CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13321	**Date: July 24, 2025**
	Change Request 13963

SUBJECT: Updates to the Medical Record Documentation Guidance Within Publication (Pub.) 100-08, Program Integrity Manual (PIM)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to add the following language to chapter 5, section 5.9. in Pub. 100-08, PIM:

"For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by eligible professionals described in [Social Security Act] section 1848(k)(3)(B)."

EFFECTIVE DATE: August 25, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: August 25, 2025

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	5/5.9/Documentation in the Patient's Medical Record

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: 13321	Date: July 24, 2025	Change Request: 13963

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II. GENERAL INFORMATION

A. Background: This instruction updates medical review guidance provided in Chapter 5 of Pub. 100-08 to explicitly clarify that, for purposes of determining the reasonableness and medical necessity of orthoses and prostheses, documentation created by an orthotist or prosthetist is considered part of the individual's medical record.

In 2018, Congress amended section 1834(h) of the Social Security Act to clarify that, for "purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by eligible professionals." Bipartisan Budget Act of 2018, Pub. L. No. 115-123, § 50402, 132 Stat. 64, 217 (2018) (codified at 42 U.S.C. § 1395m(h)(5)) (emphasis added). However, the PIM, Chapter 5, Section 5.9 has not yet been updated to reflect this statutory update. This update will align Pub.100-08, Ch.5 with the statutory language.

B. Policy: 1834(h) of the Social Security Act

III. 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	B	HHH	MAC	FISS	MCS	VMS	CWF	
13963.1	The contractor shall use this section as overall guidance when determining what documentation is part of a patient's				X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	medical record.									

IV. PROVIDER EDUCATION

None

Impacted Contractors: None

V. 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

VI. CONTACTS

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

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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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. 13321; Issued: 07-24-25)

5.9 – Documentation in the Patient's Medical Record

(Rev. 13321; Issued: 07-24-25; Effective: 08-25-25; Implementation: 08-25-25)

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). When a CMN or DIF and a medical record contain conflicting information due to a minor error or omission within the CMN or DIF, but all coverage, coding and payment criteria are substantiated through the medical record, the reviewer shall rely upon the content of the medical record (absent suspicion of abuse or gaming) and shall not issue a denial. 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 *orthotists, prosthetists*, or other health care professionals. *For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by certain eligible professionals described in [Social Security Act] section 1848(k)(3)(B), i.e., a physician, physician assistant, nurse practitioner, clinical nurse specialist, a physical therapist, or an occupational therapist. NOTE: the DME item or service must be ordered by an eligible physician, physician assistant, nurse practitioner, or clinical nurse specialist for Medicare payment.*

The documentation in the patient's medical record does not have to be routinely sent to the supplier or to the DME MACs or UPICs. However, the DME MACs or UPICs may request this information in selected cases. If the DME MACs or UPICs do 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.