CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13008	**Date: December 18, 2024**
	Change Request 13735

Transmittal 12897 issued October 17, 2024, is being rescinded and replaced by Transmittal 13008, dated December 18, 2024, to revise the effective and implementation dates and to correct the Types of Review table, under Section 3.3.1, to indicate Recovery Audit Contractors do not perform non-medical record reviews. All other information remains the same.

SUBJECT: Chapter 3 Revisions (Segment 1) in Publication (Pub.) 100-08 Program Integrity Manual (PIM)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide updates to Chapter 3 in Pub. 100-08 PIM which guides Contractors as they use medical review to determine provider compliance with Medicare coverage, coding, and billing rules.

EFFECTIVE DATE: January 17, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: No later than January 17, 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	3/TOC
R	3/3.1/Introduction
R	3/3.2/Overview of Prepayment and Post-Payment Reviews
R	3/3.2/3.2.1/Setting Priorities and Targeting Reviews
R	3/3.2/3.2.2/Provider Notice
R	3/3.2/3.2.2/3.2.2.1/ Maintaining Provider Information
R	3/3.2/3.2.3/ Requesting Additional Documentation During Prepayment and Postpayment Review
R	3/3.2/3.2.3/3.2.3.1/ Additional Documentation Requests (ADR)
R	3/3.2/3.2.3/3.2.3.2/Time Frames for Submission
R	3/3.2/3.2.3/3.2.3.3/ Third-Party ADR
R	3/3.2/3.2.3/3.2.3.4/ADR Required and Optional Elements
R	3/3.2/3.2.3/3.2.3.5/Acceptable Submission Methods for Responses to ADRs
R	3/3.2/3.2.3/3.2.3.6/Reimbursing Providers and Health Information Handlers (HIHs) for Additional Documentation
R	3/3.2/3.2.3/3.2.3.7/Special Provisions for Lab ADRs
R	3/3.2/3.2.3/3.2.3.8 - No Response or Insufficient Response to ADRs
R	3/3.2/3.2.3/3.2.3.9 - Reopening Claims with Additional Information or Denied due to Late or No Submission of Requested Information
R	3/3.2/3.2.3/3.2.3.10/Record Retention and Storage
R	3/3.2/3.2.4/Use of Claims History Information in Claim Payment Determinations
R	3/3.2/3.2.5/Targeted Probe and Educate (TPE)
R	3/3.3/Policies and Guidelines Applied During Review
R	3/3.3/3.3.1/Types of Review: Medical Record Review, Non-Medical Record Review, and Automated Review
R	3/3.3/3.3.1/3.3.1.1/ Medical Record Review
R	3/3.3/3.3.1/3.3.1.2/Non-Medical Record Review
R	3/3.3/3.3.1/3.3.1.3/Automated Review
R	3/3.3/3.3.2/3.3.2.1/Documents on Which to Base a Determination
R	3/3.3/3.3.2/3.3.2.1/3.3.2.1.1/Progress Notes and Templates
R	3/3.3/3.3.2/3.3.2.2/Absolute Words and Prerequisite Therapies
R	3/3.3/3.3.2/3.3.2.3/Mandatory Policy Provisions

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3/3.3/3.3.2/3.3.2.4/Signature Requirements
R	3/3.3/3.3.2/3.3.2.6/Psychotherapy Notes
R	3/3.3/3.3.2/3.3.2.7/Review Guidelines for Therapy Services

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: 13008	Date: December 18, 2024	Change Request: 13735

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SUBJECT: Chapter 3 Revisions (Segment 1) in Publication (Pub.) 100-08 Program Integrity Manual (PIM)

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I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide updates to Chapter 3 in Pub. 100-08 PIM which guides Contractors as they use medical review to determine provider compliance with Medicare coverage, coding, and billing rules.

II. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to update the PIM Chapter 3 to reflect current medical review contractors, processes, and regulations.

B. Policy: This CR does not involve any legislative or regulatory policies.

III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13735.1	Contractors shall conduct medical reviews in accordance with the updated Chapter 3 in Pub. 100-08 (PIM).	X	X	X	X					CERT, RAC, SMRC, UPICs

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

Pre-Implementation Contact(s): Jennifer Phillips, 410-786-1023 or jennifer.phillips@cms.hhs.gov , Alison Jenkins, 410-786-8813 or alison.jenkins@cms.hhs.gov

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

VII. 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

Table of Contents
(Rev. 13008; Issued: 12-18-24)

Transmittals for Chapter 3

3.1 – Introduction

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

A. Goals

This section applies to Medicare Administrative Contractors (MACs), *Recovery Audit Contractors (RACs),* Comprehensive Error Rate Testing (CERT), and *Supplemental Medical Review Contractor (SMRC)*, as indicated.

The MACs shall analyze claims to determine provider compliance with Medicare coverage, coding, and billing rules and take appropriate corrective action when providers are found to be non-compliant. The goal of MAC administrative actions is to correct the behavior in need of change and prevent future inappropriate billing. The priority for MACs is to minimize potential future losses to the Medicare Trust Funds through targeted claims review while using resources efficiently and treating providers and beneficiaries fairly.

For repeated infractions, MACs have the discretion to initiate progressively more severe administrative action, commensurate with the seriousness of the identified problem. (Refer to PIM chapter 3, §3.7.1). MACs shall *handle* serious problems using the most substantial administrative actions available, such as 100 percent prepayment review of claims. Minor or isolated inappropriate billing shall be remediated through provider notification or feedback with reevaluation after notification. When medical review (MR) notification and feedback letters are issued, the MAC MR staff shall ensure that Provider Outreach and Education (POE) staff has access to copies of the letters in case a provider requests further education or POE determines that future education is needed. While program savings are realized through denials of payment for inappropriate provider billing, the optimal result occurs when compliance is achieved and providers no longer incorrectly code or bill for non-covered services.

The Medicare Fee-*for*-Service *(FFS)* Recovery Audit program is a legislatively mandated program (Tax Relief and Health Care Act of 2006) that utilizes *RACs* to identify improper payments paid by Medicare to *FFS* providers. The *RACs* identify the improper payments, and the MACs adjust the claims, recoup identified overpayments and return underpayments.

MAC, CERT*, SMRC,* and *RAC* staff shall not expend Medicare Integrity Program (MIP)/ MR resources analyzing provider compliance with Medicare rules that do not affect Medicare payment. Examples of such rules include violations of conditions of participation (COPs), or coverage or coding errors that do not change the Medicare payment amount.

The COPs define specific quality standards that providers shall meet to participate in the Medicare program. A provider's compliance with the COPs is determined by the CMS Regional Office (RO) based on the State survey agency recommendation. If during a review, any contractor believes that a provider does not comply with conditions of participation, the reviewer shall not deny payment solely for this reason. Instead, the contractor shall notify the RO and the applicable State survey agency.

When a potential underpayment or overpayment is identified, certain steps are normally followed to determine if a payment error exists. These steps are referred to as the claims development process. The reviewer generally does the following:

- Investigates the claims and associated documentation;
- Performs appropriate research regarding liability, benefit categories, statutory requirements, etc.;
- Determines if a payment error exists and the nature of the error;
- Notifies the beneficiary and provider/supplier; and

- Starts the payment reconciliation process.

B. New Provider/New Benefit Monitoring

This section applies to the MACs.

The MACs shall analyze data to identify patterns of billing aberrancies of providers new to the Medicare program. The MACs have the option of performing prepayment or post-payment review of claims submitted by new providers as needed. The CMS encourages the MACs to perform these reviews on a prepayment basis to have the greatest chance of identifying and reducing the error rate of new providers. When MACs review the claims of a new provider, the MACs shall perform a limited review of generally 20-40 claims in order to evaluate accurate billing.

The MACs shall also monitor for provider use of new statutory benefits and to ensure correct coverage, coding, and billing from the beginning. New benefit edits shall continue until the MAC is satisfied that the new benefits are being used and billed appropriately or until the MAC determines that resources would best be spent on other types of review.

3.2 – Overview of Prepayment and Post-payment Reviews

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs, CERT, RACs, SMRC, and Unified Program Integrity Contractors (UPICs), as indicated.

A. Prepayment and Post-payment Review

Prepayment review occurs when a reviewer makes a claim determination before claim payment has been made. Prepayment review always results in an "initial determination". Post-payment review occurs when a reviewer makes a claim determination after the claim has been paid. Post-payment review results in either no change to the initial determination or a "revised determination" indicating that an overpayment or underpayment has occurred.

B. Prepayment Edit Capabilities

Prepayment edits shall be able to key on a beneficiary's Medicare beneficiary identifier (*MBI*), National Provider Identifier (NPI) and specialty code, service dates, and diagnosis or procedure code(s) (i.e., Healthcare Common Procedure Coding System [HCPCS] and/or International Classification of Diseases diagnoses codes), Type of Bill (TOB), revenue codes, occurrence codes, condition codes, and value codes.

The MAC systems shall be able to select claims for prepayment review using different types of comparisons. At a minimum, those comparisons shall include:

- Procedure to Procedure -permits contractor systems to screen multiple services at the claim level and in history.
- Procedure to Provider - permits selective screening of services that need review for a given provider.
- Frequency to Time- permits contractors to screen for a certain number of services provided within a given time period.
- Diagnosis to Procedure- permits contractors to screen for services submitted with a specific diagnosis. For example, the need for a

vitamin B12 injection is related to pernicious anemia, absent of the stomach, or distal ileum. Contractors must be able to establish edits where specific diagnosis/procedure relationships are considered to qualify the claim for payment.

- Procedure to Specialty Code or TOB- permits contractors to screen services provided by a certain specialty or TOB.

- Procedure to Place of Service- permits selective screening of claims where the service was provided in a certain setting such as a comprehensive outpatient rehabilitation facility *(CORF)*.

Additional MAC system comparisons shall include, but are not limited to the following:

- Diagnoses alone or in combination with related factors.

- Revenue linked to the health care common procedure coding system (HCPCS).

- Charges related to utilization, especially when the service or procedure has an established dollar or number limit.

- Length of stay or number of visits, especially when the service or procedure violates time or number limits.

- Specific providers alone or in combination with other parameters.

The MR edits are coded system logic that either automatically pays all or part of a claim, automatically denies all or part of a claim, or suspends all or part of a claim so that a trained clinician or claims analyst can review the claim and associated documentation (including documentation requested after the claim is submitted) in order to make determinations about coverage and payment under Section 1862(a) (1) (A) of the Act.

Namely, the claim is for a service or device that is medically reasonable and necessary to diagnose or treat an injury or improve the functioning of a malformed body member. All non-automated review work resulting from MR edits shall:

- Involve activities defined under the MIP at §1893(b)(1) of the Act;

- Be articulated in the MAC's medical review strategy;

- Be designed in such a way as to reduce the MAC's CERT error rate or prevent the MAC's CERT error rate from increasing, or;

- Prevent improper payments identified by the RACs.

3.2.1 – Setting Priorities and Targeting Reviews

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs and *RACs,* as indicated. *RACs* perform targeted reviews consistent with their statements of work (SOWs).

The MACs have the authority to review any claim at any time, however, the claims volume of the Medicare Program doesn't allow for review of every claim. 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. This requires establishing a priority setting process to *ensure* MR focuses on areas with the greatest potential for improper payment.

The MACs shall develop a problem-focused, outcome-based MR strategy that defines what risks to the Medicare *T*rust *F*und the MAC's MR programs will address and the interventions that will be implemented during the fiscal/option year as addressed in PIM chapter 7.

The MACs shall focus their edits where the services billed have significant potential to be non-covered or incorrectly coded. Medical review staff may decide to focus review on problem areas that demonstrate significant risk to the Medicare program as a result of inappropriate billing or improper payments. The MACs shall have in place a program of systematic and ongoing analysis of claims and data from *RACs* and CERT, among other sources, in order to focus intervention efforts on the most significant errors.

The MACs shall initiate a targeted provider-specific prepayment review only when there is the likelihood of sustained or high level of payment error. MACs are encouraged to initiate targeted service-specific prepayment review to prevent improper payments for services identified by CERT or *RACs* as problem areas, as well as, problem areas identified by their own data analysis.

The MACs have the discretion to select target areas because of:

- High volume of services;
- High cost;
- Dramatic change in frequency of use;
- High risk problem-prone areas; and/or,
- *RAC,* CERT, Office of Inspector General (OIG) or Government Accounting Office (GAO) data demonstrating vulnerability. Probe reviews are not required when targeted areas are based on data from these entities.

*T*o identify the claims most likely to contain improper billing, MACs are encouraged to use prepayment and post-payment screening tools or natural language coding software. MACs shall not deny a payment for a service simply because the claim fails a single screening tool criterion. Instead, the reviewer shall make an individual determination on each claim. MACs have the discretion to post the screening tools in use *on* their *website* or otherwise disclose to the provider community. *RACs* shall use screening tools and disclose their use to the provider community consistent with the requirements in their statements of work (SOWs).

MACs and *RACs* shall NOT target a provider for review solely based on the provider's preferred method of maintaining or submitting documentation. For example, a MAC or *RAC* shall NOT choose a provider for review based only on the fact that the provider uses an electronic health record or responds to documentation requests using the Electronic Submission of Medical Documentation (esMD) mechanism. (More information about esMD can be found in Section (3.2.3.5)

3.2.2 - Provider Notice

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs, RACs, UPICs, and SMRC as indicated.

Because the CERT contractors select claims on a random basis, they are not required to notify providers of their intention to begin a review.

Providers may submit unsolicited documentation to the MAC when submitting a claim *for*

payment. Providers are to list the PWK 02 Report Transmission Code (PWK (paperwork) modifier) on the claim when submitting this documentation. MACs should inform the providers that they are NOT required to submit unsolicited documentation (and the corresponding PWK modifier) and that the absence or presence of PWK modifier does not mean that their claim will be reviewed. MACs should, at their discretion, consider posting to their website or sending letters to providers informing them of what additional documentation is needed to make a determination on the claim.

A. Notice of Provider-Specific Review

When MAC data analysis indicates that a provider-specific potential error exists that cannot be confirmed without requesting and reviewing documentation associated with the claim, the MAC shall review a sample of representative claims. Before deploying significant medical review resources to examine claims identified as potential problems through data analysis, MACs shall take the interim step of selecting a small "probe" sample of generally 20-40 potential problem claims (prepayment or post-payment) to validate the hypothesis that such claims are being billed in error. This ensures that medical review activities are targeted at identified problem areas. The MACs shall ensure that such a sample is large enough to provide confidence in the result, but small enough to limit administrative burden. The CMS encourages the MACs to conduct error validation reviews on a prepayment basis to help prevent improper payments.

MACs shall select providers for error validation reviews in the following instances, at a minimum:

- The MAC has identified questionable billing practices (e.g., non-covered, incorrectly coded or incorrectly billed services) through data analysis;
- The MAC receives alerts from other MACs, Quality Improvement Organizations (QIOs), CERT, RACs, OIG/GAO, or internal/external components that warrant review;
- The MAC receives complaints; or,
- The MAC validates the items bulleted in §3.2.1.

Provider-specific error validation reviews are undertaken when one or a relatively small number of providers seem to be experiencing similar/recurrent problems with billing. The MACs shall document their reasons for selecting the provider for the error validation review. In all cases, they shall clearly document the issues noted and cite the applicable law, published *NCD or LCD*.

For provider-specific problems, the MAC shall notify providers in writing that a probe sample review is being conducted. MACs shall consider sending letters to providers informing them of what additional documentation is needed to make a determination on the claim.

Generally, MACs shall subject a provider to no more than one probe review at any time; however, MACs have the discretion to conduct multiple probes for very large billers *if* they will not constitute undue administrative burden.

MACs

The MACs shall notify selected providers prior to beginning a provider-specific review by

sending an individual written notice. MACs shall indicate whether the review will occur on a prepayment or post-payment basis. This notification may be issued via certified letter with return receipt requested. MACs shall notify providers of the specific reason for selection. If the basis for selection is comparative data, MACs shall provide the data on how the provider varies significantly from other providers in the same specialty, jurisdiction, or locality. Graphic presentations help to communicate the perceived problem more clearly.

RACs

The RACs are required to post a description of all approved new issues *(review topics)* to the RAC's *website* before *beginning review of the topic and* correspondence is sent to the provider. After posting, the RAC should issue an additional documentation request (ADR) to the provider, if warranted.

UPIC*s*

The UPICs shall notify selected providers prior to beginning a provider-specific review by sending an individual written notice. UPICs shall indicate whether the review will occur on a prepayment or post-payment basis. UPICs shall maintain a copy of the letter and the date it was mailed. This notification shall be mailed the same day that the edit request is forwarded to the MAC. Refer to Exhibit 45 for the letter to be sent.

B. Notice of Service-Specific Review

This section applies to MACs, RACs and SMRC as indicated.

Service-specific reviews are undertaken when the same or similar problematic process is noted to be widespread and affecting one type of service (e.g., providing tube feedings to home health beneficiaries across three (3) states).

MACs

Website **postings**

The MACs shall provide notification prior to beginning a service-specific review by posting a review description on their *website*. MACs should, at their discretion, state what additional documentation is needed from providers to make a claim determination on their *website*. MACs shall keep the *website* current by posting active reviews.

MACs should, at their discretion, create an archive for old review topics that are no longer under active review. Active review is defined as the time period during which ADRs are sent, determinations are made and findings are communicated to the providers. MACs should categorize the active review topics by provider type.

Individual written notices

MACs have the discretion to also notify providers about a service-specific review by sending individual notices to the affected providers. MACs have the discretion to issue the notice separately or include it in the ADR. MACs should, at their discretion, state what additional documentation is needed from providers to make a claim determination in the written notices.

RACs

Before beginning widespread service-specific reviews, RACs shall notify the provider community that the RAC intends to initiate review of certain items/services through a posting

on the RAC *website* describing the item/service that will be reviewed.

Additionally, for medical record reviews, the RACs shall send ADRs to providers that clearly articulate the items or services under review and indicate the appropriate documentation to be submitted.

UPIC*s*

The UPICs shall provide notification prior to beginning a service-specific review by sending individual written notices to the affected providers. This notification shall be mailed the same day that the edit request is forwarded to the MAC. The UPICs shall maintain a copy of the letter and the date it was mailed. Refer to Exhibit 45 for the letter to be sent.

SMRC

The SMRC shall operate/maintain a public *website* that displays what types of issues are under review. For each area, the SMRC shall include a link to the relevant OIG/GAO or other reports available. In addition to the *website*, the SMRC shall notify providers about a service-specific review by sending an ADR. The SMRC shall state what additional documentation is needed from providers to make a claim determination in the ADR.

3.2.2.1 - Maintaining Provider Information

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MAC.

A. Provider Tracking System (PTS)

The MACs shall have a PTS in place to identify and track all individual providers currently under action plans to correct identified problems, such, as not reasonable and necessary, incorrect coding, and inappropriate billing. MACs shall use the PTS to coordinate contacts with providers such as MR notifications, telephone calls directly related to probe reviews, and referrals to POE. The MACs shall ensure that if a provider is to be contacted as a result of more than one problem, redundant contacts are minimized. The MACs shall also coordinate corrective action information with the UPICs to ensure contacts are not in conflict with benefit integrity related activities. The MAC PTS shall contain the date a provider is put on a provider- specific edit. The MAC shall reassess all providers on provider-specific prepayment or post-payment review on a quarterly basis to determine whether the behavior has improved. The MAC shall note the results of these quarterly assessments in the PTS. If the behavior has improved sufficiently and the edit was turned off, note that date as well in the PTS. When a MAC becomes aware that the provider has appealed a medical review determination to an Administrative Law Judge (ALJ), the MAC should send a letter to the ALJ and describe the information in the PTS to demonstrate the corrective actions that have been taken by the MAC.

B. *RAC* Case Files

The *RAC* shall maintain case files following the guidelines in the *RAC* SOW.

C. Provider Addresses

This section applies to MACs, CERT, and *RACs*, as indicated.

The MACs, CERT*, SMRC,* and *RACs* shall mail the ADR to the best-known address for the provider. MACs are encouraged to indicate the procedure a provider can follow to update

address information in their ADRs and on their *websites*. If a provider wishes to have ADRs sent to one address but demand letters sent to a different address, MACs are encouraged to accommodate this request.

Note: Providers and suppliers must complete and submit a Medicare enrollment application (either the paper CMS-855 or a submission via Internet-based Provider Enrollment, Chain & Ownership [PECOS] to change existing information in the Medicare enrollment record.)

D. When the Provider or Supplier No Longer Occupies a Physical Address

This section applies to MACs, *RACs, SMRC,* and UPICs, as indicated.

When the MACs*, RACs, SMRC,* and UPICs become aware that the provider or supplier no longer occupies a physical address, any future correspondence shall reference only the claim control numbers and not list the individual beneficiary data (e.g., names and Medicare beneficiary identifiers). This process is contingent on current automated system limits.

The following are situations where the *Contractors* can assume the provider or supplier no longer occupies the last known location. This list is not exhaustive and the *Contractors* should use other means to confirm addresses, at their discretion.

- The *Contractors* receive mail that has been returned by the post office indicating no known address;
- An onsite visit has confirmed the address is vacant or is occupied by another occupant; or,
- A beneficiary complaint(s) is on record stating the provider or supplier is no longer at the address and follow up confirms the complaint.

In the above situations, correspondence from the *Contractors* shall only contain the claim control number and advise the provider or supplier to contact them for a list of the specific claims associated with the overpayment. This process will prevent the potential compromise of Medicare beneficiary names and/or Medicare beneficiary identifiers being sent to an abandoned address (or a location with a new occupant). If the letter is returned from the post office, maintain the notification on file for evidence.

3.2.3 - Requesting Additional Documentation During Prepayment and Post-payment Review

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs, CERT, RACs, and UPICs, as indicated.

A. General

In *many instances*, the MACs, CERT, RACs, *SMRC,* and UPICs may not be able to make a determination on a claim they have chosen for review based upon the information on the claim, its attachments, or the billing history found in claims processing system (if applicable) or the Common Working File (CWF). In those instances, the reviewer shall solicit documentation from the provider or supplier by issuing an additional documentation request (ADR). The term ADR refers to all documentation requests associated with prepayment review and post-payment review. MACs, CERT, RACs, *SMRC,* and UPICs have the discretion to collect documentation related to the beneficiary's condition before and after a service to get a more complete picture of the beneficiary's clinical condition. The MAC,

RAC, *SMRC,* and UPIC shall not deny other claims submitted before or after the claim in question unless appropriate consideration is given to the actual additional claims and associated documentation. The CERT contractor shall solicit documentation in those circumstances in accordance with its Statement of Work (SOW).

The term "additional documentation" refers to medical documentation and other documents such as supplier/lab/ambulance notes and includes:

- Clinical evaluations, physician evaluations, consultations, progress notes, physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation is maintained by the physician and/or provider.

- Supplier/lab/ambulance notes include all documents that are submitted by suppliers, labs, and ambulance companies in support of the claim (e.g., Certificates of Medical Necessity, supplier records of a home assessment for a power wheelchair).

- Other documents include any records needed from a biller to conduct a review and reach a conclusion about the claim.

B. Authority to Collect Medical Documentation

Contractors are authorized to collect medical documentation by the Social Security Act.

Section 1833(e) states "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period." Section 1815(a) states "…no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period." *In addition, Contractors are required to ensure that payment is limited to those items and services that are reasonable and necessary. Section 1862(a)(1)(A) of the Act states that "[n]ot withstanding any other provision of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services — which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."*

Contractors are required, when authoring correspondence related to ADRs, to cite sections 1815(a), 1833(e), and 1862(a)(1)(A) of the Act exclusively when referring to the authority for requiring submission of documentation.

The OMB Paperwork Reduction Act collection number for prepayment medical review is 0938-0969. MACs shall use this number on every additional documentation request or any other type of written request for additional documentation for prepayment medical review. It can be in the header, footer or body of the document. CMS suggests the information read "OMB #: 0938-0969" or OMB Control #: 0938-0969." Post-payment medical review does not require an OMB control number.

C. PWK (Paperwork) Modifier

Providers and suppliers have the option to follow the PWK process to voluntarily send in

additional documentation before the MAC requests such documentation. MAC medical review departments are only required to review unsolicited documentation when the claim suspends for a medical review edit/audit. MACs shall not send an ADR request for a claim with a PWK modifier until after review of the PWK unsolicited documentation or the waiting days have elapsed without receipt of documentation.

MACs shall allow 7 calendar "waiting days" (from the date of receipt of the claim) for additional unsolicited documentation to be submitted or 10 calendar "waiting days" for the unsolicited documentation to be mailed. Contractors serving island territories shall have the flexibility to adjust "waiting days" as is necessary. CMS expects that any adjustment from the core 7/10 days will be discussed with and approved by your contracting officer prior to implementation. If the contractor cannot make a determination on the claim after reviewing the unsolicited documentation submitted, they shall request additional documentation using their normal business procedures for ADR*s*.

3.2.3.1 - Additional Documentation Requests (ADR)

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

In most reviews, the MACs, CERT, RACs, SMRC, and UPICs are unable to make a determination on prepayment or post-payment claims they have chosen for review based upon the information on the claim, its attachments, or the billing history found in claims processing system (if applicable) or the Common Working File (CWF). In those instances, the reviewer shall solicit documentation from the provider or supplier by issuing an ADR.

The MACs, CERT, *RACs, SMRC,* and UPICs shall specify in the ADR only those individual pieces of documentation needed to make a determination. When reviewing documentation, the reviewer shall give appropriate consideration to all documentation that is provided in accordance with other sections of this manual.

The MACs, RACs*, and SMRC* shall also support soliciting documentation from the provider or supplier via Electronic Submission of Medical Documentation (esMD). The contractors shall send an Electronic Medical Documentation Request (eMDR) via esMD to those providers/suppliers that have registered to receive the request electronically. The contractors are encouraged to explore other ways to send eMDRs electronically (*e.g.,*, using direct exchange, clearinghouses, state Health Information Exchange (HIEs)).

Providers interested in submitting documentation via esMD can find information on the CMS esMD website at http://www.cms.gov/esMD.

3.2.3.2 - Time Frames for Submission

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

A. Prepayment Review Time Frames

When requesting documentation for prepayment review, the MACs and UPICs shall notify providers when they expect documentation to be received. *Per 42 CFR § 405.903, providers and suppliers have 45 calendar days to submit additional documentation in response to a MAC, RAC, or SMRC request. Providers and suppliers have 30 calendar days to respond to a UPIC request.*

Contractors may accept documentation received after the 45 and 30-calendar day (for UPICs) time frames for good cause. Good cause means situations such as natural disasters,

interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation. Per 42 CFR § 405.930, reviewers shall deny claims when the requested documentation to support payment is not received by the expected *time frame*.

B. Post-payment Review Time Frames

When requesting documentation for post-payment review, the MACs, CERT, SMRC, UPICs and RACs shall notify providers when they expect documentation to be received. *Per 42 CFR § 405.929, providers and suppliers have 45 calendar days to submit additional documentation in response to a MAC, RAC, SMRC or CERT request. Providers and suppliers have 30 calendar days to respond to a UPIC request. Contractors may accept documentation received after the 45 and 30-calendar day (for UPICs) time frames for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.*

Per 42 CFR § 405.930, contractors shall deny claims when the requested documentation to support payment is not received by the expected time frame (including any applicable extensions).

C. For esMD submissions

The esMD review contractor shall use the *esMD Cloud* system receipt date as the date the documentation was received. If the *esMD Cloud* receipt date is outside of the contractors normal business hours, the following business day shall be used as the receipt date. Contractors shall pull for esMD files *and latest transaction status* at least every 4 hours (business hours) daily; including a mandatory pulling between the hours of 6-7pm EST daily. If unforeseeable circumstances occur, in which contractors are not technically capable of retrieving documentation in a timely manner due to issues outside of their control, contractors are to notify the esMD Team and can use the date documentation was available to be retrieved once issues have been resolved in the *esMD Cloud* system.

3.2.3.3 - Third-party *ADR*

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

Unless otherwise specified, the MAC, CERT, SMRC, UPIC and RAC shall request information from the billing provider/supplier. The treating physician or other clinicians should provide any requested or relevant documentation. However, because the billing provider/supplier selected for review is the one whose payment is at risk, it is this billing provider/supplier who is ultimately responsible for submitting, within the established timelines, the documentation requested by the MAC, CERT, SMRC, UPIC and RAC.

The MAC, *CERT, SMRC,* UPIC and RAC have the discretion to send a separate ADR to third- party entities involved in the beneficiary's care. *For this purpose, third-party entities are other clinicians, providers, suppliers, etc. involved in the beneficiary's care but not submitting the associated claim for Medicare payment. A third-party entity is not a billing agent or agency. MACs, RACs and UPICs* shall not solicit documentation from a third-party *entity* unless they first or simultaneously solicit the same information from the billing provider or supplier. The following requirements also apply:

- The MACs, *SMRC*, and RACs shall notify the third-party *entity* and the billing provider or supplier *of the review timeframes in 3.2.3.2*. *For*

third party ADRs, the MACs shall allow 45-calendar days for the third-party entity to submit additional documentation (or 30-calendar days for UPIC claims), beginning with the date of the most recent ADR request (be it to the billing entity, or later, third party provider), before issuing a denial per 42 CFR § 405.930.

- *A contractor may accept documentation received after 45-calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.*

- The MACs and UPICs have the discretion to issue as many reminder notices as they deem appropriate to the third party via email, letter or phone call prior to the *documentation due date*, as discussed above;

- When information is requested from both the billing provider or supplier and a third-party and a response is received from one or both that fails to support the medical necessity of the service, the MACs*, SMRC,* and UPICs shall deny the claim, in full or in part, using the appropriate denial code.

- Refer to §3.2.3.7 for ADRs to ordering providers for lab services.

3.2.3.4 - *ADR* Required and Optional Elements

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to *MACs*, *RACs*, CERT, and SMRC, as indicated.

- The MAC*s, RACs, CERT, and SMRC* shall use discretion to ensure that the amount of medical documentation requested does not negatively impact the provider's ability to provide care.

- The *RACs* shall issue Additional Documentation Requests (ADR) in accordance with limits established by their Contracting Officer's Representative (COR) for each calendar year.

- The MACs, *RACs,* CERT, *and* SMRC, shall request records related to the claim(s) being reviewed and have the discretion to collect documentation related to the beneficiary's condition before and after a service.

- The MACs, *RACs*, and SMRC have the discretion to issue as many reminder notices as they deem appropriate. Reminder notices can be issued via email, letter, phone call, or equivalent method. *At a minimum, the RACs must follow reminder notice instructions prescribed by their SOWs.*

- The CERT shall issue reminder notices in accordance with its SOW.

- The MACs, *RACs*, and SMRC shall not target their ADRs to providers based solely on the provider's electronic health record status or chosen method of submitting records.

When requesting documentation for post-payment medical review, the MACs, CERT, SMRC and *RACs* shall use the unified post-payment ADR letter format. Contractors shall maintain the format of the letter but have the discretion to insert case-specific information. In other words, contractors shall not change the order of the sections on the letter but should modify the text underneath each section to provide detailed information and accurately reflect the

information specific to the subject of the letter. The detailed text in the Exhibit 46 templates serves only to provide an example of what types of information belong under each section heading. The templates show the format and order contractors shall use when constructing post-payment ADR letters.

If any of the elements are lengthy, contractors have the discretion to utilize an attachment to provide the details. If a contractor does not have attachments but has supplementary information to provide in the text of the letter, the contractor should insert the text beneath the section title "Attachments / Supplementary Information").

The MACs, *RACs,* CERT, *and* SMRC shall include the following elements in their ADRs and shall use the appropriate templates provided in Exhibit 46:

A. Introductory Paragraph

- CMS as the government agency making the request;
- The program making the request (e.g. the MAC program, the SMRC program, the Recovery Audit Program, the CERT program); and
- The regulations and/or laws that apply to the request.

The first paragraph in the ADR may identify the following:

- The program purpose;
- Where additional information about the program and regulations can be found, for example, a website reference; and
- Additional program information that may be helpful to the provider or supplier.

B. Reason for Selection

The reason the provider or supplier was sent the ADR letter and notes about the claims under review.

C. Action

The action(s) the provider or supplier shall take as a result of receiving the ADR letter.

D. When

The date a provider/supplier shall reply to the ADR letter and submit the documentation to the contractor.

E. Consequences

The consequences if the provider or supplier fails to submit the requested documentation.

F. Instructions

Instructions and notes that will help the provider or supplier respond to the ADR letter.

G. Submission Methods

The methods the provider or supplier can submit the requested documentation.

H. Questions

Contractor contact information for provider inquiries related to the ADR.

I. Attachments / Supplementary Information

- If there are attachments or other supplementary information associated with the ADR, provide a listing of the attachment titles or provide the supplementary information.

3.2.3.5 - Acceptable Submission Methods for Responses to ADRs

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

Reviewers shall be clear in their ADR letters about what documentation submission methods they will accept from a provider or Health Information Handler (HIH). The MACs, CERT, *SMRC* and *RACs* shall accept documents via paper, fax, CD/DVD, electronic submission of medical documentation (esMD), and contractor website portal.

A. Paper

The MACs, CERT, *SMRC,* and *RACs* are encouraged to state in the ADRs that paper medical documentation can be mailed by any means including US Postal Service, FedEx, UPS, or certified mail. To facilitate delivery of documentation, MACs, CERT, *SMRC,* and *RACs* should provide a physical mailing address instead of a P.O. Box.

B. Fax

If the MACs, CERT, *SMRC,* or *RACs* have the capability to offer fax confirmation, they are encouraged to send such confirmations with every successfully received fax.

C. Imaged Medical Documentation File(s) Sent on CD/DVD

The MACs*,* CERT *and SMRC* shall state in the ADR that imaged medical documentation files on CD/DVD may be mailed by any means. *RAC* ADRs shall provide a *website* link or phone number that provides information regarding the requirements for submitting imaged documentation on CD or DVD.

D. Medical Documentation Sent via Electronic Submission of Medical Documentation (esMD) Transmission

Electronic Submission of Medical Documentation (esMD) is a system that allows providers/HIHs to submit medical documentation over secure electronic means. Information about the esMD system can be found at www.cms.gov/esMD.

MACs*, SMRC,* and CERT are encouraged to state in their ADRs how providers can get more information about submitting medical documentation via the esMD mechanism.

Any time a new esMD service or document type is being offered, and any contractor wants to publish a public announcement (*website*, list serve, tweet, etc.) the contractor must clear the announcement with CMS

E. Contractor Website Portal

The MACs are encouraged to state in the ADRs that medical documentation can be submitted by this route.

3.2.3.6 - Reimbursing Providers and *Health Information Handlers (*HIHs*)* for Additional Documentation

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

A. General

1. Rules for MACs, SMRC, CERT, and UPICs

- The MACs, SMRC, CERT, and UPICs are not required to pay for medical documentation for either prepayment or post payment review.

2. Rules for RACs

- RACs performing post payment review of hospital inpatient prospective payment system (PPS) and long-term care facilities are required to pay the providers for submitting requested medical records. RACs shall pay according to the payment rate schedule listed in section B below.

- RACs performing post-payment review of provider types other than hospital inpatient PPS and long-term care facilities are required to pay the providers for submitting requested medical records, according to the payment rate schedule listed in section B below.

- Providers under a Medicare reimbursement system (such as Critical Access Hospitals) receive no reimbursement for submitting medical records.

- RACs shall pay a maximum of $15.00 per record, including first class postage if applicable, for requested documents submitted via mail/fax/CD/DVD.

- RACs shall pay a maximum of $27.00 per record, including a transaction fee of $2.00/case, for requested documents submitted via esMD.

- Payments will not be made for blank pages or documents/records that are not related to the claim being reviewed.

- RACs shall issue documentation submission payments on at least a monthly basis and shall issue all photocopying payments within 45 calendar days of receiving the documentation.

  RACs shall honor all requests from providers to issue photocopying payments to HIHs. RACs should gather, from the provider, all necessary information, such as, the HIH's name, phone number and bank routing number, etc.

- Providers interested in submitting documentation via esMD can find information on the CMS esMD website at http://www.cms.gov/esMD.

B. Payment Schedule for Requested Medical Records

	Hospital Inpatient Prospective Payment System (PPS) Facilities and Long Term Care Facilities	Non-PPS Institutions and Practitioners

Documentation sent via mail, fax, CD/DVD	- 12 cents per page - Plus first class postage, if applicable - $15.00 maximum per record	- 15 cents per page - Plus first class postage, if applicable - $15.00 maximum per record
Documentation sent via esMD	- 12 cents per page - Plus $2.00 transaction fee, per record - $27.00 maximum per record	- 15 cents per page - Plus $2.00 transaction fee, per case - $27.00 maximum per record

*Note: Providers under a Medicare reimbursement system (such as Critical Access Hospitals) receive no reimbursement for submitting medical records. Also, payments will not be made for blank pages or documents/records that are not related to the claim being reviewed.

3.2.3.7 - Special Provisions for Lab *ADRs*

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

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

When the MACs, CERT, RACs, *SMRC,* and UPICs 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 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 *are considered* medical record reviews. Contractor denial notices shall remind providers that beneficiaries cannot be held liable for these denials unless they received proper liability notification before services were rendered, as detailed in CMS Pub. IOM 100-04, chapter 30.

3.2.3.8 - No Response or Insufficient Response to *ADRs*

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

A. ADRs

The reviewer authority to request that documentation be submitted, to support claims payment, is outlined in Section 3.2.3.2 of this chapter.

If information is requested from both the billing provider or supplier and/or a third party and no response is received within the expected timeframes (or within a reasonable time following an extension), the MACs, RACs, SMRC, and UPICs shall deny the claim, in full or in part, as not reasonable and necessary. Contractors shall use:

- Claim Adjustment Group Code CO - Contractual Obligation;
- Claim Adjustment Reason Code (CARC) 50 - these are non-covered services because this is not deemed a "medical necessity" by the payer; and
- Remittance Advice Remark Code (RARC) M127 - Missing patient medical record for this service.

MACs shall count these denials as automated review or non-medical record review depending whether the denial is automated or requires manual intervention. For claims that had a PWK modifier, and the unsolicited documentation was reviewed, the review shall be counted as medical record review.

B. No Response

During prepayment review, if no response is received within the expected timeframes, the MACs and UPICs shall deny the claim *in accordance with 42 CFR §§ 405.903 and 405.930*.

During post-payment review, if no response is received within the expected timeframes (or extension), the MACs, RACs, UPICs and SMRC shall deny the claim as not reasonable and necessary. These contractors shall cite sections 1815(a), 1833(e), and 1862(a)(1)(A) of the Act*, as well as 42 CFR §§405.929 and 405.930,* when referring to the authority for requiring submission of documentation *and* denying claims for no response within the expected timeframes. The MACs shall count these denials as non-medical record reviews.

C. Insufficient Response

If the MAC, CERT, RAC, SMRC, or UPIC requests additional documentation to verify compliance with a benefit category requirement, and the submitted documentation lacks evidence that the benefit category requirements were met, the reviewer shall issue a benefit category denial. If the submitted documentation includes defective information (the documentation does not support the physician's certification), the reviewer shall deny the claim as not meeting the reasonable and necessary criteria.

3.2.3.9 - Reopening Claims with Additional Information or Denied due to Late or No Submission of Requested Information

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

Contractors shall make available general reopening process information via their website, in their ADR letters, or through remittance advice notices.

If the MACs receive the requested information from a provider or supplier after a denial has been issued but within a reasonable number of days (generally 15 calendar days after the denial date), they have the discretion to reopen the claim. MACs who choose to reopen a specific claim shall notify the provider or supplier of their intent to reopen that claim. Notification to the provider/supplier of the intent to reopen a specific claim shall be

completed through any of the following mechanisms: Interactive Voice Response (IVR), contractor website portal, telephone contact, by letter, fax, email or secure messaging within 3 business days of identification of the request to reopen or receipt of medical record documentation. MR will make an MR determination on the lines previously denied due to failure to submit requested documentation, and do one of the following, within 60 calendar days of receiving documentation in the mailroom:

- For claims originally selected for post-payment review, the reviewer shall issue a new letter containing the revised denial reason and the information required by PIM chapter 3 §3.6.4;

- For claims originally selected for prepayment review, the MAC shall enter the revised MR determination into the shared system, generating a new Medicare Summary Notice (MSN) and remittance advice with the new denial reason and appeals information;

- The workload, costs, and savings associated with this activity shall be allocated to the appropriate MR activity (e.g., MR reopenings);

In cases where the MAC or UPIC denied a claim and the denial is appealed, the appeals entity will send the claim to the contractor's MR department for reopening in accordance with CMS Pub. IOM 100-04, chapter 34, § 10.3. The claim sent back to the contractor's MR department must have been denied using Group Code: CO - Contractual Obligation and Claim Adjustment Reason Code (CARC) 50 - these are non-covered services because this is not deemed a "medical necessity" by the payer and Remittance Advice Remark Code (RARC) M127 - Missing patient medical record for this service.

The MR department of the contractor (MAC, or UPIC) who initiated the prepayment edit shall be responsible for conducting the reopening.

- The MACs who choose not to reopen claims when documentation is received past the deadline shall retain the information (hardcopy or electronic) in a location where it can be easily accessed.

If the RAC receives requested documentation from a supplier after a denial has been issued they shall not reopen the claim.

- If a RAC receives documentation after the submission deadline, but before they have issued a demand letter, the RAC shall review and consider the late documentation when making a claim determination;

- If the RAC receives a late response to a documentation request after they have issued a demand letter, the RAC shall retain the documentation so that it is available for review during the appeal process.

For information on how CERT handles late documentation, please refer to Chapter 12, Section *11 Late Documentation Received by the CERT Review Contractor*.

3.2.3.10 - Record Retention and Storage

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

The MACs, CERT, and UPICs shall abide by all documentation retention requirements listed in all litigation holds issued via Joint Signature Memoranda or Technical Direction Letters (JSM/TDL). *RACs* shall comply with the record retention requirements in its SOWs.

3.2.4 - Use of Claims History Information in Claim Payment Determinations

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

A. Contractors to Which This Section Applies

This section applies to MACs, CERT, SMRC, *UPIC,* and RACs.

B. General

In certain circumstances it may be appropriate for medical reviewers to use relevant and accessible claims history to assist in making medical record review determinations. Examples of when this may be used for payment purposes, include, but are not limited to:

1. Reviewers have the discretion to use beneficiary payment history to identify other providers, other than the billing entity, who may have documentation to support payment of a claim. MAC, CERT*, SMRC,* and RAC reviewers have the discretion to contact identified providers for supporting documentation. Example: A diabetic beneficiary may have an order from a family practitioner but is also seeing an endocrinologist. The documentation from the family practitioner does not support the level of diabetic testing, but medical records from the endocrinologist do support the level of testing.

2. Reviewers have the discretion to use claims history information to document an event, such as a surgical procedure, that supports the need for a service or item billed in limited circumstances. In some cases, this event occurs a number of years prior to the date of service on the claim being reviewed, making it difficult to collect medical record documentation. If repeated attempts to collect medical record of the event are unsuccessful, contractors have the discretion to consider claims history information as documentation of the event. Contractors shall document their repeated attempts to collect the medical record if they chose to consider claims history information as documentation of the event. Example: A beneficiary is eligible for immunosuppressant drugs only if they received an organ transplant. Patients generally remain on these life-saving drugs for the rest of their life so it is possible for the transplant to have occurred many years prior to the date of service being reviewed. If there was no record of the transplant in the medical documentation provided by the ordering physician, the contractor may use claims history to validate the transplant occurred.

3. Reviewers shall use claims history information to verify that the frequency or quantity of supplies provided to a beneficiary do not exceed policy guidelines.

4. Reviewers shall use claims history information to identify duplication and overutilization of services.

3.2.5 - Targeted Probe and Educate (TPE)

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs.

A. Overview

The purpose of Targeted Probe and Educate (TPE) is to decrease provider burden, *identify and prevent improper payments,* reduce appeals, and improve the medical review/education process.

This section describes requirements that MACs shall follow when performing medical review as part of TPE.

TPE reviews can be either prepayment or post-payment and involve MACs focusing on specific providers/suppliers that bill a particular item or service.

A round of TPE typically involves the review of 20-40 claims, per provider/supplier, per service/item, and corresponding education. In rare circumstances, CMS may approve a probe sample of other than 20-40 claims. This process is typically repeated for up to three rounds, but may involve additional rounds at CMS direction. MACs discontinue the process if/when providers/suppliers become compliant. Providers/suppliers who remain non-compliant after three rounds of TPE are referred to CMS for further action.

B. Provider Selection

The MACs shall initiate a provider-specific, prepayment or post-payment review based upon data analysis, as discussed in §3.2.1. MACs shall also initiate targeted, provider-specific, prepayment or post-payment review upon referral from the *RAC*, Comprehensive Error Rate Testing (CERT), Unified Program Integrity Contractor (UPIC), Office of Inspector General (OIG), or Government Accountability Office (GAO) when directed by CMS. MACs shall target providers/suppliers who have historically high claim denial rates, who have billing practices that vary from their peers, or when evidence suggests that there is a potential risk to the Medicare Trust Fund.

Probe Selection

The MACs shall select probe samples of typically 20-40 claims. Probe samples of different sizes may be deemed appropriate on a case-by-case basis, with approval by CMS. *The MAC should choose the volume of claims such that a round of reviews does not take longer than approximately 6 months. In cases where the provider billing volume initially supports a particular claim volume (to fulfill the 20-40 claim request) and that claim volume subsequently decreases, MACs should consider closing the round with the existing claims at the 6-month mark.*

Provider Notification Letter

The MACs shall send a notification letter to providers/suppliers being targeted for review that:

- Outlines the targeted probe & educate process,
- Explains the process by which providers/suppliers will be able to receive one-on-one education and the types of education that will be available,
- Notifies providers/suppliers that MACs shall have the option to refer providers/suppliers to the RAC or UPIC as a result of non-response to Additional Development Requests (ADRs), and
- Includes the following language to remind providers of 42 CFR §424.535

"In addition, we remind you that the regulation at 42 CFR §424.535 authorizes us to revoke Medicare billing privileges under certain conditions. In particular, we note that per 42 CFR §424.535(a)(8)(ii), CMS has the authority to revoke a currently enrolled provider or supplier's Medicare billing privileges if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements."

C. TPE One-On-One Education

For the TPE process, one-on-one education is defined as teleconference calls, face-to-face visits, electronic visits using webinar technology, or other similar technologies that enable direct communication between the MAC educator and the provider/supplier. MACs shall record these activities in monthly reporting to CMS as well as document and maintain the results of the education, and/or attempts for education, for data analysis and possible future reporting.

Intra-Probe Education

The MAC may identify errors in the claim(s) that can be easily resolved during the course of provider's/supplier's probe reviews. Easily curable errors include, but are not limited to, missing documentation that can be resolved through the submission of additional documentation and missing signatures that can be resolved with a signature attestation. When the MAC identifies an easily curable error, the MAC shall contact the provider to address the error and allow the provider to submit missing documentation, etc.

Post-Probe Education

The MAC shall contact the provider/supplier via telephone (or face-to-face, electronic visits using webinar technology, or other similar technologies as they become available) to offer a one-on-one educational session after each round of probe review. If the provider/supplier declines the offer for one-on-one education, MACs shall maintain a record of the effort and the reason for denial. The purpose of this one-on-one education is to:

> 1) Alert the provider of errors identified and how they may be resolved for future claim submissions; and
> 2) Provide education regarding the review topic to help prevent new issues from arising during future rounds of review. This post-probe one-on-one education should be individualized, claims-specific, and conducted in a format that is interactive, allowing the provider/supplier to ask questions as needed.

The MAC shall provide a minimum of 45 days after each post-probe educational session, before selecting new claims for review, to allow time for the provider/supplier to cure identified errors.

D. Post-Probe Activity

Final Results Letter

The MAC shall send the provider/supplier a letter detailing the results of the claims reviewed at the conclusion of each round of review. The MAC shall include details regarding the provider's/supplier's specific claim errors. For providers/suppliers who will be released from review due to meeting the established error rate goal, results letters shall indicate that the provider is being released from review for one year, with the caveat that additional review may occur at any time should the MAC identified changes in billing pattern. For providers/suppliers who continue to have high error rates after three rounds of TPE review, results letters shall indicate that they have not met the established goal error rate and will be referred to CMS for additional action, which may include additional rounds of TPE review, 100 percent prepayment review, extrapolation, referral to a Recovery Auditor, and/or referral for revocation. Additionally, the letter shall include the following language to remind providers of 42 CFR §424.535.

> "In addition, we remind you that the regulation at 42 CFR §424.535 authorizes us to revoke Medicare billing privileges under certain conditions. In particular, we note that per 42 CFR §424.535(a)(8)(ii), CMS has the authority to revoke a currently enrolled

provider or supplier's Medicare billing privileges if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements."

Determining the Need for Additional TPE

The MAC shall calculate the provider/supplier claim error rate and payment error rate at the conclusion of each round of TPE. The MAC shall use the provider/supplier error rate to determine whether an additional round of TPE is appropriate.

Closure and Monitoring

A provider/supplier may be removed from TPE after any round if they demonstrate low error rates or sufficient improvement in error rates, as determined by the MAC. MACs shall use data analysis to monitor the providers/suppliers who have been discontinued from the TPE process. MACs shall conduct follow-up review in one year or sooner if data analysis indicates changes in billing patterns or when potential risk to the Medicare Trust Fund is identified.

E. Referrals

If a provider/supplier continues to have a high error rate at the conclusion of three rounds of TPE, the MAC shall refer to CMS for further action. Referrals shall include details regarding the reason the provider/supplier was selected for TPE review, TPE review results, results of appealed denials (to the extent available at the time of referral), any education provided (or offered and refused), and any other relevant information that may be helpful in determining appropriate next steps.

The MAC shall refer suspected fraudulent providers to the UPIC at any time during the TPE process.

F. Next Steps

Once the MAC refers a provider/supplier to CMS, details are reviewed to determine if additional action must be taken by the MAC. Additional actions that may be required include, but are not limited to, additional rounds of TPE review, 100 percent prepayment review, extrapolation, referral to a *RAC*, and/or referral for revocation. If CMS directs the MAC to conduct an additional round of TPE review, the MAC shall send the provider/supplier a notification letter indicating that an additional round of review is required. These reviews shall be of claims with dates of service at least 45 days after the prior round's post probe education and after the provider/supplier has received the aforementioned notification letter.

3.3 – Policies and Guidelines Applied During Review

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs, CERT, *RACs*, Supplemental Medical Review Contractors (SMRC) and UPICs, as indicated.

A. Statutes, Regulations, the CMS' Rulings, National Coverage Determinations, Coverage Provisions in Interpretive Medicare Manuals, and Local Coverage Determinations

The primary authority for all coverage provisions and subsequent policies is the Social Security Act. In general, MACs, CERT, *RACs*, SMRC, and UPICs shall apply the provisions of the Act according to the following hierarchy of documents in effect at the time the item(s)

or service(s) was provided to make medical review decisions:

Social Security Act
Code of Federal Regulations
CMS' Rulings
National Coverage Determination (NCDs)
Coverage provisions in Interpretive Manuals or Internet Only Manuals (IOM) which includes Medical Review Guidance in the Medicare Program Integrity Manual
CMS coding policies
Technical Direction Letters (TDLs)*
The relevant MAC's Local Coverage Determination (LCDs)
The relevant MAC's local articles
AHA Coding Clinics.

*TDLs that contain MR guidance may provide an exception to this hierarchy.

B. Coding Guidelines

The MACs, CERT, *RACs, SMRC,* and UPICs shall apply coding guidelines to services selected for review. All contractors shall determine that an item/service is correctly coded when it meets all the coding guidelines listed in the Current Procedural Terminology (CPT) book, International Classification of Diseases Guidelines (ICD), CMS HCPCS or ICD policy or guideline requirements, LCDs, or MAC articles.

C. Internal Medical Review Guidelines

The MAC, CERT, *RACs, SMRC,* and UPIC staffs have the discretion to develop detailed written review guidelines to guide staff during claim reviews. Internal MR guidelines shall specify the information to be reviewed by reviewers and the appropriate resulting determination. *RACs* are required to develop written review guidelines in accordance with their SOW. The MACs, CERT, *RACs, SMRC,* and UPICs shall make their internal MR guidelines available to their staff, as needed. Internal MR Guidelines shall not create or change the CMS policy.

3.3.1 - Types of Review: Medical Record Review, Non-Medical Record Review, and Automated Review

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

A. General

Most of the claim review activities completed for the purpose of identifying inappropriate billing and avoiding improper payments are divided into three distinct types: Medical Record Review, Non-Medical Record Review, and Automated Review.

The chart below indicates which contractors *are eligible to* perform which types of review:

Prepayment			***Post-payment***		***Automated Reviews***
Contractor Type	Medical Record Review	Non-Medical Record	Medical Record Review	Non-Medical Record	

		Review		review	
MACs	Yes	Yes	Yes	Yes	*Yes*
CERT	No	No	Yes	No	** No*
RACs	No	No	Yes	No	*Yes*
SMRC	No	No	Yes	Yes	*No*
UPIC	Yes	No	Yes	Yes	*No*

**Refer to section 3.3.1.3*

3.3.1.1 - Medical Record Review

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs, CERT, RACs, *SMRC*, 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, *SMRC,* 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, *SMRC,* 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.

SMRC shall follow guidance related to certified coders as outlined in their SOW.

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 SMRC 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 SMRC shall attend the annual medical review training conference as directed by the CMS and/or their SOW. The MACs, CERT, RACs, and SMRC 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 SMRC 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*/BFL*.

3.3.1.2 - Non-Medical Record Review

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs, SMRC, and UPICs, as indicated.

A. Definition

Non-medical record reviews uses manual intervention, but only to the extent a reviewer can make a determination based on information on a claim. It does not require clinical judgment in review of medical record documentation. Contractors shall only perform a non-medical record review for denials of related claims and/or no receipt of ADR documentation where such denials cannot be automated.

3.3.1.3 - Automated Review

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

A. Definition

An automated review occurs when a claim determination is made at the system level without a human review of the medical record, using available electronic information.

CERT refers to all reviews where no documentation was requested as "T-claim review." T-claims are a particular category of claim reviewed by CERT. T-claims are claims that were automatically denied by the MAC.

B. Basis for Automated Reviews

Contractors shall ensure that automated denials are based on clear policy that serves as the basis for denial. The term "clear policy" means a statute, regulation, NCD, or LCD that specifies the circumstances under which a service will always be considered non-covered, incorrectly coded, or improperly billed.

When a clear policy exists (or in the case of a Medically Unlikely Edit (MUE)), MACs have the discretion to automatically deny the services without stopping the claim for manual review, even if documentation is attached or simultaneously submitted. Reviewers shall still make a determination based on the liability limitations of §1879 of the Act.

A MUE is a unit of service (UOS) edit for a Healthcare Common Procedure Coding system (HCPCS)/Current Procedural Terminology (CPT) code for services rendered by a single provider/supplier to a single beneficiary on the same date of service. The ideal MUE is the maximum UOS that would be reported for a HCPCS/CPT code on the vast majority of appropriately reported claims. The MUE program provides a method to report medically reasonable and necessary UOS in excess of a MUE. *An MUE is another example of an automated review that may be implemented by the review contractor, if permissible under their Statement of Work (SOW).*

Automated edits can be used for apparent typographical errors (e.g., 10,000 blood cultures for the same beneficiary on the same day).

MACs shall implement automated prepayment review whenever appropriate.

3.3.2.1 - Documents on Which to Base a Determination

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

The MACs, CERT, RACs, SMRC, and UPICs shall review any information necessary to make a prepayment and/or post-payment claim determination, unless otherwise directed in this manual. This includes reviewing any documentation submitted with the claim and any other documentation subsequently requested from the provider or other entity when necessary. In certain circumstances it may be appropriate for medical reviewers to consider relevant and accessible billing history or other information obtained from the Common Working File (in limited circumstances), outcome assessment and information set (OASIS), or the minimum data set (MDS), among others. For Medicare to consider coverage and payment for any item or service, the information submitted by the supplier or provider must corroborate the documentation in the beneficiary's medical documentation and confirm that Medicare coverage criteria have been met.

3.3.2.1.1 - Progress Notes and Templates

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

A. Definitions

For the purposes of Section 3.3.2.1.1, the following definitions apply:

1. "Progress Notes" -- visit notes, encounter notes, Evaluation and Management documentation, office notes, face-to-face evaluation notes or any other type of record of the services provided by a physician or other licensed/certified medical professional (LCMP) in the medical record. Progress notes may be in any form or format, hardcopy or electronic.

2. "Template" -- a tool/instrument/interface that assists in documenting a progress note. Templates may be paper or electronic.

Electronic records may involve any type of interface including but not limited to:

simple electronic documents,

sophisticated graphical user interfaces (GUIs) with clinical decision and documentation support prompts, or

electronic pen capture devices.

3. **"Licensed/Certified Medical Professional (LCMP)"** – Medical professional licensed or certified to practice in the state in which services are rendered. For the purposes of documenting DMEPOS items, the physician or LCMP must not have a financial relationship with the DMEPOS supplier.

B. Guidelines Regarding Which Documents Review Contractors Will Consider

The review contractor shall consider all medical record entries made by physicians and LCMPs. See PIM 3.3.2.5 regarding consideration of Amendments, Corrections and Delayed Entries in Medical Documentation.

The amount of necessary clinical information needed to demonstrate that all coverage and coding requirements are met will vary depending on the item/service. See the applicable National and Local Coverage Determination for further details.

The CMS does not prohibit the use of templates to facilitate record-keeping. CMS also does not endorse or approve any particular templates except for the clinical templates it publishes on its website. A physician/LCMP may choose any template to assist in documenting medical information. Contractors shall consider information captured in templates when conducting medical review.

Some templates provide limited options and/or space for the collection of information such as by using "check boxes," predefined answers, limited space to enter information, etc. CMS discourages the use of such templates. Claim review experience shows that that limited space templates often fail to capture sufficient detailed clinical information to demonstrate that all coverage and coding requirements are met.

Physician/LCMPs should be aware that templates designed to gather selected information focused primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. This is often because these documents generally do not provide sufficient information to adequately show that the medical necessity criteria for the item/service are met.

If a physician/LCMP chooses to use a template during the patient visit, CMS encourages them to **select one that allows for a full and complete collection of information** to demonstrate that the applicable coverage and coding criteria are met.

Certificates of Medical Necessity (CMN), DME Information Forms (DIF), supplier prepared statements and physician attestations by themselves do NOT provide sufficient documentation of medical necessity, even if signed by the signed by the ordering physician.. See PIM §5.7 for additional information on documentation.

C. Financial Liability

The physician/LCMP should be aware that inadequate medical record documentation can lead to a financial liability for the Beneficiary and/or Supplier, should the reviewer determine that a claim is not supported.

In addition, the physician/LCMP should be aware that when ordering an item or service that will be furnished by another entity, Section 1842(p)(4) of the Social Security Act requires that adequate documentation supporting medical necessity be provided to the entity at the time that the item or service is ordered. Physicians/LCMPs who fail submit documentation upon a supplier's request may trigger increased MAC or RAC review of the physician/LCMP's evaluation and management services.

3.3.2.2 - Absolute Words and Prerequisite Therapies

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

The MACs, CERT, *RACs, SMRC*, and UPICs shall not deviate from coverage provisions if absolute words such as “never” or “only if” are used when making claim determinations where a regulation, CMS ruling, NCD, LCD, or MAC policy article exists. In these cases, reviewers shall not make any exceptions or give individual consideration.

Requirements for prerequisite therapies shall be followed when deciding whether to cover a service if listed in coverage provisions in interpretive manuals (e.g., “conservative treatment has been tried, but failed”).

3.3.2.3 - Mandatory Policy Provisions

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

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

CERT contractors select claims for review on a random basis and do not select claims that are suspect. The CERT reviewers shall review every line on the randomly selected claim that affects payment to determine if the following types of requirements are met:

- Coding requirements;
- Benefit category requirements;
- The reasonable and necessary requirements of the NCDs and LCDs, among others.

The MACs*, RACs, SMRC,* and UPICs select claims to prevent or identify an improper payment. They are only required to review the suspect line and not every line on the selected claims. Along with reviewing the line for coding accuracy, the MACs should review for medical necessity if the provider has been notified that both types of review will occur. *The RACs shall review the claim line(s) identified, as per the CMS-approved review guidelines, as indicated to the provider in the ADR letter, and in accordance with their SOW.* The UPICs shall use discretion in notifying the provider.

3.3.2.4 - Signature Requirements

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section is applicable for Medicare Administrative Contractors (MACs), Unified Program Integrity Contractors (UPICs), Supplemental Medical Review Contractors (SMRC), Comprehensive Error Rate Testing (CERT), and Recovery Audit Contractors (RACs), as indicated.

For medical review purposes, Medicare requires that the person(s) responsible for the care of the beneficiary, including providing/ordering/certifying items/services for the beneficiary, be identifiable as such in accordance with Medicare billing and coverage policies, such as the Social Security Act §1815(a) and §1833(e). Medicare contractors shall consider the totality of the medical record when reviewing for compliance with the above.

Signatures are required upon medical review for two distinct purposes:

1. To satisfy specific signature requirements in statute, regulation, national coverage determination (NCD) or local coverage determination (LCD); and
2. To resolve authenticity concerns related to legitimacy or falsity of the documentation.

If a signature **is** required per statute, regulation, NCD or LCD:

- Contractors shall use the totality of the record to determine if the signature requirement, as outlined in statute, regulation, NCD, LCD is met.
- If the signature requirement is not met, and it is not an instance in which the statute, regulation or NCD/LCD policy indicate that a signature must be in place prior to a given event or a given date, the attestation process may be used to try and resolve the issue. If the attestation process does not resolve the issue, the contractor may pursue a denial and/or any other appropriate corrective actions.
- If the signature requirement is not met because the signature is illegible, the signature log process may be used to try and resolve the issue.

If signature **is not** required per statute, regulation, NCD, or LCD:

- Contractors shall determine if the signature is necessary to identify the author of the record for the purposes of authenticity.
    - If not, the contractor shall disregard the missing or illegible signature and continue their review of all medical documentation to determine if the claim meets coverage, coding, and billing requirements.
    - If there is not an explicit signature requirement, but in the Contractor's review of the totality of the record they have authenticity concerns related to the legitimacy or falsity of the documentation, they shall pursue the attestation, signature log, denial, and/or fraud referral process, as appropriate.

NOTE: If review contractors find reasons for denial unrelated to signature requirements, the reviewer need not proceed to signature authentication.

NOTE: When a scribe is used by a provider in documenting medical record entries (e.g., progress notes), CMS does not require the scribe to sign/date the documentation. The treating physician/non-physician practitioner's (NPP's) signature on a note indicates that the physician/NPP affirms the note adequately documents the care provided. *We note this type of*

practitioner concurrence is also required when using Artificial Intelligence (AI) technology to capture the transcription of medical record entries.

NOTE: Conditions of participation (COP) are not conditions of payment.

A. Handwritten Signature

A handwritten signature is a mark or sign by an individual on a document signifying knowledge, approval, acceptance, or obligation.

NOTE: Stamped signatures are not typically acceptable. CMS permits use of a rubber stamp for signature in accordance with the Rehabilitation Act of 1973 in the case of an author with a physical disability that can provide proof to a CMS contractor of his/her inability to sign their signature due to their disability. By affixing the rubber stamp, the provider is certifying that they have reviewed the document.

B. Electronic Signatures

Providers using electronic systems shall recognize there is a potential for misuse or abuse with alternate signature methods. For example, providers need a system and software products that are protected against modification, etc., and should apply adequate administrative procedures that correspond to recognized standards and laws. The individual whose name is on the alternate signature method and the provider bear the responsibility for the authenticity of the information for which an attestation has been provided. Physicians are encouraged to check with their attorneys and malpractice insurers concerning the use of alternative signature methods.

C. Signature Log

Providers will sometimes include a signature log in the documentation they submit that lists the typed or printed name of the author associated with initials or illegible signature. The signature log might be included on the actual page where the initials or illegible signature are used or might be a separate document. Reviewers should encourage providers to list their credentials in the log. However, reviewers shall not deny a claim for a signature log that is missing credentials. Reviewers shall consider all submitted signature logs regardless of the date they were created. Reviewers are encouraged to file signature logs in an easily accessible manner to minimize the cost of future reviews where the signature log may be needed again.

D. Signature Attestation Statement

Providers will sometimes include an attestation statement in the documentation they submit. To be considered valid for Medicare medical review purposes, an attestation statement must be signed and dated by the author of the medical record entry and must contain sufficient information to identify the beneficiary.

Should a provider choose to submit an attestation statement, they may choose to use the following statement:

“I, [print full name of the physician/practitioner], hereby attest that the medical record entry for [date of service] accurately reflects signatures/notations that I made in my capacity as [insert provider credentials, e.g., M.D.] when I treated/diagnosed the above listed Medicare beneficiary. I do hereby attest that this information is true, accurate and complete to the best of my knowledge and I understand that any falsification, omission, or concealment of material fact may subject me to administrative, civil, or criminal liability.”

Although this format is acceptable, the CMS currently neither requires nor instructs providers to use a certain form or format. A general request for signature attestation shall be considered a non-standardized follow-up question from the contractors to the providers.

In situations where the contractor identifies the need for an attestation (to fulfill a requirement or for authenticity purposes), the contractor shall ask if the billing entity would like to submit an attestation statement or signature log within 20-calendar days. (We note that this timeframe does not apply to the CERT contractor(s)). The 20-calendar day timeframe begins on the date of the telephone contact with the provider or on the date the request letter is received by the provider. Note: if sent via a mail courier without receipt notification, the contractor shall use the sent date plus anticipated mail processing timeframes to calculate. If the biller submits a signature log or attestation that resolves the signature issue, the reviewer shall consider the contents of the medical record entry.

In cases where a reviewer has requested a signature attestation or log, the time for completing the review is extended by 15-calendar days. (We note that this timeframe does not apply to the CERT contractor(s)). This extension starts upon receipt of the signature attestation or log.

The review contractors shall document all contacts with the provider and/or other efforts to authenticate the signature.

Note: Contractors shall NOT consider attestation statements where there is no associated medical record entry. Reviewers shall NOT consider attestation statements from someone other than the author of the medical record entry in question (even in cases where two individuals are in the same group, one should not sign for the other in medical record entries or attestation statements). Reviewers shall consider all attestations that meet the above requirements regardless of the date the attestation was created, except in those cases where the regulations or policy indicate that a signature must be in place prior to a given event or a given date. For example, if a statute, regulation, NCD or LCD states the physician must sign the plan of care before therapy begins, an attestation can be used to clarify the identity associated with an illegible signature. However, such attestation cannot be used to "backdate" the plan of care.

E. Signature Dating Requirements

For medical review purposes, if the relevant statute, regulation, NCD, and LCD are silent on whether the signature must be dated, the review contractors shall ensure that the documentation contains enough information for the reviewer to determine the date on which the service was performed/ordered.

Example:

> The claim selected for review is for a hospital visit on October 4th. The ADR response is one page in length and comes from the hospital medical record containing three (3) entries. The first entry is a physical therapy note dated October 4th. The second entry is a physician visit note that is undated and the third entry is a nursing note dated October 4th. The reviewer should conclude that the physician visit was conducted on October 4th.

F. Potential Fraud Referrals

At any time, suspected fraud shall result in a referral to the UPIC for development. If MAC, RAC, SMRC or CERT reviewers identify missing/illegible signature(s) that raise legitimacy

or falsity concerns, the reviewer shall consider referring to the appropriate UPIC for further development and may consider referring to the Regional Office and State Agency.

3.3.2.6 - Psychotherapy Notes

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs, CERT, *RACs, SMRC,* or UPICs, as indicated.

Psychotherapy notes are defined in 45 CFR§164.501 as "notes recorded by a mental health professional which document or analyze the contents of a counseling session and that are separated from the rest of a medical record." The definition of psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of administered treatment, results of clinical tests, and any summary of diagnosis, functional status, treatment plan, symptoms prognosis, ongoing progress and progress to date. This class of information does not qualify as psychotherapy note material. Physically integrating information excluded from the definition of psychotherapy notes and protected information into one document or record does not transform the non-protected information into protected psychotherapy notes.

Under no circumstances shall the MACs, CERT, *RACs, SMRC,* or UPICs request that a provider submit psychotherapy notes defined in 45 CFR §164.501. The refusal of a provider to submit such information shall not result in the automatic denial of a claim.

If the medical documentation includes any of the information included in the definition of psychotherapy notes in §164.501, as stated above, the provider is responsible for extracting information required to support that the claim is for reasonable and necessary services. MACs, *RACs*, CERT or UPICs shall review the claim using the supporting documentation submitted by the provider. If the provider does not submit information sufficient to demonstrate that services were medically necessary, the claim shall be denied. Beneficiaries cannot be held liable for these denials unless they received proper liability notification before services were rendered, as detailed in CMS Pub. IOM, 100-04 chapter 30, §30.1.

3.3.2.7 - Review Guidelines for Therapy Services

(Rev.: 13008; Issued: 12-18-24; Effective: 01-17-25; Implementation: 01-17-25)

This section applies to MACs.

Financial limitations on therapy services (therapy caps) were originally initiated by the Balanced Budget Act (BBA) of 1997. Section 50202 of the BBA of 2018 repeals application of the therapy caps but preserves the former therapy cap amounts as thresholds above which claims must include the KX modifier as a confirmation that services are medically necessary as justified by appropriate documentation in the medical record. Just as with the incurred expenses for the therapy cap amounts, there is one amount for PT and SLP services combined and a separate amount for OT services. This amount is indexed annually by the Medicare Economic Index (MEI). Claims for services over the KX modifier threshold amounts without the KX modifier are denied. Please use the applicable threshold for the CY under review.

Along with this KX modifier threshold, the BBA of 2018 retains the targeted medical review (MR) process (first established through Section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)), but at a lower threshold amount of $3,000. For CY 2021 (and each calendar year until 2028 at which time it is indexed annually by the MEI), the MR threshold is $3,000 for PT and SLP services and $3,000 for OT services. The targeted MR process means that not all claims exceeding the MR threshold amount are subject to review as they once were.