CMS Manual System	Department of Health & Human Services (DHHS)					
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)					
Transmittal 753	Date: October 27, 2017					
	Change Request 10244					

SUBJECT: Certificates of Medical Necessity (CMN) and Durable Medical Equipment (DME) Information Forms (DIF)

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to remove the instructions in chapter 5, section 5.3 of Pub. 100-08 that CMNs and DIFs must be two sided and that the language or content should not be modified when reprinted.

EFFECTIVE DATE: November 28, 2017

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

IMPLEMENTATION DATE: November 28, 2017

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	5/5.3/Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)			

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment - Business Requirements

Pub. 100-08 Transmittal: 753 Date: October 27, 2017 Change Request: 10244

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I. GENERAL INFORMATION

- **A. Background:** A CMN or DIF is a form required to help document the medical necessity and other coverage criteria for selected DME items. The forms are completed by suppliers and physicians. The Centers for Medicare & Medicaid Services (CMS) no longer requires that no modifications are made to the form or the form to be two-sided.
- **B.** Policy: This CR does not involve any legislative or regulatory policies.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC		DME	Shared-System Maintainers				Other	
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
10244.1	DME MACS shall be aware that CMS no longer requires the CMNs and DIFs to be two-sided.				X					RACs, SMRC, ZPICs
10244.2	DME MACs shall be aware that CMS is removing the instructions that the CMNs shall not be modified.				X					RACs, SMRC, ZPICs

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
			A/	Β	DME	CEDI
			\mathbf{M}	AC		
					MAC	
		A	В	ННН		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Debbie Skinner, 410-786-7480 or debbie.skinner@cms.hhs.gov , Paula Smith, 410-786-4709 or paula.smith@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

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

(Rev. 753: Issue: 10-27-17; Effective: 11-28-17; Implementation: 11-28-17)

A Certificate of Medical Necessity (CMN) or a DME Information Form (DIF) is a form required to help document the medical necessity and other coverage criteria for selected DMEPOS items. CMNs contain Sections A through D. Sections A and C are completed by the supplier and Sections 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. For the CMS forms 484, 846, 847, 848, 849, 854, 10125 and 10126, the OMB# is 0938-0679.

- CMN CMS-484 Oxygen
- CMN CMS-846 Pneumatic Compression Devices
- CMN CMS-847 -- Osteogenesis Stimulators
- CMN CMS-848 Transcutaneous Electrical Nerve Stimulators
- CMN CMS-849 Seat Lift Mechanisms
- CMN CMS-854 Section C Continuation Form
- DME Information Form CMS-10125 External Infusion Pumps
- DME Information Form CMS-10126 Enteral & Parenteral Nutrition

The TENS CMN is for purchases only. A TENS CMN will no longer be necessary for rentals.

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. For these items, a supplier must have a signed original, faxed, photocopied, or electronic CMN or DIF in their records *when submitting* a claim for payment to Medicare.

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

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.

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:

- o Pitch may vary from 10 characters per inch (cpi) to 17.7 cpi;
- o Line spacing must be 6 lines per inch
- o Each 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 detailed written order if the narrative description in section C is sufficiently detailed. This would include quantities needed and frequency of replacement for accessories and supplies. For items requiring both a CMN and a written order prior to delivery (e.g., 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 ZPICs/*UPICs* 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 a CMN 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 ZPICs/*UPICs*, refer the supplier to the primary GTL or associate GTL and SME) as a potential civil monetary penalty case.

CMS will 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, original hardcopy, or an electronic signed CMN or DIF in their records *when* they submit a claim to Medicare, the claim will be denied.

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 MACs, *and* ZPICs/*UPICs*.

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 MACs, or ZPICs/*UPICs* must accept the copied, faxed or electronic document as fulfilling the requirements for these documents.

When a ZPIC/*UPIC 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. ZPICs/*UPICs* 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* MACs, ZPICs/*UPICs*, *SMRC* or *DME* RACs, suppliers must provide the CMN or DIF, in a format that the DME MACs, ZPICs/*UPICs*, *SMRC*, and *DME* RACs can accept, in a timely manner. Upon medical review, the DME MACs, ZPICs /*UPICs*, *SMRC*, and *DME* RACs should not deny claims solely because the CMN or DIF is faxed, copied, or electronic. The DME MACs, ZPICs /*UPICs*, *SMRC*, and *DME* RACs may request the supplier to download and print a hard copy of an electronic order, CMN or DIF if the DME MACs, ZPICs/*UPICs*, *SMRC*, and *DME* RACs 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 *when* 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 *ZPICs/UPICs* need not make any shared system changes to electronically accept e-CMNs or *e*-DIFS as CMS views e-CMNs or *e*-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 *ZPICs/UPICs*.