p> | | | | X | | | | X |

| Requirement Number | Requirements | Responsibility (“X” indicates the columns that apply) | | | | | | | | |
|--------------------|--|---|-------------|---------------------------------|-----------------------|---------------------------|-------------|--|--|-----------------------------------|
| | | F I | R H I | C a r r i e r | D M E R C | Shared System Maintainers | | | | Other- DME- PSC and DME MAC |
| F I S S | M C S | | | | | V M S | C W F | | | |
| 5107.8 | Contractors shall update all supplier manuals, bulletins, articles, and other educational documents to reflect the new changes contained in this CR. | | | | X | | | | | X |
| 5107.9 | Contractors shall provide very specific guidance to providers and suppliers on how to properly document and submit claims in the absence of a TENS CMN for rentals (RR) as of January 1, 2007. | | | | 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 2, 2006 | Medicare contractors shall implement these instructions within their FY 2007 operating budgets. |
| Implementation Date: January 2, 2007 | |

Transition Period: October 1, 2006-December 31, 2006

Pre-Implementation Contact(s):

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

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

(Rev. 168, Issued: 10-31-06; Effective: 10-02-06; Implementation: 01-02-07)

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

**Beginning January 1, 2007, the new TENS CMN is for purchases only. A TENS CMN will no longer be necessary for rentals.*

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-CMN) or electronic DIFs (e-DIFs). E-CMN or e-DIFs must adhere to all privacy, security, and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMN 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.