CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 657	**Date: June 17, 2016**
	Change Request 9670

SUBJECT: Special Provisions for Lab Additional Documentation Requests (ADRs)

I. SUMMARY OF CHANGES: This Change Request (CR) provides an update for the special provisions for lab ADRs.

EFFECTIVE DATE: July 18, 2016 *the date of service.*
IMPLEMENTATION DATE: July 18, 2016

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	3/3.2/ 3.2.3/3.2.3.7 - Special Provisions for Lab Additional Documentation Requests

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: 657	Date: June 17, 2016	Change Request: 9670

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EFFECTIVE DATE: July 18, 2016
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IMPLEMENTATION DATE: July 18, 2016

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services is updating Chapter 3, Subsection 3.2.3.7 (Special Provisions for Lab Additional Documentation Requests) of Pub. 100-08, by removing the following line: "The MACs, CERT and Recovery Auditors shall implement these requirements to the extent possible without shared systems changes."

As previously instructed in the Program Integrity Manual, the contractors deny the claim if a benefit category, statutory exclusion, or coding issue is in question, or send an ADR to the ordering provider in order to determine medical necessity. The contractor reviews the information from the lab before contacting the ordering provider and sends an ADR to the ordering physician that includes sufficient information to identify the claim in question.

B. Policy: 42 CFR section 410.32(d)

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	
9670.1	The contractors shall, when reviewing a lab service claim to determine if the lab service is medically necessary and reasonable, send an ADR to the ordering physician if needed.	X	X	X						RA, SMRC, ZPICs
9670.2	The MACs shall adjust their medical review strategy and medical review workloads as necessary to accommodate this change request, as no additional funding will be provided.	X	X	X						
9670.3	MACs shall describe any necessary workload changes in detail, including the rationale for these changes, to their Contracting Officer Representative and Medical	X	X	X						

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Review Business Function Lead.									

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:

"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): Andrea Glasgow, 410-786-4695

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

3.2.3.7 - Special Provisions for Lab Additional Documentation Requests
(Rev.657; Issued; 06-17-16 Effective: 07-18-16, Implementation: 07-18 - 16)

This section applies to MACs, CERT, Recovery Auditors, ZPICs, and SMRC as indicated.

ICD-10-CM is used for diagnoses on inpatient discharges and for other services provided upon implementation of ICD-10. ICD-9-CM is used for discharges and other services before that implementation.

When the MACs, CERT, Recovery Auditors and ZPICs send an ADR for a lab service, the following documentation shall be requested from the billing lab:

- The order for the service billed (including sufficient information to allow the reviewer to identify and contact the ordering provider);
- Verification of accurate processing of the order and submission of the claim; and
- Diagnostic or other medical information supplied to the lab by the ordering provider, including any diagnosis codes or narratives.

The contractor shall deny the claim if a benefit category, statutory exclusion, or coding issue is in question, or send an ADR to the ordering provider in order to determine medical necessity. The contractor shall review information from the lab and find it insufficient before the ordering provider is contacted. The contractor shall send an ADR to the ordering provider that shall include sufficient information to identify the claim in question.

If the documentation received does not demonstrate that the service was reasonable and necessary, the contractor shall deny the claim. These denials count as complex reviews. Contractor denial notices shall remind providers that beneficiaries cannot be held liable for these denials unless they have received proper liability notification before services were rendered, as detailed in CMS Pub. IOM 100-04, chapter 30.