CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 850	**Date: December 14, 2018**
	Change Request 10908

Transmittal 836, dated October 19, 2018, is being rescinded and replaced by Transmittal 850, dated December 14, 2018, to revise Business Requirement 10908.1 to include all the options of how a contractor will consider order requirements met when doing medical review of laboratory claims, and to change the effective and implementation dates to allow contractors additional time to implement. All other information remains the same.

SUBJECT: Medical Review of Diagnostic Laboratory Tests

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to add instructions to chapter 6 of Publication (Pub.) 100-08 regarding medical review of diagnostic laboratory tests.

EFFECTIVE DATE: December 17, 2018 - Reviews conducted on/after 30 days from issuance
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: December 17, 2018 - Reviews conducted on/after 30 days from issuance

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	6/Table of Contents
N	6/6.9/Medical Review of Diagnostic Tests
N	6/6.9.1/Medical Review of Diagnostic Laboratory Tests

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: 850	Date: December 14, 2018	Change Request: 10908

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I. GENERAL INFORMATION

A. Background: Chapter 6 of Pub. 100-08 contains instructions to medical review contractors on how to conduct medical review. This CR clarifies how medical review contractors should review orders for diagnostic laboratory test claims.

B. Policy: There are no regulatory, legislative, or statutory requirements related to this CR.

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	B	HHH	MAC	FISS	MCS	VMS	CWF	
10908.1	Contractors shall consider order requirements for diagnostic laboratory tests met if there is: 1. A signed order or signed requisition listing the specific test; or 2. An unsigned order or unsigned laboratory requisition listing the specific tests to be performed AND an authenticated medical record that supports the physician/practitioner's intent to order the	X	X	X						CERT, RAC, SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	tests (e.g. "order labs", "check blood", "repeat urine"); or 3. An authenticated medical record that supports the physician/practitioner's intent to order tests (e.g. "order labs, "check blood", "repeat urine"). See Pub. 100-08, chapter 3, section 3.3.2.4 for authentication requirements. See Pub. 100-08, chapter 3, section 3.3.2.4 for authentication requirements.									
10908.1.1	Contractors shall, regardless of how the order requirements are met, verify that the authenticated medical record contains sufficient information supporting the ordered/provided tests are reasonable and necessary per 42 CFR §410.32.	X	X	X						CERT, RAC, SMRC, UPICs

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

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): Marissa Petto, 212-616-2354 or marissa.petto@cms.hhs.gov , Nancy Allert, 410-786-4317 or Nancy.Allert@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 6 - Medicare Contractor Medical Review Guidelines for Specific Services

Table of Contents

(Rev.850, Issued: 12-14-18)

Transmittals for Chapter 6

6.9 – Medical Review of Diagnostic Tests
(Rev.850, Issued: 12-14-18; Effective: 12-17-18; Implementation: 12-17-18)

This section applies to MACs, RACs, UPICs, SMRC and CERT.

6.9.1 – Medical Review of Diagnostic Laboratory Tests
(Rev.850, Issued: 12-14-18; Effective: 12-17-18; Implementation: 12-17-18)

42 CFR §410.32 states that all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary and that tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

Pub. 100-02, Chapter 15, Section 80.6.1 states that while a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed.

Contractors shall consider order requirements for diagnostic laboratory tests met if there is:

1. *A signed order or signed requisition listing the specific test; or*
2. *An unsigned order or unsigned laboratory requisition listing the specific tests to be performed AND an authenticated medical record that supports the physician/practitioner's intent to order the tests (e.g. "order labs", "check blood", "repeat urine"); or*
3. *An authenticated medical record that supports the physician/practitioner's intent to order the specific tests.*

See Pub. 100-08, Chapter 3, Section 3.3.2.4 for authentication requirements.

Regardless of how the order requirements are met, contractors shall verify that the supporting authenticated medical record documentation contains sufficient information supporting the ordered/provided tests are reasonable and necessary per 42 CFR §410.32.

Note: As noted in Pub. 100-02, Chapter 15, Section 80.6.1, if the order is communicated via telephone, both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.