

# Medicare Program Integrity Manual

## Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

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### **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 Postpayment 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 Trust Fund 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.

To 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.

### UPICs

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.

### UPICs

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]otwithstanding 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 ADRs.

### 3.2.3.1 - Additional Documentation Requests (ADR)

*(Rev. 13595; Issued: 01-26-26; Effective: 02-26-26; Implementation: 02-26-26)*

This section applies to MACs, RACs, SMRC, CERT, UPICs, *and the Investigations Medicare Drug Integrity Contractor (I-MEDIC)* 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>.

*The UPICs and I-MEDIC are authorized by CMS to use Kiteworks for purposes of facilitating the secure exchange of records and information with providers and suppliers (see Subsection 3.6.4 – Notifying the Provider for additional information).*

### **3.2.3.2 - Time - Frames for Submission**

*(Rev. 13595; Issued: 01-26-26; Effective: 02-26-26; Implementation: 02-26-26)*

#### **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.

#### ***D. Kiteworks Submissions***

*This section applies to the UPICs and the I-MEDIC. When requesting additional documentation for medical review using Kiteworks, if, after no more than two attempts of sending the ADR request via Kiteworks (to include at least 3 calendar days between attempts for a response), there is no response (i.e., no acknowledgment/download/receipt email is received from Kiteworks), the request shall be sent via certified mail, FedEx, UPS, fax etc.*

### **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 MACs, 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. 13595; Issued: 01-26-26; Effective: 02-26-26; Implementation: 02-26-26)*

This section applies to MACs, RACs, CERT, SMRC, UPICs, *and I-MEDIC*, 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/HHs to submit medical documentation over secure electronic means. Information about the esMD system can be found at [www.cms.gov/esMD](http://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.

F. *Kiteworks*

*The UPICs and I-MEDIC may accept medical documentation submitted via this route.*

**3.2.3.6 - Reimbursing Providers and Health Information Handlers (HHs) 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**

	<b>Hospital Inpatient Prospective Payment System (PPS) Facilities and Long Term Care Facilities</b>	<b>Non-PPS Institutions and Practitioners</b>
<b>Documentation sent via mail, fax, CD/DVD</b>	<ul style="list-style-type: none"> <li>- 12 cents per page</li> <li>- Plus first class postage, if applicable</li> <li>- \$15.00 maximum per record</li> </ul>	<ul style="list-style-type: none"> <li>- 15 cents per page</li> <li>- Plus first class postage, if applicable</li> <li>- \$15.00 maximum per record</li> </ul>
<b>Documentation sent via esMD</b>	<ul style="list-style-type: none"> <li>- 12 cents per page</li> <li>- Plus \$2.00 transaction fee, per record</li> <li>- \$27.00 maximum per record</li> </ul>	<ul style="list-style-type: none"> <li>- 15 cents per page</li> <li>- Plus \$2.00 transaction fee, per case</li> </ul>

		- \$27.00 maximum per record
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\*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:

Contractor Type	Prepayment		Post-payment		Automated Reviews
	Medical Record Review	Non-Medical Record Review	Medical Record Review	Non-Medical Record 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., dietitians 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 Section 1893 (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 - Medical Review Guidance**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

This section describes the requirements that MACs, CERT, Recovery Auditors, and UPICs shall follow when reviewing submitted documentation. Additional requirements for UPICs are located in PIM chapter 4. When UPIC staff is performing benefit integrity reviews, their focus is different than that of MACs, CERT, and Recovery Auditors. For example, UPIC staff looks for some of the following situations when reviewing documentation:

- Possible falsification or other evidence of alterations including, but not limited to: obliterated sections; missing pages, inserted pages, white out; and excessive late entries;
- Evidence that the service billed for was actually provided; or,
- Patterns and trends that may indicate potential fraud.

#### **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.

#### **3.3.2.1.2 –DMEPOS Orders**

**(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”).

### **3.3.2.2 - Absolute Words and Prerequisite Therapies**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

The MACs, CERT, Recovery Auditors, 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 4<sup>th</sup>. 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 4<sup>th</sup>. The second entry is a physician visit note that is undated and the third entry is a nursing note dated October 4<sup>th</sup>. The reviewer should conclude that the physician visit was conducted on October 4<sup>th</sup>.

#### **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.

### **3.3.2.5 - Amendments, Corrections and Delayed Entries in Medical Documentation**

**(Rev. 12633; Issued: 05-09-24; Effective: 06-10-24; Implementation: 06-10-24)**

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

All services provided to beneficiaries are expected to be documented in the medical record at the time they are rendered. Occasionally, certain entries related to services provided may not be properly documented. In this scenario, the documentation may need to be amended, corrected, or entered after rendering the service. The date and author of any amendment, correction or delayed entry should be identifiable, and the change/addenda should be clearly and permanently denoted. Contractors shall review any amendment, correction, or delayed entry in accordance with section 3.3.2.4 of this chapter.

If the MACs, CERT, SMRC or RACs identify medical documentation with potentially fraudulent entries, the reviewers shall refer the cases to the UPIC and may consider referring to the RO 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.

### **3.3.2.8 - MAC Articles**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to MACs.

#### **A. General**

The MACs have the discretion to publish articles communicating certain information to providers, such as any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy. The MACs are required to enter articles that address LCDs, coding or medical review-related billing and claims considerations into the Medicare Coverage Database (MCD).

For the purposes of this manual, the term "publish" will be used to describe any form of dissemination including posting on a Web site, distributing at a seminar, e-mailing, or printing in a hardcopy bulletin. The MAC Medical Review Departments are responsible for the development of articles associated with new or revised LCDs and for entering those articles into the Medicare Coverage Database. Other widespread educational

articles shall not be charged to MR.

The MAC medical review departments shall send articles to the appropriate department within the MAC for publishing. All newly created articles shall be posted on the MAC's Web site where duplicate copies can be obtained by providers/suppliers.

When NCDs or other coverage instructions issued by the CMS include specific conditions or parameters for covered services, the MACs have the discretion to develop and publish a list of covered codes associated with the coverage provision. MACs have the discretion to automate denials for codes not included on the list without the development of a LCD if the NCD indicates or states that no other condition or parameters will be covered.

MACs also have the discretion to:

- Publish definitions of procedure codes, lists of items that may be billed under a particular code, or minimum requirements that providers must meet in order to bill using a certain code.
- Publish a product classification list that instructs providers about which specific products meet the definitional requirements of a particular HCPCS code. Developing or revising an LCD for this article is unnecessary.
- Explain which off-labeled uses of the Food and Drug Administration (FDA) approved drugs are considered reasonable and necessary within the diagnosis codes that reflect such uses.
- Explain the benefit category decisions and publish a list of drugs/biologicals that are considered usually self-administered. MACs should enter their self-administered medication exclusion list into the Medicare Coverage Database. This database can be accessed at [www.cms.gov/mcd](http://www.cms.gov/mcd).
- MACs have the discretion to explain which HCPCS code or group of codes properly describes a particular service.
- MACs have the discretion to publish State non-physician licensure information that governs services billed by the physician under the "incident to" provision.

The MACs shall ensure that articles do not conflict with NCDs, LCDs, policy, or coverage provisions in interpretive manuals. Although a comment and notice process is not required, MACs are encouraged to consult with stakeholders in the provider community when developing articles. MACs shall monitor comments about articles from clinician providers and respond to their concerns, as needed, by issuing revised or

clarifying articles.

**NOTE:** Nothing in this section precludes the MACs or UPICs from making individual claim determinations, even in the absence of an article or LCD.

### **3.3.3 - Reviewing Claims in the Absence of Policies and Guidelines (Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

The MACs, CERT, Recovery Auditors, and UPICs have the discretion to review claims, in the absence of polices, whether a NCD, coverage provision in an interpretive Medicare manual, or LCD exists for that service. When making individual claim determinations, they shall determine that the service in question is covered based on whether the service meets all of the conditions listed in section 3.6.2.1.

### **3.4 - Prepayment Review of Claims (Rev. 12772; Issued: 08-09-24; Effective: 09-20-24; Implementation: 09-20-24)**

This section applies to MACs and UPICs.

#### A. General

Non-random (targeted) review is defined as review conducted with a specific reason or logic to substantiate the cause for review. MACs are encouraged to initiate non-random service-specific prepayment review to prevent improper payments for services identified by CERT or Recovery Auditors or other sources.

The MACs shall initiate targeted provider-specific prepayment review only when there is the likelihood of a sustained or high level of improper payments.

#### B. 100 Percent Prepayment Review and Random Review Instructions

Section 1302 of the Health Care and Education Reconciliation Act (HCERA) repealed section 1874A (h) of the Social Security Act which had placed restrictions on prepayment medical review. CMS review contractors shall comply with Section 1 random review and Section 2 100 percent prepayment review.

##### 1. Random Review

Random review is defined as review conducted without a specific reason or logic to substantiate the cause for review. MACs have the discretion to conduct random reviews of services; however, CMS does not recommend random reviews. MACs shall notify the CMS Contracting Officer's Representative (COR), Regional Office Technical Monitor (TM), and Business Function Lead (BFL) of its intent to conduct random review. The MAC shall describe what the intended result of the random review will be, an estimate of the number of claims to be reviewed randomly and the rationale as to why random review would be more effective than targeted review.

## 2. 100 Percent Prepayment Review

100 percent prepayment review is defined as review of every claim submitted by a targeted provider for a specific code (i.e., DRG, CPT, HCPCs). 100 percent prepayment review also includes review of every claim submitted by the targeted provider.

MACs have the discretion to conduct 100 percent prepayment review of providers. CMS considers 100 percent prepayment review to be appropriate when a provider has a prolonged time period of non-compliance with CMS policies. Any MAC that plans to conduct 100 percent prepayment review shall inform the CMS COR, Regional Office TM, and BFL in advance about any provider being placed on 100 percent prepayment review. In addition, the MAC shall provide

- The background information on attempts to educate the provider.
- The historical improper payment rate of the provider before beginning 100 percent prepayment review.
- The length of time the provider is expected to be on 100 percent prepayment reviews.
- The estimated number of claims and the dollar value of claims expected to be reviewed per month.
- The criteria for removing the provider from 100 percent prepayment review.

## 3. UPIC Initiated Prepayment Reviews

No UPIC shall initiate a 100 percent prepayment review without CMS approval. Therefore, the UPIC shall provide its COR and BFL a summary of the investigation, any prior history (if applicable) with the provider/supplier in question, and any other relevant information in a format agreed upon by the COR and BFL.

If the COR and BFL agree that 100 percent prepayment review is appropriate, the UPIC shall include the case on the next case coordination meeting agenda for discussion and final approval. During the case coordination meeting, the UPIC may receive additional guidance from CMS related to subsequent actions related to these investigations. If the UPIC has subsequent questions following the case coordination meeting, the UPIC shall coordinate with its COR and BFL.

### **3.4.1 - Electronic and Paper Claims**

**(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)**

This section applies to MACs.

The Administrative Simplification Compliance Act (ASCA, Section 3 of Pub. L, 107-105, 42 CFR 424.32) requires that all Medicare claims be submitted electronically using the ASC X12 837 institutional or professional claim formats with few exceptions. MACs shall not require providers to submit paper claims when they are targeted for prepayment medical record review. The MACs shall allow providers that qualify for an ASCA mandatory electronic billing exception to submit paper claims when they are targeted for prepayment review (See IOM Pub.100-04, chapter 24, §90 for exceptions).

#### **3.4.1.1 - Linking LCD and NCD ID Numbers to Edits (Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)**

The MACs shall ensure that any edit that could result in a denial based on a LCD or NCD includes the LCD or NCD ID number(s) associated with the denial. The MACs shall ensure that any edit that could result in a denial based on a lab negotiated NCD includes the NCD ID number(s) associated with the denial.

#### **3.4.1.2 - Not Otherwise Classified (NOC) Codes (Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)**

This section applies to MACs.

The MAC MR staff should assist claims processing staff in making coverage and pricing determinations on NOC HCPCS/CPT codes. The claims processing staff will need information from the MR staff so that they can price the service in accordance with CMS pricing methodologies described in the Claims Processing Manual (IOM Pub. 100-04). MACs shall keep track of pricing determinations for frequently billed services so that the claims processing staff can price future claims using established MR pricing guidelines for that service.

#### **3.4.1.3 - Diagnosis Code Requirements (Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to MACs and UPICs, as indicated.

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

Section 1833(e) of the Act states that no payment should be made “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...” MACs and UPICs should require submission of information, in accordance with the requirements below, that they deem necessary to make a claim determination and determine appropriate payment. Some provider types are required to submit diagnosis codes on all claims while other provider types are required to submit diagnosis codes only if such information is required by a LCD.

### **A. Claims Submitted by Physicians or Certain Non-Physician Practitioners Must Contain Diagnosis Codes.**

Section 1842 (p) (1) of the Act states that for each claim submitted by physicians or certain non-physician practitioners (defined in 1842(b) (18) (C) of the Act) “shall include the appropriate diagnosis code (or codes). . . .” For claims submitted with invalid, truncated, or missing diagnosis codes, MACs and UPICs shall classify the claim as rejected as unprocessable within the MCS. See the Claims Processing Manuals IOM Pub.100-04.

### **B. Claims Submitted by All Other Provider Types Must Contain Diagnosis Codes if required by a LCD**

During a service-specific review to address potential abuse or overutilization, MACs and UPICs should require that diagnosis codes be submitted with each claim for the targeted service. The diagnosis information is used to determine if the services are covered and correctly coded. MACs and UPICs should require that ICD diagnosis codes be submitted by all non-physician billers with every claim for a targeted service only if such a requirement appears in a LCD for that service. This outreach shall occur via Web site, bulletin articles, etc.

For provider-specific reviews, MACs and UPICs have the discretion to require submission of diagnosis codes to support that the reasonable and necessary criteria has been met on all claims submitted by individual non-physician providers who have been targeted because of unusual billing practices, fraud referrals, etc., even if no LCD exists requiring such codes. For claims submitted with invalid, truncated, or missing diagnosis codes, reviewers shall classify the claim as unable to be processed, and return the claim to the provider (RTP). See the Claims Processing Manual IOM Pub.100-04.

### **C. Requirements for Lab Claims**

The American Medical Association’s (AMA) 1998 edition of the Current Procedural Terminology (CPT) established three new and one revised Organ and Disease Oriented laboratory panels. Since these panels are composed of clinically relevant groupings of automated multichannel tests there is a general presumption of medical necessity. If there is data or reason to suspect abuse of the panel codes, contractors may review these claims. Should contractors determine the need to develop a LCD for laboratory panel codes the MAC shall develop these policies at the panel code level. In some instances of perceived abuse of the panel codes, the contractors may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test.

#### **3.4.1.4 - Prepayment Review of Claims Involving Utilization Parameters (Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)**

This section applies to MACs.

### **A. For Non-lab Claims**

The MACs shall implement prepayment edits that will prevent payment to providers who have a pattern of billing for items or services that are not covered, incorrectly coded or inappropriately billed. The MACs shall respond quickly when they identify providers who seem to have egregious overutilization of a non-lab item or service and who bill for egregious amounts. The identification of, and response to these providers shall be within the context of the MAC's MR Strategy and prioritization of review targets.

### **B. Utilization Denials**

The MACs have the discretion to establish edits to automatically deny services when overutilization of a non-lab service is identified and clear policy serves as the basis for denial.

The MACs shall establish medical record review edits and make individual claim determinations when overutilization of a non-lab service is identified and there is not clear policy to serve as the basis for denial.

The MACs shall establish medical record review edits that do not involve utilization parameters and make individual claim determinations when overutilization of a lab service is identified and there is no clear policy to serve as the basis for denial. For example, if the problem is limited to a few laboratory providers, the MAC could develop a provider-specific prepayment edit to suspend payment for all of the lab services in question from the problem providers. If the problem is widespread, the MAC could develop a service-specific edit to suspend payment for all of the lab services in question or all of the services in question for a particular diagnosis or revenue code. Based on data analysis within each MAC jurisdiction, the MACs shall focus the edit by provider, diagnosis, procedure code, or in any other way except by use of a utilization parameter.

### **3.4.1.5 - Prepayment Review Edits**

**(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)**

This section applies to MACs.

#### **A. Automated Edits**

Automated prepayment edits, designed by MAC staff, are put in place to prevent payment for non-covered, incorrectly coded, or inappropriately billed services. Most automated payment edits will be service-specific. The MAC will rarely install a provider-specific automated prepayment edit.

#### **B. Limits on Automated Prepayment Review**

The MACs shall not install edits that result in the automatic denial of payment for items or services based solely on the diagnosis of a progressively debilitating disease when

treatment may be reasonable and necessary. The appearance of a progressively debilitating disease on a claim or history does not permit automated denials that presume a stage of that disease that negates the effectiveness of treatment. Likewise, when a beneficiary with a progressively debilitating disease experiences an illness or injury unrelated to his or her progressively debilitating disease, the provider should submit a claim with a primary diagnosis that most accurately reflects the need for the provided item or service. For instance, a claim for treatment for an acute urinary tract infection cannot be denied by automatic edit just because the beneficiary has a diagnosis of multiple sclerosis.

### **3.4.2 – Prepayment Medical Record Review Edits**

**(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)**

This section applies to MACs.

The MACs shall focus prepayment medical record review edits to suspend only claims with a high probability of aberrant billing practices. Focused edits reduce provider burdens and increase the efficiency of MR activities. The MACs shall ensure that edits are specific enough to identify only the services that they determine to be questionable based on data analysis. MACs are encouraged to ensure that most MR edits are located in the table driven portion of the system and are not hard coded. It is important to have the flexibility to modify MR edits based on workload demands and changes in provider behavior.

The MACs have the discretion to establish prepayment medical record review edits that are either service-specific or provider-specific. Provider-specific edits can suspend all claims from a particular provider or focus on selected service(s), place of service, or other parameters.

### **3.5 - Postpayment Medical Record Review of Claims**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

The MACs shall initiate targeted provider-specific or service-specific postpayment medical record review only when there is the likelihood of a sustained or high level of payment error. RACs, UPICs, and SMRC shall perform postpay review of claims as outlined in their SOW.

#### **3.5.1 - Re-opening Claims**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

The MACs, CERT, RACs, SMRC, and UPICs shall adhere to the rules found in CFR 405.980 through 986 when conducting automated or postpayment medical record reviews. High error rate and/or potential overutilization, identified by data analysis, are

reasons to perform postpayment review and represent sufficient cause to reopen claims in accordance with 42 CFR 405.986. See Pub. 100-04, chapter 34 for more information on good cause for reopening.

### **3.5.2 - Case Selection**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

#### **Case review and development provisions:**

The MACs and the SMRC shall not perform postpayment review of unassigned claims. A claim submitted for a service or supply by a provider who has not accepted the Medicare fee schedule is an unassigned claim.

- The MACs, SMRC, and UPICs have the discretion to select cases for postpayment review on a claim-by-claim basis or use statistical sampling for overpayment estimation.
  - When MACs, SMRC, and UPICs conduct claim-by-claim postpayment review, they shall only collect or refund the actual overpayment or underpayment amount.
  - When MACs, SMRC, and UPICs conduct statistical sampling for overpayment estimation as specified in PIM chapter 8, they shall extrapolate the sampling results to the known universe of similar claims when calculating the projected overpayment or underpayment amount.
- The MACs, RACs, SMRC, and UPICs have the discretion to conduct the postpayment review onsite at the provider or supplier's location.
- MAC staff shall review their provider tracking system, using RAC Data Warehouse (RACDW) data, and consult with the UPICs to ensure non- duplication during the process of selecting providers for postpayment review.
- To prevent duplicate claim reviews, the MACs, SMRC, and RACs shall use the RACDW to identify, and exclude from review, claims that were previously reviewed, or that are under current review, by another contractor.
- CERT shall duplicate another contractor's review, when appropriate, if those claims are chosen as part of a statistically valid random sample to measure the improper payment rate.

- This instruction does not prevent the UPICs from reviewing a claim that has been reviewed by another contractor in order to support their case development or other administrative action.
- When the MACs, CERT, RACs, SMRC and UPICs choose to send the provider an ADR for a postpayment review, they shall do so in accordance with PIM chapter 3, §3.2.3.2. The contractors may grant an extension of the submission timeframes at their discretion or in accordance with their SOWs.
- The MACs, CERT, RACs, SMRC and UPICs make coverage, coding, and/or other determinations when re-adjudicating claims.
- The MACs, CERT, RACs, SMRC and UPICs shall document all incorrectly paid, denied, or under-coded (e.g., billed using a procedure/supply or other code that is lower than what is supported by medical documentation) items or services.
- Services newly denied as a result of re-adjudication shall be reported as positive values.
- Services that were denied, but are reinstated as a result of re-adjudication shall be reported as negative values.
- The MACs, CERT, RACs, SMRC and UPICs shall document the rationale for denial and include the basis for revisions in each case (important for provider appeals). MACs, CERT, and UPICs should include copies of the NCD, coverage provisions from interpretive manuals, or LCD and any applicable references needed to support individual case determinations. RACs and the SMRC shall include detailed rationale as outlined in their SOWs.
- The MACs have the discretion to deny payment without the review of the claim with a medically unlikely service edit.

### **3.5.3 - CMS Mandated Edits**

**(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)**

In past years, CMS created mandated edits that suspend certain claims for medical review coverage and coding review. However, more recently, CMS has given the contractors the discretion to prioritize workload to effectively lower the error rate. CMS is now in the process of removing such mandated coverage and coding review edits from CWF, pricer, grouper, fee schedules, etc.

Contractors may override CMS mandated edits that suspend for medical review coverage and coding review without performing review if one or more of the following conditions apply:

1. The contractor does not have MR responsibility for the claim, or
2. The contractor's data analysis/priority setting/ MR strategy does not indicate this service is a problem in their jurisdiction, or
3. It is not a skilled nursing facility (excluding swing beds) or a home health demand bill (these demand bills must be reviewed).

### **3.5.4 - Tracking Medicare Contractors' Prepayment and Postpayment Reviews**

**(Rev. 11933; Issued: 03-30-23; Effective: 04-01-23; Implementation: 04-03-23)**

Shared System Maintainers shall create a pre-payment claim file that is automatically uploaded to the RACDW by the VDC. Medicare Administrative Contractors (MACs) shall input all postpayment complex reviews into the Recovery Audit Data Warehouse. All claims chosen for review by the MAC where an additional documentation request letter was issued to the provider before or after payment was made shall be included. MACs shall include all reviews, even those that did not result in an improper payment.

Claims may be manually uploaded into the data warehouse or submitted by flat file. The Shared System Maintainers and MACs shall use the file layout provided by CMS for claims uploaded to the Recovery Audit Data Warehouse. Postpayment claims shall be submitted to the Recovery Audit Data Warehouse by the 20<sup>th</sup> day of every month for the previous month. Prepayment claims shall be submitted to the Recovery Audit Data Warehouse daily.

MAC staff who need access to the Data Warehouse shall contact [RAC@cms.hhs.gov](mailto:RAC@cms.hhs.gov).

### **3.6 - Determinations Made During Review**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

#### **A. General**

The MACs, CERT, Recovery Auditors, and UPICs shall be able to differentiate the type of determination made, ensuring that limitation of liability determinations are appropriate.

When the MAC determines, through prepayment data analysis or postpayment review, that an inappropriate claim has been submitted; or the Recovery Auditor determines, in

post-payment review, that an improper payment has been made, the MAC and Recovery Auditor shall verify that the error represents an unacceptable practice and not just an explainable aberrancy. Some legitimate reasons for anomalous data include:

- The provider may be associated with a medical school, research center, or may be a highly specialized facility, for instance, the facility may be a Medicare- dependant hospital or CAH, which might skew the type of claims submitted; or
- The community in which the provider practices may have special characteristics such as socio-economic level or a concentration of a specific age group that leads to an apparent aberrancy in the use of certain services.

The MACs, CERT, Recovery Auditors, and UPICs have the discretion to make other determinations during the review of a claim to avoid or identify improper payments for such things as duplicate claims, etc. Other examples are listed below:

**Example 1:** A Medicare policy states that when three (3) procedures are performed during the same operative session, Medicare pays 100 percent for the first, 50 percent for the second and 25 percent for the third. A claim is identified where all three (3) procedures were paid at 100 percent.

**Example 2:** A claim was paid using the fee schedule from the prior year.

**Example 3:** A Medicare payment policy states that in order to pay for a capped rental item, consideration shall be given to whether the item was in “continuous use” by the beneficiary for a specified time period. A claim is found to have been paid out of compliance with this policy provision.

If, at any time, the medical review detects potential fraud, MACs, CERT, and Recovery Auditors, shall refer the issue to the appropriate UPIC.

### **3.6.1 - Determining Overpayments and Underpayments (Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to MACs, and UPICs. It does not apply to CERT or Recovery Auditors.

#### **A. General**

The results of the re-adjudication are used to determine the overpayment or underpayment amount for each claim. Re-adjudicating claims may not result in a payment correction. Where statistical sampling for overpayment estimation is used, refer to instructions in the PIM chapter 8, §8.4 and to Exhibits 9, 10, 11 and 12 for projection methodologies based on FFS claims. For claims paid under PPS rules, MACs and UPICs

shall develop projection methodologies in conjunction with their statisticians that are consistent with the requirements found in PIM chapter 8, §8.4. MACs and UPICs shall net out the dollar amount of services underpaid during the cost accounting period, meaning that amounts owed to providers are balanced against amounts owed from providers.

Amounts of the following overpayments are to be included in each provider's or supplier's estimate for the reviewed sample:

- According to the provisions of §1879 of the Act, the provider or supplier is liable for the overpayment of initially paid claims that were later denied on re- adjudication if :
  - (1) The basis for denial is by reason of §1862(a) (1) or (9) of the Act
  - (2) The provider or supplier knew or could reasonably have been expected to know that the items or services were excluded from coverage, and
- For denials of non-assigned claims make a §1842(1) determination on denials for §1862(a)(1)
- The provider or supplier was not without fault for the overpayment as defined in §1870 of the Act.

For appeal purposes, overpayment estimations applicable under §1879 of the Act will be identified separately from denials in which §1879 of the Act does not apply. Where both types of denials occur in the sample, MACs and UPICs calculate and document separate under/overpayments for each type of denial. For recovery purposes, however, both denial results are combined.

### **3.6.2 - Verifying Errors**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

Understanding the characteristics of the service area of the provider is a key element of claim data analysis. The areas selected for review by the contractor (e.g., providers, services) must be deemed high priority and contractors must be able to document the rationale for selection.

#### **3.6.2.1 - Coverage Determinations**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

The MACs, CERT, Recovery Auditors, and UPICs shall deny an item or service if it does not meet any of the conditions listed below:

- The item or service does not fall into a Medicare benefit category.
- The item or service is statutorily excluded on grounds other than §1862(a) (1) (A) of the Act.
- The item or service is not reasonable and necessary under §1862(a) (1) (A) of the Act.
- The item or service does not meet other Medicare program requirements for payment.

### **3.6.2.2 - Reasonable and Necessary Criteria**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

CMS issues national coverage determinations (NCDs) that specify whether certain items, services, procedures or technologies are reasonable and necessary under §1862(a) (1) (A) of the Act. In the absence of an NCD, Medicare contractors are responsible for determining whether services are reasonable and necessary. If no local coverage determination (LCD) exists for a particular item or service, the MACs, CERT, Recovery Auditors, and UPICs shall consider an item or service to be reasonable and necessary if the item or service meets the following criteria:

- It is safe and effective;
- It is not experimental or investigational; and
- It is appropriate, including the duration and frequency in terms of whether the service or item is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the beneficiary's medical needs and condition;
  - Ordered and furnished by qualified personnel; and,

- One that meets, but does not exceed, the beneficiary's medical need.

There are several exceptions to the requirement that a service be reasonable and necessary for diagnosis or treatment of illness or injury in order to be considered for payment. The exceptions appear in the full text of §1862(a) (l) (A) of the Act. See also PIM chapters 13, §5.1 and 7.1.

### **3.6.2.3 - Limitation of Liability Determinations**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

Section 1879(a)-(g) of the Act limits the financial liability of beneficiaries, providers, and suppliers by permitting Medicare payments, or requiring refunds, for certain services and items for which Medicare payment would otherwise be denied. The purpose of this provision is to protect beneficiaries from liability in certain cases of denied services. The limitation of liability provisions apply only to claims for services not statutorily excluded, that are denied for the following reasons:

- The service or item did not meet the reasonable and necessary criteria;
- The beneficiary or provider did not know, or could not have been reasonably expected to know that the service or item would not be covered; and
- The beneficiary receives certain screening tests and preventive services in excess of the guidelines.

(See IOM Pub. 100-04, chapter30, §20 for more information).

The MACs, CERT, and UPICs shall first examine benefit categories and statutory exclusions to determine if a service or item is covered. Recovery Auditors shall examine categories and exclusions as outlined in their SOW. If the item or service meets the requirements of the appropriate benefit category and is not excluded by statute, the next consideration is whether the service was reasonable and necessary. When a claim is denied, in full or in part, because an item or service is not reasonable and necessary, MACs, CERT, Recovery Auditors, and UPICs shall make and document determinations as appropriate to §§1879, 1870, and 1842(l) of the Act. Because the determinations can be appealed, it is important that the rationale for the determination be documented initially and at each level of appeal.

Limitations of liability provisions do not apply if there is a statutory exclusion, even if the service meets the reasonable and necessary criteria.

### **3.6.2.4 - Coding Determinations**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

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

The MACs, CERT, SMRC, Recovery Auditors, and UPICs shall determine that an item/service is correctly coded when it meets all the coding guidelines listed in the Current Procedural Terminology-4 (CPT-4), Coding Clinic for ICD, Coding Clinic for HCPCS, and any coding requirements listed in CMS manuals or MAC articles.

In certain situations, it is appropriate for contractors to up code or down code a claim (or items or services on a claim) and adjust the payment. When the medical record supports a higher or lower level code, the MACs, SMRC, CERT, UPICs and Recovery Auditors shall not deny the entire claim but instead shall adjust the code and adjust the payment.

The MACs, SMRC, CERT, UPICs and Recovery Auditors shall up code or down code when it is possible to pay for the item or service actually provided without making a reasonable and necessary determination or if otherwise specified in applicable CMS medical review instructions. The MACs, SMRC, CERT, UPICs and Recovery Auditors shall not substitute the payment amount of one item or service for a different item or service based on a reasonable and necessary determination.

Example situations where it is appropriate to up code or down code a claim are:

1. CBC with diff was ordered and billed but CBC without diff was provided;
2. X-ray with contrast was ordered and billed but X-ray without contrast was provided;
3. E&M level 3 was billed but the medical record supports level 2 (or other level);
4. PPS (DRG/RUG/HHRG) code was billed but the medical records supports a different code; and
5. Quantity of diabetic test strips exceeds limits; for example, quantity was provided for insulin treated but the patient was not insulin treated.

### **3.6.2.5 - Denial Types**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

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

#### **A. Distinguishing Between Benefit Category, Statutory Exclusion and Reasonable and Necessary Denials**

The MACs, CERT, RACs, and UPICs shall be cognizant that the denial type may affect the financial liability of beneficiaries. They shall ensure that benefit category denials take precedence over statutory exclusion and reasonable and necessary denials. They shall ensure that statutory exclusion denials take precedence over reasonable and necessary denials. MACs, CERT, and UPICs shall use the guidelines listed below in selecting the appropriate denial reason. RACs shall follow denial reason guidance outlined in their SOW.

- If additional documentation was requested from the provider or other entity for any MR reason (benefit category, statutory exclusion, reasonable/necessary, or coding), and the information is not received within 45 calendar days or a reasonable time thereafter, the MACs, CERT, and UPICs shall issue a reasonable and necessary denial, in full or in part.
- If additional documentation was requested because compliance with a benefit category requirement is questioned and the documentation received fails to support compliance with the benefit category, the MACs, CERT, and UPICs shall issue a benefit category denial.
- If additional documentation was requested because compliance with a benefit category requirement is questioned and the received documentation shows evidence that the benefit category requirement is present but is defective, the MACs, and UPICs shall issue a reasonable and necessary denial.

**EXAMPLE 1:** A MAC is conducting a review of partial hospitalization (PH) claims from a provider who has a pattern of

failing to comply with the benefit category requirement that there be a signed certification in the medical record. In the first medical record, the MAC finds that there is no signed certification present in the medical record. The MAC shall deny all PH services for this beneficiary under §1835(a) (2) (F) of the Act (a benefit category denial). However, in the second medical record, the MAC determines that a signed certification is present in the medical record, but the documentation does not support the physician's certification, the services shall be denied under §1862(a) (1) (A) of the Act (a reasonable and necessary denial) because the certification is present but defective.

**Example 2:** The MAC performs a medical record review on a surgical procedure claim and determines that the procedure was cosmetic in nature and was not reasonable and necessary; the denial reason would be that the service is statutorily excluded since statutory exclusion denials take precedence over reasonable and necessary denials.

The MACs, CERT, RACs, and UPICs shall deny payment on claims either partially (e.g., by down coding or denying one line item on a multi-line claim) or in full, and provide the specific reason for the denial whenever there is evidence that a service:

- Does not meet the Benefit Category requirements described in Title XVIII of the Act, NCD, or coverage provision in an interpretive manual;
- Is statutorily excluded by other than §1862(a)(1) of the Act;
- Is not reasonable and necessary as defined under §1862(a) (1) of the Act. MACs, CERT, RACs, and UPICs shall use this denial reason for all non-responses to documentation requests;
- Was not billed in compliance with the national and local coding, payment or billing requirements; and/or
- Was not delivered or provided to the beneficiary, or not provided as billed.

The denial explanation needs to be more specific than merely repeating one of the above bullets. The general exception to the need for a full denial explanation is in the event of a clerical error, for example, the billing entity transposes two digits in the Medicare beneficiary identifier on a claim. The claim is quickly returned, usually electronically, to the provider for correction. In the case of dual-eligible beneficiaries where there is a State-specific policy, see CMS IOM Pub. 100-04, chapter 30, §60.5 A for a detailed explanation of handling administrative denials.

### **3.6.3 - Beneficiary Notification**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

#### **A. General**

If a claim is denied through prepayment or postpayment review, the MAC shall notify the beneficiary consistent with the requirements in PIM chapter 3, §3.6.2.3. The MAC shall include limitation of liability and appeals information. Notification can occur via Medicare Summary Notice (MSN). The CERT, RACs, and UPICs are not required to issue beneficiary notices for claims they deny. Instead, CERT, RACs, and UPICs shall communicate sufficient information to the MAC to allow the MAC to develop an appropriate beneficiary notice.

The MACs are required to give notice to Medicare beneficiaries when claims are denied in part or in whole based on application of a LCD. All denials that result from LCDs shall provide the MSN message 15.19 in addition to the current applicable message. Message 15.19 states (IOM Pub. 100-04, chapter 21):

“A local coverage determination (LCD) was used when we made this decision. A LCD provides a guide to assist in determining whether a particular item or service is covered by Medicare. A copy of this policy is available from your local intermediary, carrier or (Medicare Administrative Contractor) by calling the number in the customer service information box on page one. You can compare the facts in your case to the guidelines set out in the LCD to see whether additional information from your physician would change our decision.”

The MACs shall make these messages available in Spanish where appropriate. The 15.19 portion of the MSN message states:

Una Determinación de Cobertura Local (LCD, por sus siglas en inglés) fue utilizada cuando se tomó esta decisión. La LCD es una guía que ayuda a determinar si un artículo o servicio en particular está cubierto por Medicare. Una copia de esta póliza está disponible en su intermediario, local o en su empresa de seguros Medicare, o en su Contratista Administrative de Medicare, al llamar al número que aparece en la información de Servicios al Cliente en la página uno. Usted puede comparar los datos de su caso con las reglas establecidas en la LCD para ver si obteniendo información adicional de su médico pudiera cambiar nuestra decisión.

The MACs shall use the above message in every instance of a prepayment denial where a LCD was used in reviewing the claim. Use this message, and message 15.20 (now for

FISS MACs, and when 15.20 is fully implemented for contractors on the MCS/VMS systems) on both full and partial denials, whether the denial was made following automated, non-medical review, or medical record review. MACs shall not use this message on denials not involving LCDs. For claims reviewed on a postpayment basis, include the language exactly as contained in the MSN message above if sending the beneficiary a new MSN. If sending a letter, include the language exactly as contained in the MSN message above. Message 15.20 currently states:

“The following policies [insert LCD ID# and NCD#] were used when we made this decision.”(Pub.100-04, chapter 21).

The MACs shall continue to use 15.19 in conjunction with the MSN message 15.20, where 15.19 is applicable. MACs should, at their discretion, combine these messages if necessary, but 15.19 shall not be deleted.

In the case where the results of claims sampling are extrapolated to the universe, only those beneficiaries in the sample need to be notified. In RAC cases, the RAC and MAC Joint Operating Agreement (JOA) shall specify what information the RAC will supply to allow the MAC to notify the beneficiary when re-adjudication results in a change to the initial determination.

### **3.6.4 - Notifying the Provider**

*(Rev. 13595; Issued: 01-26-26; Effective: 02-26-26; Implementation: 02-26-26)*

This section applies to the MACs, RACs, UPICs, *and I-MEDIC*, as indicated.

#### **A. General**

*UPICs and the I-MEDIC may use Kiteworks to facilitate the secure exchange of records and information between contractors, providers/suppliers, and MACs. Kiteworks is authorized in the Federal Risk and Authorization Management Program (FedRAMP) for secure file transfer and sharing functions. The UPICs and I-MEDIC, including all approved subcontractors, shall continue to ensure Federal Information Security Management Act (FISMA)/FedRAMP compliance in accordance with the CMS Office of Information Technology's (OIT) security requirements.*

*The exchange of records and information may include, but is not limited to:*

- *Additional Documentation Request (ADR),*
- *Overpayment/education letters,*
- *Post-payment medical review outcomes documentation,*
- *Administrative actions notices, and*
- *Statistical sample spreadsheets and methodologies.*

At the conclusion of postpayment review, the MACs shall send a Review Results Letter

to the provider even if no overpayment determination is made. If the MACs choose to send a Review Results Letter separately from the demand letter they shall do so within the timeframes listed in PIM chapter 3, §3.3.1.1F. Likewise, the RACs shall issue a Review Results Letter for all audits as outlined in their SOW requirements.

UPICs shall comply with the requirements listed below when issuing Review Results Letters. Each Review Results Letter shall include:

- Identification of the provider or supplier—name, address, and NPI;
- Reason for conducting the review or good cause for reopening;
- A narrative description of the overpayment situation that states the specific issues involved in the overpayment as well as any recommended corrective actions;
- The review determination for each claim in the sample, including a specific explanation of why any services were determined to be non-covered, or incorrectly coded and if others were payable;
- A list of all individual claims that includes the actual non-covered amount, the reason for non-coverage, the denied amounts, under/overpayment amounts, the §1879 and §1870 of the Act determinations made for each specific claim, along with the amounts that will and will not be recovered from the provider or supplier;
- Any information required by PIM chapter 8, §8.4 for statistical sampling for overpayment estimation reviews;
- Total underpayment amounts;
- Total overpayment amounts that the provider or supplier is responsible for;
- Total overpayment amounts the provider or supplier is not responsible for because the provider or supplier was found to be without fault;
- MACs shall include an explanation that subsequent adjustments may be made at cost settlement to reflect final settled costs;
- An explanation of the procedures for recovery of overpayments including Medicare's right to recover overpayments and charge interest on debts not repaid within 30 days (not applicable to RACs or UPICs);
- The provider's or supplier's right to request an extended repayment schedule (not applicable to RACs or UPICs);

- The MACs and UPICs shall include limitation of liability and appeals information in the provider notices;
- The MACs shall include appeals information in the provider notices;
- The MACs shall include the provider or supplier financial rebuttal rights under PIM chapter 3, §3.6.5; and
- For MAC Review Results Letter only, a description of any additional corrective actions or follow-up activity the MAC is planning (i.e., prepayment review, re-review in 6 months).

If a claim is denied through prepayment review, the MACs and UPICs are encouraged to issue a notification letter to the provider but may use a remittance notice to meet this requirement. However, if a claim is denied through postpayment review, the MAC and RAC shall notify the provider by issuing a notification letter to meet this requirement. The UPIC shall use discretion on whether to issue a notification letter.

The CERT contractor is NOT required to issue provider notices for claims they deny. Instead, the CERT contractor shall communicate sufficient information to the MAC to allow the MAC to develop an appropriate provider notice.

## **B. MACs**

The MACs need provide only high-level information to providers when informing them of a prepayment denial via a remittance advice. In other words, the shared system remittance advice messages are sufficient notices to the provider. However, for medical record review, the provider should be notified through the shared system, but the MAC shall retain more detailed information in an accessible location so that upon written or verbal request from the provider, the MAC can explain the specific reason the claim was denied as incorrectly coded or otherwise inappropriate.

## **C. RACs**

For overpayments detected through medical record review, the RAC shall send a review results letter as indicated in the RAC SOW. In addition, the RAC shall communicate sufficient information to the MAC so that the MAC can send a remittance advice to the provider and collect the overpayment.

For underpayments, the RAC shall notify the provider as indicated in the RAC SOW. In addition, the RAC shall communicate sufficient information to the MAC so that the MAC can send a remittance advice to the provider and pay back the underpayment.

## **D. UPICs**

For overpayments detected through medical record review, and after coordination

between the UPIC and OIG, the UPIC shall send a review results letter (the MAC sends the demand letter). In addition, the UPIC shall communicate sufficient information to the MAC so that the MAC can send a demand letter to the provider and collect the overpayment. The UPIC shall use discretion on whether to send the review results letter.

#### **E. Indicate in the Denial Notice Whether Records Were Reviewed**

For claims where the MAC or UPIC had sent an ADR letter and no timely response was received, they shall issue a denial and indicate in the provider denial notice, that the denial was made without reviewing the documentation because the requested documentation was not received or was not received within the allowable time frame (§1862(a) (1) of the Act). This information will be useful to the provider in deciding whether to appeal the decision. When denying the claims, contractors shall use 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.

For claims where the reviewer makes a denial following medical record review, the reviewer has the discretion to indicate in the denial notice, 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 that the denial was made after review of submitted documentation. This includes those claims where the provider submits documentation along with the claim and the reviewer selects that claim for review.

### **3.6.5 - Provider Financial Rebuttal of Findings**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to the MACs. It does not apply to Recovery Auditors, CERT, and UPICs.

#### **A. General**

Providers or suppliers have the right to submit a financial rebuttal statement in accordance with 42 CFR 405.370-375 following receipt of the review results letter and prior to recoupment of the overpayment. The rebuttal statement and any accompanying evidence must be submitted within 15 calendar days from the date of the results letter unless the MAC staff find cause to extend or shorten the time frame.

#### **B. Review of Financial Rebuttal Statement(s)**

Within 15 calendar days of receipt of a financial rebuttal, MAC staff shall consider the statement and any evidence submitted to reach a determination regarding whether the facts justify the recoupment. However, the MAC shall not delay recovery of any overpayment beyond the date indicated in the review results letter in order to review and

respond to the rebuttal statement even if the principal of the debt is modified after reviewing the rebuttal statement (See 42 CFR 405.375(a)). The MAC shall provide a copy of the rebuttal request and a copy of the MAC's response on the rebuttal outcome to the UPICs.

### **C. Cost Report Issues**

Because of the cost report relationship to the overpayment, it is important to note that the projected overpayment recovered from a provider as a result of a postpayment review using statistical sampling for overpayment estimation is based on the interim payment rate in effect at the time of the review.

#### **3.6.6 - Review Determination Documentation Requirements (Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

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

For each claim denied, in full or in part, the MACs, CERT, and UPICs shall carefully document the basis for the denial in the internal claim record. If there are several reasons for denial they shall document each reason in the internal claim record. In addition, the internal claim record should document the date and content of the provider notice of review (§ 3.2.2), additional documentation requests (§3.2.3), and third party documentation requests and response (§3.2.3.3).

In verifying an overpayment, MACs, CERT, Recovery Auditors, and UPICs shall carefully document claims for services not furnished or not furnished as billed so that the denials are more likely to be sustained upon appeal and judicial review.

#### **3.7 - Corrective Actions (Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)**

This section applies to MACs.

The MACs shall take corrective actions they deem necessary based upon their findings during or after a review. These actions may include payment suspension, imposition of civil money penalties, institution of prepayment or postpayment review, additional edits, etc.

Providers/suppliers who show a pattern of failing to comply with requests for additional supporting documentation for any claims submitted to CMS may be subject to medical record review for all claims. This paragraph applies to both providers and suppliers and to instances in which CMS or its contractors request documentation directly from these entities to support services billed on the claim. This paragraph does not change or diminish the provider's or supplier's responsibility to provide required documentation.

For purposes of this paragraph, a pattern is two or more ADRs that have gone unanswered.

### **3.7.1 - Progressive Corrective Action (PCA)**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to MACs.

The MACs shall ensure that actions imposed upon Medicare providers or suppliers for failure to meet Medicare rules, regulations and other requirements are appropriate given the level of non-compliance.

When an error has been validated through MR, the corrective action imposed by the MACs should match the severity of the error. PCA is a means of evaluating the relative risk of the error and assigning appropriate corrective actions. The principles of PCA are:

- It is data-driven. Errors are validated by prepayment and postpayment claims review. (See below).
- Hypotheses and edits are tested prior to implementation to determine facility, utility, and return on investment.
- Workloads are targeted, specific, and prioritized.
- Money is collected when errors are validated.
- Referrals for potential fraud are made when necessary.
- Provider feedback and education are mandatory.
- Medical review resources should be used efficiently.

For each provider data identifies as being at risk, the potential error is validated with prepayment or postpayment review of generally 20-40 potentially erroneous claims. Payments are either denied or recouped. Any underpayments by Medicare will be netted out during the financial reconciliation process. Corrective actions are then implemented based on whether the error represents a minor, moderate, or major concern.

For potentially risky services, errors are validated by prepayment and postpayment review of generally up to 100 potential problem claims for that service from a representative sample of providers. Service-specific errors may require more widespread education for providers and may require the implementation of service-specific prepayment edits.

An example of a minor concern would be a provider with a low error rate and no pattern of errors who has made a relatively minor error with low financial impact. Education and

collection of the overpayment may be sufficient corrective actions.

For moderate concerns, where a provider with a low error rate has made an error with substantial financial impact, some level of prepayment review should be considered. The prepayment review should be tracked and adjusted or eliminated according to the provider's response.

A major concern would be a provider with a high error rate who has made a high-dollar error with no mitigating circumstances, indicating the need for stringent administrative action. A high level prepayment review should be considered along with possible payment suspension and referral to the UPICs.

### **3.7.1.1 - Provider Error Rate**

**(Rev. 738; Issued: 08-18-17; Effective Date: 09-19-17; Implementation Date: 09-19-17)**

This section applies to MACs.

If the MAC identifies a provider-specific problem, the provider error rate is an important consideration in deciding how to address the problem. For instance, a provider with a low error rate with no history of patterns of errors may require a fairly minor corrective action plan such as education with recoupment of overpayment. Other factors such as the total dollar value of the problem and the past history of the provider also deserve consideration. The MAC assesses the nature of the problem as minor, moderate or major and uses available tools such as data analysis and evaluation of other information to validate the problem.

#### **A. Provider Error Rate Formula**

The MACs shall include claims denied due to no response to ADRs when calculating the provider error rate.

The MACs shall use the following formula for prepayment review to calculate the provider's service specific error rate:

Total Dollar amount of allowable\*\* charges for services billed in error as determined by MR\*\*\*

Total Dollar amount of allowable\*\* charges for services subject to a medical review documentation request

For postpayment review, the MACs shall use the following formula to calculate the provider's service specific error rate:

Total Dollar amount of services paid in error as determined by MR\*\*\*

Total Dollar amount of services subject to a medical review documentation request

\*\*If allowable charges are not available, submitted charges may be used until system changes are made.

\*\*\*Net out (subtract) the dollar amount of charges under billed

### **3.7.1.2 - Vignettes**

**(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)**

This section applies to MACs.

The following vignettes provide guidance on how the MACs shall characterize and respond to varying levels of confirmed errors. These are examples of results from medical review accompanied by suggested corrective actions. This information should only be used as a guide and is not meant to be a comprehensive list of vignettes nor an inclusive list of administrative actions. The MAC MR department shall include communication and follow-up with provider outreach and education (POE) throughout the PCA process to coordinate efforts toward problem resolution. The MACs shall monitor trends indicating widespread educational need and shall ensure that POE staff has access to copies of all MR provider notification and feedback letters so they are prepared for provider requests for education (See IOM Pub. 100-04, chapter 20, §3.4.2, for further information).

1. Twenty claims from one provider are reviewed. Once claim is denied because a physician signature is lacking on the plan of care. The denial reflects 7 percent of the dollar amount of claims reviewed. Judicious assessment of medical review resources indicates no further review is necessary at this time. The MAC uses data analysis to determine where to target medical review activities in the future.
2. Forty claims from one provider are reviewed. Twenty claims are for services determined to be not reasonable and necessary. These denials reflect 50 percent of the dollar amount of claims reviewed. One hundred percent prepayment review is initiated due to the high number of claims denied and the high dollar amount denied. The MAC provides notification to the provider about specific errors made and makes a priority referral to POE to inform them of the severity of the problem.
3. Forty claims from one provider are reviewed. Thirty-five claims are denied. These denials reflect 70 percent of the dollar amount of claims reviewed. Payment suspension is initiated due to the high denial percentage and the Medicare dollars at risk. The MAC provides notification to the provider about the specific errors made and makes a priority referral to POE to inform them of the severity of the problem.
4. Forty claims from one provider are reviewed. Thirty-three claims are denied. These denials reflect 25 percent of the dollar amount of the claims reviewed. The MAC provides notification to the provider about the specific errors made. The

- MAC initiates a moderate amount (e.g., 30 percent) of prepayment medical review to ensure proper billing.
5. Thirty-five claims from one provider are reviewed. Thirty claims are denied representing 75 percent of the dollar amount of the claims reviewed. Many of the denials represent services provided to beneficiaries who did not meet the Medicare eligibility requirements. The MAC provides notification to the provider about specific errors made and makes a priority referral to POE to inform them of the severity of the problem. A consent settlement offer is made but declined by the provider. A postpayment review of statistical sampling for overpayment estimation is performed and an overpayment is projected to the universe of similar claims from the provider. Overpayment collection is initiated.
  6. Twenty-five claims from one supplier are reviewed. Five claims representing 5 percent of the dollar amount of the claims are denied. This supplier is known to the DME MAC as one who has a significant decrease in billing volume when targeted medical review is initiated. The DME MAC is concerned that this supplier may be selectively submitting bills when placed on medical review and chooses to continue some level of prepayment medical review despite the low error rate.
  7. Twenty claims from one provider are reviewed. Ten claims are denied for incomplete physician orders representing 65 percent of the dollar amount of the claims. The MAC issues a letter to inform the home health agency (HHA) about the denials and the reason for the denials. In response to the notification letter, the agency owner initiated a mandatory training program for select staff. The HHA was put on 30 percent prepayment medical review. Results of the review indicated an improvement in the error rate to 30 percent (based on dollars denied divided by dollars reviewed). On appeal, most of the denials were overturned. The MAC consults with the ALJ to understand why the cases are being overturned and consults with the RO on appropriate next steps.

### **3.7.1.3 - Provider Notification and Feedback**

**(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)**

This section applies to MACs.

Direct communication between the MAC and the provider is an essential part of solving problems. This process is carried out through written communication or by telephone as a result of specific claims or a group of reviewed claims. The overall goal of providing notification and feedback is to ensure proper billing practices and appropriate consideration of coverage criteria so claims will be submitted and paid correctly.

The MACs shall include an offer to provide individualized education in the notification letter along with contact information for POE. When inquiries are received in response to a provider notification or feedback letter, only responses to those inquiries directly

related to a specific claim or group of claims reviewed on probe or targeted medical review shall be charged to medical review. This charge must be in the appropriate activity code or applicable SOW section for the type of review performed.

### **3.7.2 - Comparative Billing Reports (CBRs)**

**(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)**

This section applies to MACs.

The MACs have the discretion to develop and issue comparative billing reports in the following three (3) situations:

#### **1. Provider-specific CBRs for providers with aberrant billing patterns.**

The MACs have the discretion to give provider-specific comparative billing reports to providers with the highest utilization for the services they bill in order to address potential over-utilization. The MACs have the discretion to send the CBRs based solely on data analysis, without further review or CBRs may be included in the feedback and notification information issued as a result of probe and targeted medical review. These reports shall provide comparative data on how the provider varies from other providers in the same specialty payment area or locality. MACs should not charge a fee for providing these reports.

#### **2. Provider-specific or specialty-specific CBRs requestors.**

To provide good customer service, MACs have the discretion to provide specific reports to providers or provider associations who request such a report. They may charge a fee for providing these discretionary reports. However, any money collected shall be reported as a credit in the appropriate activity code or the applicable SOW section and be accompanied with a rationale for charging the fee. Revenues collected from these discretionary activities shall be used only to cover the cost of these activities, and shall not be used to supplement other MAC activities. If the MACs choose to make such reports available, the MACs shall describe on their Web site the mechanism by which a provider or provider association can request the report and state the associated fee.

#### **3. CBRs for service-specific problems**

When widespread problems are verified, MACs shall refer that information to their POE department for possible Web site posting. For example, data analysis may reveal that home health providers in a particular state bill three (3) times more of a particular code than do home health providers in other surrounding states. The MACs shall not charge a fee for posting these reports.

The MACs shall ensure that POE staff has ready access to copies of all MR provider notification and feedback letters so that they will have this information available in

the event that a provider contacts POE requesting education. If the problem identified by MR is of medium or high priority, the MAC shall make a priority referral to POE, alerting POE staff to the degree of severity and educational need.

### **3.7.3 - Evaluating the Effectiveness of Corrective Actions**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to MACs.

The MACs shall evaluate the effectiveness of their corrective actions on targeted providers or problem areas at least every three (3) months until there is evidence that the poor practice has been corrected. MACs shall establish a method to determine the disposition of educational referrals made to POE to ensure coordination of efforts and resolution of identified problems. MACs have the discretion to use the PTS to perform this function, but are not mandated to do so. MACs shall use the PTS to coordinate contacts with providers regarding MR activities. MACs shall also coordinate this information with the UPICs to ensure contacts are not in conflict with fraud related activities.

#### **3.7.3.1 - Evaluation of Prepayment Edits**

**(Rev. 721; Issued: 06-09-17; Effective: 07-11-17; Implementation: 07-11-17)**

This section applies to MACs.

The MACs shall develop prepayment edits based on the findings of data analysis, followed by identification and prioritization of identified problems. The MACs shall evaluate all service-specific and provider-specific prepayment edits as follows:

- Automated edits shall be evaluated annually, and
- Non-medical record review or medical record review edits shall be evaluated quarterly.

The edit evaluations are to determine their effectiveness on the provider or service area while assessing the effect of the edit tasks on workload. The MACs shall consider an edit to be effective when it has a reasonable rate of denial relative to suspensions and a reasonable dollar return on cost of operation or potential to avoid significant risk to beneficiaries. The MACs shall revise or replace edits that are ineffective. Edits may be ineffective when payments or claims denied are very small in proportion to the volume of claims suspended for review. It is appropriate to leave edits in place if sufficient data are not available to evaluate effectiveness, for instance, a measurable impact is expected, or a quarter is too brief a time period to observe a change. The MACs shall analyze prepayment edits in conjunction with data analysis to confirm or re-establish priorities. The MACs should replace existing effective edits to address problems that are potentially more costly, if appropriate.

#### **3.7.3.2 - Evaluating Effectiveness of Established Automated Edits**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to MACs.

MACs shall consider the following factors when looking at edit effectiveness for established automated edits:

- Time and staffing needs for review and appeal reviews. MACs shall implement mechanisms (e.g., manual logs, automated tracking systems) to allow the appeals unit to communicate to the MR unit information such as when denial categories are causing the greatest impact on appeals, the outcome of the appeal, and
- MACs shall maintain and make available to the appropriate CMS staff documentation demonstrating that they consider appeals in their edit evaluation process; and specificity of edits in relation to identified problem(s).

The MACs should note that even an automated edit that results in no denials may be effective as long as the presence of the edit is not preventing the installation of other automated edits. The MAC shall provide the claims data necessary to the UPIC to evaluate the effectiveness of edits implemented at UPIC request. The MACs shall provide this report on a monthly basis by the 15<sup>th</sup> business day of each month. This requirement could also be met by the UPICs retrieving claim data necessary directly from the EDC if available.

#### **A. Edit Effectiveness for all Other Edits**

The MACs shall consider the following factors when looking at edit effectiveness for all other edits:

- Time and staffing needs for review and appeal reviews. MACs shall implement mechanisms (e.g., manual logs, automated tracking systems) to allow the appeals unit to communicate to the MAC MR unit and the UPIC just specific to UPIC edits information such as which denial categories are causing the greatest impact on appeals, and the outcome of the appeal. MACs shall maintain and make available to CMS documentation demonstrating that appeal outcomes are considered in their edit evaluation process;
- Specificity of edits in relation to identified problem(s);
- Demonstrated change in provider behavior, i.e., the MAC can show a decrease in frequency of services per beneficiary, the decrease in the number of beneficiaries receiving the services, the service is no

longer billed, or another valid measure can be used to reflect a change in provider behavior over time;

- Impact of educational or deterrent effect in relation to review costs; and
- The relative priorities or competing edits in terms of the number of claims/days/charges.

The MACs shall test each edit before implementation to verify that the edit accomplishes the objective of efficiently selecting claims for review and to determine the edit's impact on workload.

### **3.7.3.3 - Evaluation of Postpayment Review Effectiveness (Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to MACs.

The MACs shall determine if any other corrective actions are necessary such as:

- Uncovering potential fraud in the course of MR postpayment review activities. The MR unit shall refer these cases to the UPIC. If it is believed that the overpayment resulted from potential fraud, a refund may not be requested from the provider until the potential fraud issue is resolved.
- Initiating provider or supplier specific edits to focus prepayment view on the problem provider or supplier or group of providers or suppliers, if appropriate ;
- Working with the CMS Central Office Division of Benefit Integrity Management Operations (DBIMO) Fraud and Abuse Suspensions and Sanctions (FASS) Team to suspend payment to the provider or group of providers;
- Referring provider certification issues to the State survey agency through CMS staff;
- Referring quality issues involving inpatient hospital services to the RO and QIO; and
- Coordinating with the QIO and MAC on interrelated billing problems

The MACs periodically perform a follow-up analysis of the provider(s) or supplier(s) for

as long as necessary to determine if further corrective actions are required. In some cases, it may be feasible and timely to perform the follow-up analysis of the provider or supplier after the three (3) month time period. The MACs shall continue to monitor the provider(s) or supplier(s) until there is a referral to the UPICs for potential fraud, evidence that the utilization or billing problem is corrected, or data analysis indicating resources would be better utilized elsewhere.

### **3.7.4 - Tracking Appeals**

**(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)**

This section applies to MACs.

The MACs shall track and evaluate the results of appeals. It is not an efficient use of medical review resources to deny claims that are routinely reversed upon appeal. When such outcomes are identified, MACs shall take steps to understand why hearing or appeals officers viewed the case differently from them, and discuss appropriate changes in policy, procedure, outreach or review strategies with the regional office.

### **3.7.5 - Corrective Action Reporting Requirements**

**(Rev.: 10100; Issued: 05-08-2020; Effective: 06-09-2020; Implementation: 06-09-2020)**

#### **A. General**

This section applies to MACs.

The CMS will provide information to the MACs regarding CMS Recovery Audit Contractor (RAC), and OIG-identified issues via Technical Direction Letters (TDLs). The TDLs will be sent to the MACs on a quarterly basis. Each MAC shall report corrective actions by the dates stated in the TDLs.

#### **B. Corrective Action Reporting on CMS and OIG-Identified Issues**

The CMS will provide MACs with a list of issues on an Excel spreadsheet template (Corrective Actions Taken on CMS and OIG-Identified Issues). These issues may be uncovered by the RAC, OIG audits, internal CMS analysis, or other means. The MACs shall review the spreadsheet, type precise responses on the template (see interim and final reportable action statement samples below), and upload the excel file or flat file to the RAC Data Warehouse (RAC DW).

For each of the issues, MACs shall report interim actions, final actions, and action dates (see interim and final reportable action statement examples below). The common factor between all reportable actions is quantifiability. The distinguishing factor between the two types of reportable actions is intervention implementation. Interim reportable actions generally indicate in-progress reviews of issues prior to the initiation of final actions.

Final reportable actions indicate specific interventions completed to prevent future improper payments.

**Examples of interim reportable action statements:**

- MAC is planning a 50% post-payment review (to be performed between 08/01/2014 – 08/31/2014) of 200 claims (with dates of service between 01/01/2012 – 12/31/2012).
- MAC performed a 100% pre-payment review for DRG numbers #### – #### on 02/14/2014 (with dates of service between 01/01/2012 – 12/31/2012).
- MAC performed a pre-payment widespread review using a 100 claim probe on 03/26/2014 (with dates of service between 01/01/2012 – 12/31/2012).
- MAC performed a provider-specific pre-payment review on 04/17/2014 (with dates of service between 01/01/2012 – 12/31/2012).
- Due to resource limitations, not yet able to fully research issue (with dates of service between 01/01/2012 – 12/31/2012).

**Examples of final reportable action statements:**

- MAC held a provider seminar for 500 chiropractors regarding documentation requirements on 11/12/2013.
- MAC published an article regarding billing for nebulizer drugs on 02/27/2014 that explained the coverage policy for nebulizer drugs.
- MAC installed an automated edit and validated functionality on 03/19/2014 for codes #### – ####.
  - If readily available, please provide edit effectiveness as defined in PIM section 3.7.3.1 – Evaluation of Prepayment Edits. <Please insert cost savings and number or percentage of claims denied.>
- MAC performed a provider -specific review resulting in a provider education activity. <Comparative Billing Report, letter, one-on-one telephone explanation,...>...on 05/19/2014.
- Based on analysis, this is not an issue within jurisdiction X.

**Interim and final reportable action statement rationales:**

- In the additional comments section of the TDL template, MACs shall provide brief supplementary rationales for the reported actions. ○ For example, rationales may state that analysis produced no significant findings due to low volume, claims paid, lower risk and lower priority ranking when compared with other issues.
- The MACs have the discretion to also utilize the additional comments section to briefly explain pertinent background information regarding the MACs processes

for specific issues. The MACs may also utilize the space to communicate suggestions for CMS to consider regarding possible future actions.

The MACs shall use the format (Corrective Actions Taken on CMS and OIG-Identified Issues) located in Exhibit 18, section A for reporting purposes. The MACs shall use the prescribed format, acceptable to the RAC DW. The MACs shall upload the file by the date specified in the TDL. If the due dates fall on a weekend or a federal holiday, the MAC shall upload the file on the closest business day after the weekend or holiday. A TDL may occasionally provide an exception to the submission criteria described in the PIM and the exception will be stated within the text of the memorandum.

### **Updates to previous reportable actions**

The MACs shall keep CMS informed of any updates or changes to interim or final reportable actions on top issues from past TDL responses. The format located in Exhibit 18, Section A will include a column titled 'Updated Responses.' The MACs shall enter the following information, in a single cell, for each update:

- The New Issue number being updated
- The Issue Label
- The fiscal year and quarter that the responses were first provided
- The type of response originally provided [Interim or Final]
- The type of response being provided in the update [Interim or Final]
- The response statement in the format described above

The MACs should leave this section blank if they have no updates for the quarter.

### **C. Overpayment Recovery Reporting**

The CMS will provide the MACs with specific claims information from Office of the Inspector General (OIG) audits on a quarterly basis via TDLs. These specific claims have not been reviewed by the OIG and overpayments have not yet been identified. The MACs have the discretion to review these specific OIG-identified claims. The MACs shall report overpayment recoveries pertaining to the specific OIG-identified claims to the CMS on a quarterly basis. If the MAC does not plan on conducting review or cannot conduct review on the specific OIG-identified claims, the MAC shall indicate that no medical review will be conducted and shall also indicate the reason why no medical review and/or overpayment recovery will be conducted on the particular claims set. The reporting shall include the Medicare contractor number, the OIG audit number (e.g. A-01-08-00528, OEI-01-04-0060) and the cumulative amount collected on the overpayments resulting from the specific set of OIG-identified claims. The cumulative amount shall include appeals. The CMS will indicate the "final reporting date" in the reporting document when the recovery process has been completed for a specific set of OIG-identified claims. CMS will indicate when the report shall be closed. The MACs have the discretion to report on overpayments that have been referred or are uncollectable at this time resulting from the specific set of OIG-identified claims.

The MACs shall submit their response to CMS on or before March 1, June 1, September 1, and December 1. If the due dates fall on a weekend or a federal holiday, the MACs shall submit the report on the closest business day after the weekend or holiday. The MACs shall submit their response in Excel via email to the CMS contact indicated in the most recent TDL from CMS which includes the claim information and report number. The MACs shall use the format titled "Overpayment Recovery on OIG Claims Format" located in Exhibit 18 for reporting purposes. The MAC has the discretion to readjust the format for use in Excel. The MAC shall complete all fields in the format except for the one optional column. The MACs have the discretion to complete the column titled "Overpayments referred or uncollectable (in dollars)."

### **3.8 - Administrative Relief from MR During a Disaster**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

This section applies to MACs and Recovery Auditors. UPICs refer to the PIM chapter 4.

#### **A. General**

When a disaster occurs, whether natural or man-made, MACs and Recovery Auditors shall anticipate both an increased demand for emergency and other health care services, and a corresponding disruption to normal health care delivery systems and networks. In disaster situations, MACs should do whatever they can to ensure that all Medicare beneficiaries have access to the emergency or urgent care they need. MACs are encouraged to let providers know (via Web site, responses to provider calls, etc.) that the provider's first responsibility, as in any emergency, is to provide the needed emergency or urgent service or treatment. The MACs should assure providers they will work with providers to ensure that they receive payment for all covered services. The administrative flexibility available to MACs and Recovery Auditors is discussed below. These actions will prevent most inappropriate denials and subsequent appeals.

#### **B. Definition of Disaster**

A disaster is defined as any natural or man-made catastrophe (such as hurricane, tornado, earthquake, volcanic eruption, mudslide, snowstorm, tsunami, terrorist attack, bombing, fire, flood, or explosion) which causes damage of sufficient severity and magnitude to partially or completely destroy medical records and associated documentation that could be requested by the MACs and Recovery Auditors in the course of a Medicare audit, interrupt normal mail service (including US Postal delivery, overnight parcel delivery services, etc.), and/or otherwise significantly limit the provider's daily operations.

A disaster may be widespread and impact multiple structures (e.g., a regional flood) or isolated and impact a single site only (e.g., water main failure). The fact that a provider is located in a presidentially declared disaster area under the power of the Stafford Act is not sufficient in itself to justify administrative relief, as not all structures in the disaster area may have been subject to the same amount of damage. Damage must be of sufficient

severity and extent to compromise retrieval of medical documentation.

### **C. Basis for Providing Administrative Relief**

In the event of a disaster, MACs and Recovery Auditors shall grant temporary administrative relief to any affected providers for up to 6 months (or longer with good cause). Administrative relief is to be granted to providers on a case-by-case basis in accordance with the following guidelines:

- The MACs and Recovery Auditors shall make every effort to be responsive to providers who are victims of the disaster and whose medical documentation may be partially or completely destroyed.
- Providers must maintain and submit verification upon contractor request by the MAC or Recovery Auditor that (1) a disaster has occurred and (2) medical record loss resulted from this disaster to the point where administrative relief from medical review requirements is necessary to allow the provider sufficient time to retrieve copies of, or restore damaged, medical documentation.

Verification of the disaster and the resultant damage should include but is not limited to:

- (1) Copies of claims filed by the provider with his/her insurance and liability company; and
- (2) Copies of police reports filed to report the damage, (3) copies of claims submitted to FEMA for financial assistance, (4) copies of tax reports filed to report the losses, or (5) photographs of damage. MACs and Recovery Auditors shall not routinely request providers to submit verification of damage or loss of medical record documentation.

### **D. Types of Relief**

#### Providers Directly Affected By Disaster

The MACs and Recovery Auditors shall stop sending ADR letters to providers who have been directly affected for at least 60 calendar days. The MACs and Recovery Auditors shall allow up to an additional six months beyond the original due date for the submission of requested records. Requests for extensions beyond this date can be granted with good cause at the discretion of the MAC or Recovery Auditor.

In the case of complete destruction of medical records where no backup records exist, MACs and Recovery Auditors shall accept an attestation that no medical records exist and consider the services covered and correctly coded. In the case of partial destruction, MACs and Recovery Auditors should instruct providers to reconstruct the records as much as possible with whatever original records can be salvaged. Providers should note on the face sheet of the completely or partially reconstructed medical record: "This record

was reconstructed because of disaster."

### Providers Indirectly Affected By Disaster

For providers that are indirectly affected by a disaster (e.g., an interruption of mail service caused by a grounding of US commercial air flights), MACs and Recovery Auditors shall take the following actions:

For ADRs, extend the parameter that triggers denial for non-receipt of medical records from 45 calendar days to 90 calendar days. ADRs shall reflect that the response is due in 90 calendar days rather than 45 calendar days. This action will prevent most inappropriate denials and unnecessary increases in appeals workload.

If the MAC or Recovery Auditor receives the requested documentation after a denial has been issued but within a reasonable number of days beyond the denial date, the MAC or Recovery Auditor has the discretion to reopen the claim and make a medical review determination. Many reviewers follow a standard 15 calendar days although MACs and Recovery Auditors shall make these decisions on a case-by-case basis. The MACs and Recovery Auditors shall allocate the workload, costs and savings to the appropriate MR activity.

The MACs and Recovery Auditors shall review reopened claims retroactively to the date of the disaster. The MAC's data analyses shall take into consideration the expected increase in certain services in disaster areas.

### **E. Impact on MAC Performance Evaluations**

During performance evaluations, CMS will consider a waiver to all MAC MR requirements, as necessary, to allow MACs the flexibility to handle issues that arise in the aftermath of a disaster. Examples of such waived requirements include workload targets and any other MR administrative rules. MACs shall retain documentation of how their MR operations were affected during the disaster and make it available to Performance Evaluation Teams and other CMS Staff, upon request.

## **3.9 - Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings**

**(Rev. 853, Issued: 01-04-19; Effective: 02-05-19; Implementation: 02-05-19)**

This section in its entirety applies to MACs. This section applies to Recovery Auditors, CERT, UPICs, and the SMRC, as indicated in their SOWs.

### **Overview:**

Effective March 20, 2017 several changes were made to the regulations that outline the activities related to contractor participation in ALJ hearings. Under the new regulations, CMS contractors are limited to 3 roles in an ALJ hearing: a Participant, a Party, or a

Witness (defined in detail below). These changes are outlined in 42 CFR §405.1010 and 42 CFR §405.1012.

A physician overseeing participation shall be a current Contractor Medical Director (CMD), a contractor employed physician or any combination thereof. Nurses and other staff may assist the physician with the tasks described in this section. While the physician is generally the primary individual overseeing and/or taking party or participant status, a contractor may elect to have an attorney or clinician take party or participant status, or another experienced qualified individual if approved by their COR. In either situation, the contractor must be prepared to discuss details related to the facts of each claim under appeal, the relevant coverage policies and payment requirements, including any clarification required on decisions made earlier in the appeals process. For post-pay audit/overpayment cases, the contractor must be prepared to discuss the background on how the provider/supplier was selected for review, results of the sample case adjudications, as well as matters related to the extrapolation methodology and/or processes.

This section establishes expectations related to the contractor's participation and associated coordination activities, although CMS may provide additional guidance and direction as needed. Further rules and procedures related to the ALJ hearing process are contained in 42 CFR §405.1000.

The MAC shall capture and report the ALJ participation and party data in their monthly status report to CMS. Contractors shall record the frequency of their support as a witness in the narrative field of the monthly status reports. Contractors shall ensure that JOAs are sufficient to support the ALJ hearing process and related coordination activities.

### **Role of the Participant:**

In accordance with the revised regulation under 42 CFR Part §405.1010(c) and (d), all contractors' participation as a participant (i.e., non-party) shall be limited to submitting written testimony and/or position papers (except in those instances when non-party participants are able to provide testimony to clarify factual or policy issues in the case—as noted in the scenario below).

The regulations do not prohibit multiple CMS contractors and/or related entities from participating in the ALJ hearing as a participant. However, if no contractor or CMS invokes party status, then the first entity to submit their election to participate as a non-party participant to the ALJ may participate in the oral hearing (limited to clarification of factual or policy issues, as requested by the ALJ). All other entities may participate, but are precluded from the hearing and may only submit written testimony and/or position papers as indicated in 42 CFR §405.1010(d)(1) and (2). If the contractor is able to participate in the hearing, they shall be adequately prepared to respond to questioning by the ALJ regarding all issues related to the claims under appeal. Because participation status does not include the same rights as full party status, the contractor may not call

witnesses or cross-examine witnesses of another party, as indicated in 42 CFR §405.1010(c)(1).

(Note: At this time, CMS would not expect contractors to be responsible for clarifying factual or policy issues for cases/claims outside of their jurisdiction.)

### **Role of the Party:**

Contractors shall invoke party status in ALJ hearings in accordance with the regulatory provisions in 42 CFR § 405.1012 and the CMS-prescribed prioritization process, described below, for cases or items/services of interest to CMS. Under 42 CFR §405.1012(d)(1), the first contractor to invoke party status with the ALJ is made the party to the hearing. All other contractors who invoke party status for that particular hearing are made participants and are precluded from the hearing (See Role of the Participant section above).

Note: At this time, CMS would not expect contractors to be responsible for representing cases/claims outside of their jurisdiction.

If the contractor is interested in a particular case, but is precluded from invoking party status based on the CMS-prescribed prioritization of cases or otherwise, the contractor may request 'leave' from the ALJ in accordance with 42 CFR §405.1012(d)(2). The request for 'leave' process occurs outside of the Administrative Qualified Independent Contractor (AdQIC) portal, described below. In submitting a request for 'leave' to the ALJ, the contractor is formally requesting that the ALJ grant the contractor the right to be a secondary party to the hearing. Requests for 'leave' to the ALJ shall also include the reason(s) why the contractor believes that their presence as a secondary party in the ALJ Hearing is necessary. The ALJ shall make the determination as to whether the contractor is granted 'leave.' If this is approved, the contractor shall become a secondary party to the hearing. Alternatively, if denied, the contractor may participate as a participant or as a witness, based on the circumstance. (See Role of Witness section for additional information).

As a party, the contractor is able to orally participate in the hearing and may file position papers, call witnesses, and/or cross-examine witnesses of other parties. The contractor shall submit any position paper or additional evidence requested by the ALJ in accordance with 42 CFR §405.1012(c)(2)(i) and (ii). The contractor shall be adequately prepared to respond to questioning by the ALJ or other parties regarding all issues related to the claims under appeal. As a party to the hearing, contractors are subject to discovery by the other party to the hearing in accordance with 42 CFR §405.1037.

For Notice of Hearings (NOHs) received that include issues deemed significant by CMS or the contractor, the contractor shall, at a minimum:

- Invoke party status in ALJ cases per volume of ALJ cases funded for this activity;

- Participate in any pre-ALJ hearing conference calls, as needed, with other contractors (as facilitated by the appropriate Qualified Independent Contractor (QIC));
- Coordinate with Medical Director(s) or related personnel from other contractors intending to participate as consultants/expert witnesses, as necessary, in accordance with 42 CFR §405.1010(d)(3). In addition, the MAC shall coordinate with other contractors for those hearings in which they do not invoke party status, but decide to participate as a consultant/expert witness; and/or,
- Participate in the hearings as a party via telephone, video teleconferencing, or in-person.

### **Role of the Witness:**

If the ALJ declines the request for contractor ‘leave’ on a particular hearing, the contractor may be called as a ‘witness’ by CMS or another CMS contractor that is a party to the hearing. A determination regarding the need for a ‘witness’ by the participating party shall be determined by the party and communicated to the contractor prior to the hearing. Contractors should, at their discretion, participate as a ‘witness’ in any case in which another CMS contractor and/or CMS has requested their support in a hearing. Contractors shall notify the requesting party no later than 10 days prior to the scheduled hearing in those instances in which contractors are unable to support the hearing as a ‘witness.’ As a ‘witness,’ contractors shall be tasked with supporting the party to the hearing in responding to policy or factual issues related to a particular case through direct examination and is subject to cross examination by the opposing party.

Note: Contractors who are interested in acting as a witness may indicate their interest via the AdQIC Portal. CMS contractors may indicate interest in participating as a witness without first making a request for ‘leave’ with an ALJ. Additionally, in accordance with 42 CFR §405.1020, witness designations/elections shall be made during the coordination of interest/role selection process, as described below, and shall be included in the response to a given NOH.

### **3.9.1 - Election of Status**

**(Rev. 10365; Issued: 10-02-20; Effective: 08-27-20; Implementation: 08-27-20)**

The contractor shall establish a process for assessing the NOHs received to determine which cases should be selected for participation, as well as the type of participation (participant, party, or witness) to be employed. Factors to be examined should include, but not be limited to: originator of initial denial, policy implications, dollars at issue, program integrity matters, and the extent to which a particular issue is, or has been, a recurring issue at the ALJ level of appeal.

Contractors shall, for those cases in which they were the medical reviewer issuing the denial subject to appeal, have a prioritized ability to invoke party status (in lieu of other

appeals support contractors). This process is further described below.

**A. Election of Participation Status Prior to Receipt of a Formal NOH**

The election to participate as a participant shall be made consistent with 42 CFR §405.1010 and can be done either prior to receipt of a formal NOH or after the receipt of a formal NOH.

The regulations allow CMS contractors to elect to participate as a participant before issuance and/or receipt of the formal NOH. See section of 42 CFR §405.1010(b)(1) for additional information. If the contractor elects to participate before the receipt of the NOH, it shall send written notice of its intent to the assigned ALJ or attorney adjudicator, or the designee of the Chief ALJ, if no contact assigned yet, and to all parties on the reconsideration (per the prescribed OMHA process) within 30 calendar days after notification that a request for hearing had been filed. In accordance with the regulations, a position paper or written testimony must either be submitted within 14 calendar days of an election to participate, if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing, if a hearing is scheduled, unless the ALJ grants additional time to submit the position paper or written testimony. Contractors should note that there is a risk that the case may be later resolved by the ALJ, or an Attorney Adjudicator within the OMHA, without a hearing.

**B. Election of Participation or Party Status Following Receipt of the Formal NOH**

The election to be a participant or a party to a hearing after receipt of the formal NOH shall be made consistent with 42 CFR §405.1010(b) or 42 CFR §405.1012, respectively, and the CMS-prescribed prioritization process, described below. If through the CMS-prescribed prioritization process it is determined that the contractor may act as either the party or a participant to a hearing, elections of participation must be sent by the Contractor within 10 calendar days of receipt of the NOH at the AdQIC to all parties listed on the NOH. Submission of a position paper, written testimony, and/or evidence must be submitted no later than five calendar days before the date of the scheduled hearing. Copies of these items must also be sent to those parties listed on the NOH in accordance with 42 CFR §405.1010(c)(3)(ii) and 42 CFR §405.1012(c)(2)(ii).

**C. CMS-prescribed Prioritization Process and AdOIC Portal for Providing a Response to the Formal NOH**

As the AdQIC is tasked with coordinating contractor interest in participation among the related CMS contractors and/or CMS, all NOHs will be sent directly to the AdQIC from the OMHA. The AdQIC, within two (2) calendar days of receipt of the formal NOH from OMHA, will create a record in the AdQIC portal that will generate an email notification to all applicable CMS contractors (e.g., DME MAC, A/B MAC, UPIC, SMRC, and/or RAC) notifying them that a hearing has been scheduled.

Upon receipt of the formal NOH e-mail alert, all applicable CMS contractors shall log onto the AdQIC website, <https://participation.q2a.com>, to access the NOH information. All applicable CMS contractors shall make their elections, via the AdQIC website, within five (5) calendar days of the formal NOH e-mail sent date. To make an election, contractors must sign-in on the website (see above), and a dashboard will be available listing all appeals for the respective contractor that they may choose to participate in.

Users can also search for appeals based on the information provided in the notification email. Next, the contractors shall select the applicable NOH identifier and complete/submit the CMS Contractor Participation Form indicating for each appeal whether they would like to participate as a party, participant, or witness, and/or if they would like to call a witness if made a party to the hearing. CMS contractors that fail to sign-in to the AdQIC system and make their respective participation role selections, in the required timeframe, may be precluded from the prioritization process.

Note: Users will not be able to view the actual NOH document on the site. The website/dashboard will allow contractors to view all scheduled hearings for which they received an NOH.

For all NOH communications (e.g., NOHs received from OMHA, NOH email alerts) received after standard business hours (e.g., 4:00 p.m., ET) and/or during weekends or business Holidays, as defined by the respective entity, the AdQIC portal is programmed to calculate the response time beginning with the next applicable business day [e.g., if the AdQIC receives the formal NOH on a Friday at 4:00 pm, the five (5) calendar day timeframe begins on Monday (with Monday being day zero (0))].

The AdQIC portal will evaluate all submissions received and determine which entity shall have the primary opportunity to participate as a ‘party,’ and which entities can participate as ‘participants’ or ‘witnesses’ based on CMS’ prioritization logic.

The anticipated prioritization for the role of party status is as follows:

- 1) Primary opportunity for the ‘party’ role in an ALJ hearing will be granted to the entity that conducted the initial claim denial (e.g., UPIC, RAC, SMRC or medical review unit within the MAC).
- 2) If the entity that issued the initial claim denial does not have interest in participating as a party (due to workload considerations or otherwise) the QIC will have the primary opportunity to participate as a party.
- 3) If no CMS contractors and/or CMS wish to invoke ‘party’ status in a hearing and multiple entities wish to be a participant, the primary participant shall be the entity that conducted the initial claim denial (e.g., UPIC, RAC, SMRC, or medical review unit within the MAC).
- 4) If the entity that identified/conducted the initial claim denial does not wish to be the ‘primary’ participant on the case, the QIC will

have the next opportunity to assume this role.

The AdQIC portal will review and prioritize contractor roles in a respective ALJ hearing (i.e., which contractor shall be the 'party', 'participants,' etc.), within 2 calendar days of receipt of the completed Contractor Participation forms. The website will automatically calculate the contractor's Participation Form response due date and each contractor's role determination, and prioritize participation elections on the next calendar day after the contractor response timeframe expires. Participation/role designations will be sent via a system-generated email notification to any contractors who expressed interest in participation. The status of elections for a given NOH will be available on the AdQIC's website once determinations have been made and notifications have been sent to the applicable CMS contractors.

On rare occasion, the QIC may need to facilitate a call with the CMS and the related contractors to determine the roles and/or responsibilities on a particular hearing.

Within 10 calendar days from the initial NOH receipt date, the AdQIC will reply on behalf of all applicable CMS contractors to the NOH and OMHA with a consolidated response. The consolidated response shall include a Notice of Election form for each applicable CMS contractor for a given NOH.

In the event that OMHA issues an amended NOH, the amended NOH email will be sent from OMHA directly to the AdQIC. The AdQIC will alert all applicable CMS contractors of the amended NOH within 2 calendar days of receipt of the amended NOH email from OMHA. CMS contractor participation roles, as determined via the prioritization process in the response to the original NOH and submitted to OMHA via a Notice of Intent (NOI), shall remain intact following issuance of an amended NOH by OMHA. However, if a CMS contractor wishes to change their method of participation following the receipt of an amended NOH, then the CMS contractor shall notify/work with the AdQIC and OMHA, as applicable (e.g., if another CMS contractor was designated as the Party and the QIC was made a non-party Participant, but now the QIC wishes to serve as a Party following the receipt of an amended NOH, then the QIC must request 'leave' with the ALJ and notify the AdQIC if the request for 'leave' is approved).

#### **D. Communications Outside of the Portal/AdOIC Process**

While the AdQIC and its prioritization portal provide useful vehicles for assessing information transcribed from the notices of hearing received from OMHA and providing formal response, contractors are reminded of regulatory communications that occur outside of this process.

Contractors are reminded that the AdQIC portal and prioritization process is initiated by receipt of an NOH from OMHA. Therefore, Contractors electing status prior to receipt of an NOH shall follow the regulatory process (outlined in 42 CFR §405.1010) to alert OMHA and other parties that were sent a copy of the notice of reconsideration of their

intent to participate, which occurs outside of the portal.

In accordance with section of 42 CFR §405.1010(b)(2) and (3), if a contractor elects to participate in an ALJ hearing, the contractor (not the AdQIC) shall provide written notice of its intent to participate to the parties who were sent a copy of an NOH. Failure to notify the other parties to the appeal, of the intent to participate, may result in the ALJ determining the contractor's election for a given NOH invalid. This requirement remains applicable in the event of an amended NOH, and contractors shall ensure compliance. All pertinent information (e.g. party names, mailing address) will be available in the portal for a given NOH.

Additionally, CMS contractors participating or taking party status shall provide copies of all submitted position papers, written testimony, and/or evidence to the ALJ and other appropriate parties within the time frames as set forth in 42 C.F.R. sections 405.1010, 405.1012, or 423.2010, as applicable. Failure to provide copies of submitted position papers, written testimony, and/or evidence within the required timeframe will result in the submissions not being considered by the respective ALJ. Providing copies of all submitted position papers, written testimony, and/or evidence to the appropriate parties remains applicable in the event an amended NOH is issued and contractors shall ensure compliance.

If a contractor requests 'leave' to the ALJ, or formally requests the ALJ to grant the contractor the right to be a secondary party to the hearing, this process occurs outside of the portal.

The ALJ sets the hearing date, time, and method by video teleconferencing (VTC), telephone, or in-person if VTC is not available or special circumstances exist. A party may object in writing to the time and place of the hearing, as soon as possible before the originally scheduled time but no later than 5 calendar days prior to the hearing, and include the reason for the objection along with a proposed alternative date and time. In addition, a party may request an in-person hearing by notifying the ALJ in writing and following the same procedures noted above for an objection to the time/place of the hearing. The ALJ may reschedule if good cause is established per 42 CFR §405.1020(f) or (g).

### **3.9.2 - Coordination of the ALJ Hearing**

**(Rev. 748, Issued: 10-13-17; Effective: 11-14-17; Implementation: 11-14-17)**

As needed, if multiple entities are participating in a hearing as a party, participant, or witness, the QIC will set up a brief pre-hearing conference call to discuss the respective entity's participation in the case, roles and responsibilities, etc. Examples in which this may be necessary include high dollar cases, extrapolated overpayments, policy implications, and/or fraud related cases, etc.

Pre-hearing briefing topics may include: coordination with OMHA on scheduling matters, the manner of participation, coordination on position papers or other written

testimony submitted, and lessons learned from participation in the ALJ process.

There may be cases in which testimony from another contractor is necessary. The contractor may call those entities as a witness only if the contractor has declared party status. However, if the contractor submits a position paper as a participant, the contractor may collaborate with other contractors and document their views on the case in the paper—although only one contractor may typically participate via the hearing.

The contractor shall establish a single point of contact for ALJ offices on administrative matters involving notifications, scheduling, information sharing, and other coordination necessary between the ALJ, the appellant, and other contractors.

### **3.10 – Prior Authorization**

**(Rev. 876; Issued: 04-12-19; Effective: 05-13-19; Implementation: 05-13-19)**

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

#### **A. Overview**

Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the item or service is furnished to the beneficiary and before the claim is submitted for processing. It is a process that permits the submitter (e.g., provider, supplier, beneficiary, etc.) to send in medical documentation in advance of providing and billing for an item or service, to verify its eligibility for Medicare claim payment. Contractors shall, at the direction of CMS or other authorizing entity, conduct prior authorizations and alert the submitter of any potential issues with the information, as submitted.

For any item or service to be covered by Medicare it must:

- Be eligible for a defined Medicare benefit category,
- Be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and
- Meet all other applicable Medicare coverage, coding and payment requirements.

Contractors shall communicate to the submitter (and beneficiary upon request) their prior authorization decision and the assigned unique tracking number (UTN), which indicates that the submitter requested a prior authorization, for corresponding claim submissions.

For certain prior authorization programs, the requirement to prior authorize is a condition of payment, as further described in the sections below.

Absent any explicit CMS instruction to the contrary, submitters may correct identified issues with their prior authorization request(s) and resubmit their request(s) for prior authorization without restriction. Contractors shall conduct prior authorization reviews within the timeframes defined by CMS in the corresponding prior authorization program operational instruction(s).

The prior authorization process is further described in following sections.

## **B. Condition of Payment**

Contractors shall determine if the requirement to prior authorize a particular item or service is a condition of payment, as specified in the individual operational instruction(s). If prior authorization is a condition of payment, claims submitted without an indication that the submitter made a prior authorization request (i.e., UTN) shall be denied upon receipt.

## **C. Outreach and Education**

Contractors shall educate stakeholders each time a new prior authorization program is launched for a particular item or service, the requisite information and timeframes for prior authorization submissions, and the vehicle(s) for submitting such information to the contractor for assessment. Contractors shall make sure submitters are aware of the timeframes for contractors to render prior authorization decisions, for each individual prior authorization program.

Each prior authorization program will have an associated Operational Guide and will be available on the CMS website. Contractors shall, at a minimum, provide public access to agency-developed prior authorization operational guides, by posting the link(s) on their website.

Contractors shall hold group or individualized training sessions, as appropriate, to notify the stakeholders of upcoming prior authorization programs and to make sure there is ongoing understanding of the specific requirements for those applicable prior authorization programs.

## **D. Prior Authorization Submission**

Contractors shall assess the information/documentation included in the prior authorization submission for completeness. Requisite information for individualized prior authorization programs will be included in the operational guides, and shall be available on the CMS website.

Requisite information may include, but is not limited to:

- Beneficiary Information (i.e., name, Medicare beneficiary identifier, date of birth)
- Physician/Practitioner Information (i.e., name, provider identification number, address)
- Supplier Information (i.e., name, national supplier clearinghouse (NSC) number, identification number, address)
- Documentation from the medical record to support the medical necessity of the item or service, and
- Any other relevant documents as deemed necessary by the contractor to process the prior authorization.

#### **E. Prior Authorization Decisions**

Contractors shall notify the submitter if their prior authorization submission results in a provisional affirmative, or non-affirmative decision.

- A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the item or service likely meets Medicare's coverage, coding, and payment requirements.
- A non-affirmative decision is a finding that the submitted information/documentation does not meet Medicare's coverage, coding, and payment requirements, and if a claim associated with the prior authorization is submitted for payment, it would not be paid. Contractors shall provide notification of the reason(s) for the non-affirmation, if a request is non-affirmative, to the submitter. If a prior authorization request receives a non-affirmative decision, the prior authorization request can be resubmitted an unlimited number of times, unless otherwise specified.

Contractors shall send detailed decision letters to submitters. As appropriate for the given prior authorization program, contractors shall send detailed decision letters to other stakeholders (e.g., beneficiaries) using their official address on file. In addition, there may be certain prior authorization programs that require the contractors to notify the appropriate entity by other means, such as telephone.

If a claim is submitted for payment without an affirmative prior authorization decision on file, contractors shall use their existing processes to either suspend claims for additional review or to process claims as denials, based on each individualized prior authorization program, as detailed in the operational instruction.

#### **F. Expedited Request**

For certain items or services, delays in receipt of a prior authorization decision could jeopardize the life or health of the beneficiary. Contractors shall, for such items or services, expedite their decisions based on the operational instruction.

If the claim processing systems would unavoidably delay the delivery of the UTN in an expedited fashion, contractors shall nonetheless render an affirmative or non-affirmative decision to the submitter within the mandated, expedited timeframe. Contractors shall alert the submitter that the decision is being provided as expeditiously as possible, so that the item or service may be provided, but that the submitter should hold their claim and not submit it until such time as the UTN is received (in order to avoid a claims payment denial).

### **3.10.1 - Prior Authorization Program for Certain DMEPOS (Rev. 937; Issued: 01-31-20; Effective: 03-02-20; Implementation: 03-02-20)**

A prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization is described in 42 CFR §405 and §414.234. Among other things, these sections establish a Master List of certain DMEPOS items meeting inclusion criteria and potentially subject to prior authorization. CMS will select Healthcare Common Procedure Coding System (HCPCS) codes from the Prior Authorization Master List that shall require prior authorization, at its discretion. In selecting HCPCS codes, CMS may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis, and may implement prior authorization nationally or locally.

The Prior Authorization Master List is the list of DMEPOS items that have been identified using the inclusion criteria described in 42 CFR 414.234. The Master List can be found on the CMS website.

The Required Prior Authorization List is the items selected from the Prior Authorization Master List to be implemented in the Prior Authorization Program. The Required Prior Authorization List can be found on the CMS website, and will be updated as additional codes are selected for prior authorization.

CMS may elect to exempt suppliers from prior authorization program upon demonstration of compliance with Medicare coverage, coding, and payment rules.

The CMS may suspend prior authorization requirements generally or for a particular item or items at any time and without undertaking rulemaking. CMS provides notification of the suspension of the prior authorization requirements via—(i) Federal Register notice; and (ii) Posting on the CMS prior authorization Web site.

#### **3.10.1.1- Voluntary Prior Authorization (PA) for DMEPOS Accessories**

**(Rev: 12056; Issued: 05-25-23; Effective: 06-26-23; Implementation: 06-26-23)**

The 2019 ESRD and DMEPOS final rule (84 Fed. Reg. 60648 (Nov. 8, 2019)) permits CMS to develop a program to allow suppliers to voluntarily include certain accessories on prior authorization requests submitted for items on the Required Prior Authorization List. These accessories may receive a prior authorization decision for operational simplicity, even if the accessory itself is not on the Required Prior Authorization List. Voluntarily submitting a prior authorization request for accessories does not create a condition of payment and is not mandatory.

Prior authorization requests for accessories must include a corresponding item on the Required Prior Authorization List; otherwise, the prior authorization request for the accessory will be rejected. Accessories submitted on a prior authorization request where the corresponding item on the Required Prior Authorization List is non-affirmed will also be non-affirmed.

The list of DME items that require prior authorization can be found on [Required Prior Authorization List](#), and the list of selected accessories that can be voluntarily added to prior authorization requests can be found on the [Voluntary Prior Authorization List](#). The Required Prior Authorization List and the Voluntary Prior Authorization List will be updated as additional codes are selected.

For more information, please see the [CMS DMEPOS Prior Authorization website](#).

### **3.10.2 - Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services**

**(Rev. 937; Issued: 01-31-20; Effective: 03-02-20; Implementation: 03-02-20)**

A prior authorization process for certain hospital OPD services is described in 42 CFR §§419.80 through 419.89 as a method for controlling unnecessary increases in the volume of covered services. These sections establish requirements for the submission of a prior authorization request (PAR), the timeframes for the review of a PAR, and the process for CMS to exempt providers from prior authorization requirements.

The list of hospital OPD services requiring prior authorization will be updated through formal notice-and-comment rulemaking. Technical updates to the list of services, such as changes to the name of the service or the HCPCS code, will be published on the CMS website.

The CMS may elect to exempt a provider from this prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules after semiannual assessments. Providers must reach a prior authorization provisional affirmation threshold of 90 percent or greater to be eligible for exemption.

The CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on the CMS website.

## Transmittals Issued for this Chapter

<b>Rev #</b>	<b>Issue Date</b>	<b>Subject</b>	<b>Impl Date</b>	<b>CR#</b>
<u>R13595PI</u>	01/26/2026	Updates of Chapters 3, 4, and Exhibits in Publication (Pub.) 100-08, Including Updates to the Provider Notification Process and Vetting with the CMS Process	02/26/2026	14362
<u>R13008PI</u>	12/18/2024	Chapter 3 Revisions (Segment 1) in Publication (Pub.) 100-08 Program Integrity Manual (PIM)	01/17/2025	13735
<u>R12897PI</u>	10/17/2024	Chapter 3 Revisions (Segment 1) in Publication (Pub.) 100-08 Program Integrity Manual (PIM)- Rescinded and Replaced by Transmittal 13008	01/17/2025	13735
<u>R12772PI</u>	08 /09/2024	Updates of Chapter 1, Chapter 2, Chapter 3, Chapter 4, and Chapter 9 in Publication (Pub.) 100-08, Including Complaint Referral Coordination Between Contractors	09/20/2024	13719
<u>R12633PI</u>	05/09/2024	Medical Review Policies for Signature Requirements	06/10/2024	13556
<u>R12056PI</u>	05/25/2023	Update to Chapter 3 of Publication (Pub.) 100-08 (Program Integrity Manual (PIM)) for the Voluntary Prior Authorization (PA) Process for Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) Accessories	06/26/2023	13185
<u>R11933PI</u>	03/30/2023	Update to Process and Responsibility for Tracking Medicare Contractors' Prepayment and Post Payment Reviews in the RAC Data Warehouse (RACDW)	04/03/2023	12281
<u>R11697PI</u>	11/09/2022	Update to Process and Responsibility for Tracking Medicare Contractors' Prepayment and Post Payment Reviews in the RAC Data Warehouse (RACDW)- Rescinded and Replaced by Transmittal 11933	04/03/2023	12881
<u>R11529PI</u>	07/28/2022	Update of Chapter 3 in Publication (Pub.) 100-08, Including Update to Medicare Program Integrity Contractor Post-Payment Review Process, and Update of Chapter 8 Pub. 100-08, Including Revision to When Contractor Suspects Additional Improper Claims	08/30/2022	12827

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<u>R11032PI</u>	09/30/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08	11/10/2021	12375
<u>R10984PI</u>	09/09/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08 - Rescinded and Replaced by Transmittal 11032	11/10/2021	12375
<u>R10365PI</u>	10/02/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08	08/27/2020	11884
<u>R10228PI</u>	07/27/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08 Rescinded and Replaced by Transmittal #10365	08/27/2020	11884
<u>R10197PI</u>	06/26/2020	Publication (Pub.) 100-08 Chapter 3 Updates to Section 3.2.3.2 (Timeframes for Submission) and Section 3.2.3.8 (No Response or Insufficient Response to Additional Documentation Requests (ADRs))	07/27/2020	11730
<u>R10190PI</u>	06/19/2020	Revising Chapters 3 and 5 of Publication (Pub.) 100-08, to Reflect the Recent Final Rule CMS-1713-F	07/01/2020	11599
<u>R10171PI</u>	06/12/2020	Updates to Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) and Ambulance Certification Signature Requirements	07/13/2020	11763
<u>R10132PI</u>	05/15/2020	Revising Subsection 3.2.5, Targeted Probe and Educate (TPE), in Chapter 3 of Publication (Pub.) 100-08	06/16/2020	11695
<u>R10100PI</u>	05/08/2020	Revision to Language in Chapter 3, Section 3.7.5 (Corrective Action Reporting Requirements) of Publication (Pub.) 100-08	06/09/2020	11756
<u>R937PI</u>	01/31/2020	Updates to the Prior Authorization (PA) Guidance Within Publication (Pub.) 100-08	03/02/2020	11633
<u>R933PI</u>	01/10/2020	Update to Chapter 3, Section 3.2.3.1 Additional Documentation Requests (ADR) of Publication (Pub) 100-08	01/06/2020	10828
<u>R912PI</u>	10/18/2019	Medicare Administrative Contractor (MAC) Verification of Potential Errors and Corrective Actions Taken	11/19/2019	11463
<u>R907PI</u>	10/04/2019	Update to Chapter 3, Section 3.2.3.1	01/06/2020	10828

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		Additional Documentation Requests (ADR) of Publication (Pub) 100-08- Rescinded and Replaced by Transmittal #933		
<u>R902PI</u>	09/27/2019	Updates to Chapters 3, 4, 8, 15, and Exhibits of Publication (Pub.) 100-08	10/28/2019	11425
<u>R876PI</u>	04/12/2019	Update to Publication (Pub.) 100-08 to Provide Language-Only Changes for the New Medicare Card Project	05/13/2019	11109
<u>R853PI</u>	01/04/2019	Updates to the Appeals Prioritization Process	02/05/2019	10641
<u>R833PI</u>	10/12/2018	Templates in Medical Review	11/13/2018	10930
<u>R825PI</u>	09/21/2018	Credentials of Reviewers (This Change Request (CR) Rescinds and Fully Replaces CR 10157.)	10/22/2018	10909
<u>R819PI</u>	08/17/2018	Adding a Targeted Probe and Educate (TPE) Sub-Section Into Section 3.2 of Chapter 3 in Publication (Pub.) 100-08	09/17/2018	10876
<u>R796PI</u>	05/11/2018	Intent to Reopen	08/13/2018	9855
<u>R802PI</u>	06/21/2018	Use of Accessible and Applicable Claims History During Medical Review	07/24/2018	10640
<u>R791PI</u>	04/27/2018	Restoring Section 3.2.3 B. and Section 3.2.3 C. to Chapter 3 of Publication (Pub.) 100-08 in the Internet Only Manual (IOM)	05/29/2018	10505
<u>R786PI</u>	04/13/2018	Reimbursing Providers and Health Information Handlers (HIHs) for Additional Documentation	05/14/2018	10529
<u>R768PI</u>	02/08/2018	Post-Payment Review Timeliness Requirements	04/01/2018	9990
<u>R755PI</u>	11/09/2017	Tracking Medicare Contractors' Prepayment and Postpayment Reviews	12/11/2017	10177
<u>R751PI</u>	10/20/2017	Clarifying Signature Requirements	11/20/2017	10322
<u>R748PI</u>	10/13/2017	Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings	11/14/2017	10226
<u>R738PI</u>	08/18/2017	Provider Error Rate Formula	09/19/2017	10210
<u>R732PI</u>	07/21/2017	Clarifying the Instructions for Amending or Correcting Entries in Medical Records	08/22/2017	10120
<u>R721PI</u>	06/09/2017	Elimination of Routine Reviews Including Documentation Compliance Reviews and Instituting Three Medical Reviews	07/11/2017	9809
<u>R713PI</u>	05/05/2017	Scribe Services Signature Requirements	06/06/2017	10076

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<u>R698PI</u>	01/20/2017	The Process of Prior Authorization	02/21/2017	9940
<u>R674PI</u>	09/02/2016	Duplicate Postpayment Claim Reviews	11/04/2016	9665
<u>R663PI</u>	07/15/2016	Denial Codes for Missing or Insufficient Documentation	08/16/2016	9690
<u>R657PI</u>	06/17/2016	Special Provisions for Lab Additional Documentation Requests (ADRs)	07/18/2016	9670
<u>R634PI</u>	01/22/2016	Reviewers' Credentials, Notifying the Provider, CARC Code Update	04/22/2016	9333
<u>R628PI</u>	12/04/2015	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.2 (Time Frames for Submission)	01/06/2016	9438
<u>R620PI</u>	10/16/2015	Pub. 100-08 Chapter 3 Updates: Section 3.2.3.2 Timeframes for Submission and Section 3.2.3.8 - No response to Additional Documentation Requests – Rescinded and not replaced	11/17/2015	9226
<u>R617PI</u>	10/09/2015	Update to Chapter 3 of Pub. 100-08	11/10/2015	9303
<u>R615PI</u>	10/02/2015	Signature Requirements	11/02/2015	9332
<u>R613PI</u>	09/25/2015	Postpayment Review Requirements	10/26/2015	9323
<u>R608PI</u>	08/14/2015	Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	09/14/2015	8747
<u>R604PI</u>	07/24/2015	Signature Requirements	08/25/2015	9225
<u>R585PI</u>	04/03/2015	Coding Determinations	05/04/2015	8937
<u>R568PI</u>	02/04/2015	Review Timeliness Requirements for Complex Review	03/01/2015	8443
<u>R567PI</u>	02/04/2015	New Timeframe for Response to Additional Documentation Requests	04/06/2015	8583
<u>R566PI</u>	01/07/2015	New Timeframe for Response to Additional Documentation Requests – Rescinded and replaced by Transmittal 567	04/06/2015	8583
<u>R565PI</u>	12/31/2014	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.2 (Time Frames for Submission)	02/02/2015	9012
<u>R557PI</u>	11/26/2014	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.4 (Additional Documentation Request Required and Optional Elements)	12/29/2014	8948

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<u>R554PI</u>	11/14/2014	New Timeframe for Response to Additional Documentation Requests – Rescinded and replaced by Transmittal 566	04/06/2015	8583
<u>R547PI</u>	10/17/2014	Review Timeliness Requirements for Complex Review – Rescinded and replaced by Transmittal 566	02/24/2015	8443
<u>R543PI</u>	09/26/2014	Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings	10/27/2014	8501
<u>R541PI</u>	09/12/2014	Claims that are Related	09/08/2014	8802
<u>R540PI</u>	09/04/2014	Claims that are Related – Rescinded and replaced by Transmittal 541	09/08/2014	8802
<u>R534PI</u>	08/08/2014	Claims that are Related – Rescinded and replaced by Transmittal 540	09/08/2014	8802
<u>R527PI</u>	07/03/2014	Provider Notice on MAC Web sites	09/05/2014	8690
<u>R523PI</u>	04/20/2014	Update to CMS Pub. 100-08, Chapter 3 – Rescinded and not replaced	07/22/2014	8791
<u>R512PI</u>	04/18/2014	Revision to the Program Integrity Manual, Chapter 3 Section 3.3	05/19/2014	8716
<u>R505PI</u>	02/05/2014	Removing Prohibition - Rescinded	03/06/2014	8425
<u>R501PI</u>	01/09/2014	Complex Medical Review	10/07/2013	8429
<u>R500PI</u>	12/27/2013	Third-party Additional Documentation Request CERT Update	01/28/2014	8547
<u>R498PI</u>	12/27/2013	Notifying the Provider of Postpayment Review Results	01/28/2014	8541
<u>R496PI</u>	12/12/2013	Tracking Medicare Contractors' Postpayment Reviews	10/03/2013	8362
<u>R489PI</u>	10/18/2013	100% Prepayment Review and Random Review Instructions	11/19/2013	8427
<u>R488PI</u>	09/20/2013	Acceptable Submission Methods for Responses to ADRs	10/21/2013	8436
<u>R487PI</u>	09/13/2013	Tracking Medicare Contractors' Postpayment Reviews	10/03/2013	8362
<u>R486PI</u>	09/06/2013	Complex Medical Review – Rescinded and replaced by Transmittal 501	10/07/2013	8429
<u>R485PI</u>	08/21/2013	Program Safeguard Contractor (PSC) and Zone Program Integrity Contractor (ZPIC) Provider Notification	01/29/2013	8079
<u>R484PI</u>	08/21/2013	OMB Collection Number	05/21/2012	7750

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<u>R477PI</u>	08/02/2013	Tracking Medicare Contractors' Postpayment Reviews – Rescinded and replaced by Transmittal 487	10/03/2013	8362
<u>R465PI</u>	05/17/2013	Use of a Rubber Stamp for Signature	06/18/2013	8219
<u>R464PI</u>	05/17/2013	Reopening Claims with Additional Information or Denied due to Late or No Submission of Requested Information	06/18/2013	8267
<u>R458PI</u>	04/12/2013	EsMD RC Public Announcement	05/13/2013	8208
<u>R455PI</u>	03/15/2013	Progress Notes and Forms	12/10/2012	8033
<u>R453PI</u>	03/13/2013	Progress Notes and Forms – Rescinded and replaced by Transmittal 455	12/10/2012	8033
<u>R447PI</u>	01/18/2013	Medical Review Timeliness Requirements	02/19/2013	8131
<u>R446PI</u>	12/28/2012	Program Safeguard Contractor (PSC) and Zone Program Integrity Contractor (ZPIC) Provider Notification – Rescinded and replaced by Transmittal 485	01/29/2013	8079
<u>R442PI</u>	12/07/2012	Update for Amendments, Corrections and Delayed Entries in Medical Documentation	01/08/2013	8105
<u>R438PI</u>	11/09/2012	Progress Notes and Forms – Rescinded and replaced by Transmittal 453	12/10/2012	8033
<u>R426PI</u>	06/15/2012	Process for Handling Electronic Submission of Medical Documentation (esMD)	07/16/2012	7835
<u>R422PI</u>	05/25/2012	Request Records Related to the Claim Being Reviewed	06/26/2012	7837
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<u>R084PI</u>	10/22/2004	Payment for Emergency Medical Treatment and Labor Act (EMTALA) - Mandated Screening and Stabilization Services - Replaced by Transmittal 86	11/22/2004	3437
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<u>R066PI</u>	02/20/2004	Progressive Corrective Action Program Memorandum and Updated Instructions on How Contractors Must Identify, Verify, and Correct Billing Errors	04/02/2004	3124
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<u>R053PI</u>	10/31/2003	Prepayment Edits	04/05/2004	2916
<u>R049PI</u>	09/26/2003	Changing the Use of Remittance Advice Code N109 From Mandatory to Contractor's Discretion	10/10/2003	2873
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<u>R038PI</u>	02/03/2003	When Contractors May Publish Coverage/Coding Articles In Their Bulletins And Web Sites	02/14/2003	2120
<u>R035PI</u>	11/29/2002	Types of Prepayment and Postpayment Review	01/01/2003	2418
<u>R033PI</u>	11/01/2002	FY 2003 Budget Performance Requirements	11/01/2002	2407
<u>R032PI</u>	10/25/2002	Consent Settlements, CMPs Delegated to CMS and Referrals to OIG	10/25/2002	2333
<u>R031PI</u>	10/25/2002	Revised Prepayment Edits	09/01/2002	1793
<u>R017PIM</u>	12/12/2001	Reorganizes chapter 3, sections 4, 5, and 6 and Removes reference to outdated MCM and MIM overpayment collection instructions and lists the more current CFR	04/01/2002	1891

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<u>R016PIM</u>	11/28/2001	Adds Various Program Memoranda for BI Requests for Information, Organizational Requirements, Unsolicited Voluntary Refund Checks, Anti-Kickback Statute Implications	11/28/2001	1732
<u>R013PIM</u>	09/26/2001	Administrative Relief from Medical Review and Benefit Integrity in Disaster Situations	09/26/2001	1879
<u>R003PIM</u>	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292
<u>R001PIM</u>	06/2000	Initial Release of Manual	NA	931

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