CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11529	**Date: July 28, 2022**
	Change Request 12827

SUBJECT: Update of Chapter 3 in Publication (Pub.) 100-08, Including Update to Medicare Program Integrity Contractor Post-Payment Review Process, and Update of Chapter 8 Pub. 100-08, Including Revision to When Contractor Suspects Additional Improper Claims

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update a section within Chapter 3 in Pub. 100-08. The update in this CR includes updating the Medicare Program Integrity Contractor post-payment review process, specifically advising the contractor to document when they are unable to complete a post-payment medical review in 60 days. Additionally, a section within Chapter 8 in Pub. 100-08 is being revised to remove guidance that is no longer relevant.

EFFECTIVE DATE: August 30, 2022
**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: August 30, 2022
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	3/3.3/3.3.1.1/Medical Record Review
R	8/8.3/8.3.2.7/Contractor Suspects Additional Improper Claims

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 Instructions

Attachment - Business Requirements

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I. GENERAL INFORMATION

A. Background: The CMS will revise various sections in Chapter 3 and Chapter 8 in Pub. 100-08 based on updates to the Unified Program Integrity Contractor (UPIC) and Investigations Medicare Drug Integrity Contractor processes.

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	B	HHH	MAC	FISS	MCS	VMS	CWF	
12827.1	The contractor shall document in the Unified Case Management Systems (UCM) when they are unable to complete a post-payment medical review within 60 days.									UPICs
12827.1.1	The contractor shall document the reason for the delay in the UCM when they are unable to complete a post-payment									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	medical review within 60 days.									

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): Jesse Havens, 410-786-6566 or jesse.havens@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 3 - Verifying Potential Errors and Taking Corrective Actions

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(Rev. 11529; Issued:07-28-2022)

3.3.1.1 - Medical Record Review

(Rev. 11529; Issued: 07-28-2022; Effective: 08-30-2022; Implementation: 08-2022)

This section applies to MACs, CERT, RACs, Supplemental Medical Review Contractor(s) and UPICs, as indicated.

A. Definition

Medical record review involves requesting, receiving, and reviewing medical documentation associated with a claim.

Medical record review, for the purpose of determining medical necessity, requires a licensed medical professional to use clinical review judgment to evaluate medical record documentation.

B. Clinical Review Judgment

Clinical review judgment involves two steps:

1. The synthesis of all submitted medical record information (e.g. progress notes, diagnostic findings, medications, nursing notes, etc.) to create a longitudinal clinical picture of the patient; and

2. The application of this clinical picture to the review criteria is to make a reviewer determination on whether the clinical requirements in the relevant policy have been met. MAC, CERT, RAC, and UPIC clinical review staff shall use clinical review judgment when making medical record review determinations about a claim.

   Clinical review judgment does not replace poor or inadequate medical records. Clinical review judgment by definition is not a process that MACs, CERT, RACs and UPICs can use to override, supersede or disregard a policy requirement. Policies include laws, regulations, the CMS' rulings, manual instructions, MAC policy articles attached to an LCD or listed in the Medicare Coverage Database, national coverage decisions, and local coverage determinations.

C. Credentials of Reviewers

The MACs, MRAC, and CERT shall ensure that medical record reviews for the purpose of making coverage determinations are performed by licensed nurses (RNs), therapists or physicians. Current LPNs may be grandfathered in and can continue to perform medical record review. The MACs, MRAC, and CERT shall not hire any new LPNs to perform medical record review. UPICs, RACs and the SMRC shall ensure that the credentials of their reviewers are consistent with the requirements in their respective SOWs.

During a medical record review, nurse and physician reviewers may call upon other health care professionals (e.g., dieticians or physician specialists) for advice. The MACs, MRAC, and CERT, shall ensure that services reviewed by other licensed health care professionals are within their scope of practice and that their MR strategy supports the need for their specialized expertise in the adjudication of particular claim type (i.e., speech therapy claim, physical therapy). RACs and the SMRC shall follow guidance related to calling upon other healthcare professionals as outlined in their respective SOWs.

RACs shall ensure that a licensed medical professional will perform medical record reviews for the purpose of determining medical necessity, using their clinical review judgment to evaluate medical record documentation. Certified coders will perform coding determinations.

CERT and MACs are encouraged to make coding determinations by using certified coders. UPICs have the discretion to make coding determinations using certified coders.

D. Credential Files

The MACs, MRAC, CERT, RACs, and UPICs shall maintain a credentials file for each reviewer (including consultants, contract staff, subcontractors, and temporary staff) who performs medical record reviews. The credentials file shall contain at least a copy of the reviewer's active professional license.

E. Quality Improvement (QI) Process

The MACs, CERT, RACs, and SMRCs shall establish a Quality Improvement (QI) process that verifies the accuracy of MR decisions made by licensed health care professionals. The MACs, CERT, RACs, and SMRCs shall attend the annual medical review training conference as directed by the CMS and/or their SOW. The MACs, CERT, RACs, and SMRCs shall include inter-rater reliability assessments in their QI process and shall report these results as directed by CMS.

F. Advanced Beneficiary Notice (ABN)

The MACs, CERT, RACs, UPICs, and SMRCs shall request as part of the ADR, during a medical record review, a copy of any mandatory ABNs, as defined in Pub. 100- 04, Medicare Claims Processing Manual Chapter 30 section 50.3.1. If the claim is determined not to be reasonable and necessary, the contractor will perform a face validity assessment of the ABN in accordance with the instructions stated in Pub. 100-04 Medicare Claims Processing Manual chapter 30 section 50.6.3.

The Face Validity assessments do not include contacting beneficiaries or providers to ensure the accuracy or authenticity of the information. Face Validity assessments will assist in ensuring that liability is assigned in accordance with the Limitations of Liability Provisions of section 1879 of the Social Security Act.

G. MAC Funding Issues

The MAC-medical record review work performed by medical review staff for purposes other than MR (e.g., appeals) shall be charged, for expenditure reporting purposes, to the area requiring medical review services.

All medical record review work performed by MACs shall:

- Involve activities defined under the Medicare Integrity Program (MIP) at Section 1893(b)(1) of the Act;
- Be articulated in its medical review strategy; and
- Be designed in such a way as to reduce its Comprehensive Error Rate Testing (CERT) error rate or prevent the contractor's error rate from increasing.

The MACs shall be mindful that edits suspending a claim for medical review to check for issues other than inappropriate billing (i.e. completeness of claims, conditions of participation, quality of care) are not medical review edits as defined under Section 1893(b)(1) of the Act and cannot be funded by MIP. Therefore, edits resulting in work other than that defined in Section1893 (b) (1) shall be charged to the appropriate Program Management activity cost center. Activities associated with claims processing edits shall not be charged to MIP.

H. Review Timeliness Requirements

Prepayment Review Requirements for MACs

When a MAC receives requested documentation for prepayment review within 45 calendar days of the date of the ADR, the MAC shall do the following within 30 calendar days of receiving the requested documentation: 1) make and document the review determination and 2) enter the decision into the Fiscal Intermediary Shared System (FISS), Multi-Carrier System (MCS), or the VIPS Medicare System (VMS). The 30 calendar day timeframe applies to prepayment non-medical record reviews and prepayment medical record reviews. The 30 calendar day timeframe does not apply to prepayment reviews of Third Party Liability claims. The MACs shall make and enter a review determination for Third Party Liability claims within 60 calendar days.

Counting the 30 Calendar Day Timeframe

The MACs and RACs shall count day one as the date each new medical record is received in the mailroom. The MACs and RACs shall give each new medical record received an independent 30 day review time period.

Prepayment Review Requirements for UPICs

When a UPIC receives all documentation requested for prepayment review within 45 calendar days of the date of the ADR, the UPIC shall make and document the review determination and notify the MAC of its determination within 60 calendar days of receiving all requested documentation. Medical review for the purpose of fraud, waste, or abuse requires 60 days to allow for the integration of information from the investigative process. This information may be a result of recent/concurrent investigative actions such as beneficiary/provider/supplier interviews, site visits and/or receipt of additional internal/external information.

Post-payment Review Requirements for MACs

The MAC shall make a review determination, and mail the review results notification letter to the provider within 60 calendar days of receiving the requested documentation.

For claims associated with any referrals to the UPIC for program integrity investigation, MACs shall stop counting the 60-day time period on the date the referral is made. The 60-day time period will be restarted on the date the MAC received requested input from the UPIC or is notified by the UPIC that the referral has been declined.

For claims sent to MR for reopening by the contractor appeals department, in accordance with Pub. 100-04, chapter 34, §10.3, begin counting the 60 days from the time the medical records are received in the MR department.

Post-payment Review Requirements for RACs

When a RAC receives requested documentation for review within 45 calendar days of the date of the ADR, the RAC shall do the following within 30 calendar days of receiving the requested documentation: 1) make and document the review determination, and 2) communicate the results to the provider.

State Laws that Affect Prepayment Review Timeliness Requirements

The MACs shall adhere to state laws that require an evidentiary hearing for the beneficiary before any denials are processed. The MAC shall review the claim within 30 days, allow the time required for the evidentiary hearing, and then continue with the processing of the claim on the next business day.

Post-payment Review Requirements for UPICs

To promote the timeliness of the investigative process, the UPICs shall complete post-payment medical review and provide the lead investigator with a final summary of the medical review findings that includes reference to the allegations being substantiated/not substantiated by medical review, reasons for denials, and any observations or trends noted within 60 calendar days, unless otherwise directed by CMS. The counting for the 60-day time period begins when all of the documentation is received by the UPIC. The UPIC shall have a HIPAA compliant process to receive this documentation that includes the application of the date the documents are received at the UPIC's designated mailing address for all methods described in section 3.2.3.5 of this chapter. The medical review unit shall communicate the medical review findings in a summary document to the investigative lead within 60 calendar days of receiving all of the requested documentation. Medical review for the purpose of fraud, waste, or abuse requires 60 days to allow for the integration of information from the investigative process. This information may be a result of recent/concurrent investigative actions such as beneficiary/provider/supplier interviews, site visits and/or receipt of additional internal/external information.

If the UPIC is unable to complete the post-payment medical review in 60 days, they shall *document this and the reason for the delay in the UCM, and* communicate this to their COR.

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Chapter 8 – Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation

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(Rev. 11529; Issued: 07-28-2022)

8.3.2.7 – Contractor Suspects Additional Improper Claims

(Rev. 11529; Issued: 07-28-2022; Effective: 08-30-2022; Implementation: 08-2022)

If the payment suspension is in the process of being terminated or has been terminated, and the UPIC believes that the provider will continue to submit noncovered, misrepresented, or potentially fraudulent claims, the UPIC shall consider implementing or recommending other actions as appropriate (e.g., education, prepayment review, revocation, a new suspension of payment).