

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12512	Date: February 15, 2024
	Change Request 13480

Transmittal 12468 issued January 18, 2024, is being rescinded and replaced by Transmittal 12512, dated February 15, 2024, to add business requirement 13480.5, clarifying that while this CR reiterates the regulatory framework for refillable DMEPOS, it does not mandate review of any particular items or policy elements. All other information remains the same.

SUBJECT: Documentation Requirements for Refillable Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update the documentation requirements for refillable DMEPOS, as clarified and codified in the CMS calendar year (CY) 2024 Home Health Prospective Payment System (HH PPS) final rule. The rule is available at 88 Federal Register (FR) 77676, or <https://www.govinfo.gov/content/pkg/FR-2023-11-13/pdf/2023-24455.pdf>.

EFFECTIVE DATE: January 1, 2024

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

IMPLEMENTATION DATE: February 19, 2024

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	5/5.2/5.2.6/Documentation Requirements for DMEPOS Supplied as Refills to the Original Order

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: 12512	Date: February 15, 2024	Change Request: 13480
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SUBJECT: Documentation Requirements for Refillable Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

EFFECTIVE DATE: January 1, 2024

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IMPLEMENTATION DATE: February 19, 2024

I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to update the documentation requirements for refillable DMEPOS, as clarified and codified in the CMS CY 2024 HH PPS final rule. The rule is available at 88 FR 77676.

B. Policy: 88 FR 77676.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DM E MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
13480.1	Contractors shall assess documentation requirements for refillable items of DMEPOS per the manual updates-- which reflect the clarified and codified policy, as available at 88 FR 77676.				X					CERT, RAC, SMRC, UPICs
13480.1.1	Contractors shall require documentatio				X					CERT, RAC, SMRC

Number	Requirement	Responsibility								Other
		A/B MAC			DME MAC	Shared-System Maintainers				
		A	B	HH H		FIS S	MC S	VM S	CW F	
	n indicating that the beneficiary has confirmed their need for the DMEPOS refill within the 30-day period prior to the end of the current supply.									, UPICs
13480.1.1.1	Contractors shall not require the beneficiary to count their remaining supply when assessing their need for refill.				X					CERT, RAC, SMRC , UPICs
13480.1.2	Contractors shall, for shipped items, look for documentation of the beneficiary's name, date of contact, the item requested, and an affirmative response from the beneficiary, indicative of the need for refill, prior to dispensing the product, as is required.				X					CERT, RAC, SMRC , UPICs
13480.1.3	Contractors shall, for items obtained in-person from a retail				X					CERT, RAC, SMRC , UPICs

Number	Requirement	Responsibility								
		A/B MAC			DM E MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	store, look for documentation of the delivery slip signed by the beneficiary or their representative, or a copy of the itemized sales receipt, as sufficient documentation of a request for refill.									
13480.2	<p>Contractors shall note that we do not prescribe the mode of communication used to gather this information, so long as it is individualized to the beneficiary (i.e., they affirm their need) and can be documented in the record.</p> <p>NOTE: For example, automated text messaging or email may be used so long as the captured information demonstrates the beneficiary name, item(s), date of</p>				X				CERT, RAC, SMRC, UPICs	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	contact, and affirmative response.									
13480.3	Contractors shall look for documentation to support the DMEPOS product was delivered no sooner than 10 calendar days prior to the end of usage for the current product.				X					CERT, RAC, SMRC, UPICs
13480.4	Contractors shall apply the codified documentation requirements for refillable DMEPOS when reviewing DMEPOS claims with dates of service 1/1/2024 or later.				X					CERT, RAC, SMRC, UPICs
13480.5	Contractors shall note that while this CR reiterates the regulatory framework for refillable DMEPOS, it does not mandate review of any particular items or policy				X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	<p>elements.</p> <p>Contractors are reminded of Program Integrity Manual 100-08, Chapter 3, which states: “The MACs shall target their efforts at error prevention to those services and items that pose the greatest financial risk to the Medicare program and that represent the best investment of resources.”</p>									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13480.6	<p>Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don’t need to separately track and report MLN content releases. You may supplement with</p>				X	

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	your local educational content after we release the newsletter.					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Olufemi Shodeke, 410-786-1649 or Olufemi.Shodeke@cms.hhs.gov , Nancy Allert, 410-786-4317 or Nancy.Allert@cms.hhs.gov , Jennifer Phillips, 410-786-1023 or Jennifer.Phillips@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

Medicare Program Integrity Manual

Chapter 5 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items and Services Having Special DME Review Considerations

Table of Contents
(Rev. 12512; Issued:02-15-24)

Transmittals for Chapter 5

5.2.6 - Documentation Requirements for DMEPOS Supplied as Refills to the Original Order

5.2.6 - Documentation Requirements for DMEPOS Supplied as Refills to the Original Order

(Rev. 12512; Issued: 02-15-24; Effective: 01-01-24; Implementation: 02-19-24)

*Per 42 CFR 410.38 related to DMEPOS products that are supplied as refills to the original order/prescription, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary and to confirm any changes/modifications to the SWO. **The DMEPOS supplier must document contact with the beneficiary or their representative to verify the refill is needed. This documentation must include the following:***

- *Evidence of the beneficiary or their representative's affirmative response of the need for supplies, which should be obtained as close to the expected end of the current supply as possible. However, such contact and affirmative response must be within 30 calendar days from the expected end of the current supply.*
 - *For shipped items: the beneficiary's name, date of contact, the item requested, and an affirmative response from the beneficiary, indicative of the need for refill, prior to dispensing the product is required. Beneficiary's need not count the remaining supply.*
 - *For items obtained in-person from a retail store, the delivery slip signed by the beneficiary or their representative or a copy of the itemized sales receipt is sufficient documentation of a request for refill.*

Suppliers are permitted to use any mode of communication so long as the beneficiary affirmation is received, and documentation of the contact is captured and can be provided upon request.

- *For example, automated text messaging or email may be used so long as the captured information demonstrates the beneficiary's name, item(s), date of contact, and affirmative response.*

For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DME MACs shall allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.