Medicare Program Integrity Manual
Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

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

All references to Medicare Administrative Contractors (MACs) include Affiliated Contractors (ACs). Affiliated Contractors are FI's and Carriers.

All references to Zone Program Integrity contractors (ZPICs) include Program Safeguard Contractors (PSCs).

A. Goals
This section applies to Medicare Administrative Contractors (MACs), Comprehensive Error Rate Testing (CERT), and Recovery Auditors, as indicated.

The Medicare Administrative Contractors (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 deal with 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 Recovery Audit program is a legislatively mandated program (Tax Relief and Health Care Act of 2006) that utilizes Recovery Auditors to identify improper payments paid by Medicare to fee-for-service providers. The Recovery Auditors identify the improper payments, and the MACs adjust the claims, recoup identified overpayments and return underpayments.

MAC, CERT and Recovery Auditor 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 postpayment 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. 608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

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

A. Prepayment and Postpayment 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”

Postpayment review occurs when a reviewer makes a claim determination after the claim has been paid. Postpayment 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 Health Insurance Claim Number (HICN), 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 in order 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.

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 (routine review) 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 Recovery Auditors.

3.2.1 – Setting Priorities and Targeting Reviews

(Rev. 399, Issued: 11-04-11, Effective: 12-05-11, Implementation: 12-05-11)

This section applies to MACs and Recovery Auditors, as indicated. Recovery Auditors 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 assure MR focuses on areas with the greatest potential for improper payment.

The MACs shall develop a problem-focused, outcome-based MR strategy and Strategy Analysis Report (SAR) 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 Recovery Auditors 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 Recovery Auditors 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,
- Recovery Auditor, 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.

In an effort to identify the claims most likely to contain improper billing, MACs are encouraged to use prepayment and postpayment 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 to their Web site or otherwise disclose to the provider community. Recovery Auditors shall use screening tools and disclose their use to the provider community consistent with the requirements in their statements of work (SOWs).

MACs and Recovery Auditors 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 Recovery Auditor 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. 527, Issued: 07-03-14, Effective: 09-05-14, Implementation: 09-05-14)

This section applies to MACs, Recovery Auditors, ZPICs 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. 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 postpayment) 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 in order 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, Recovery Auditors, 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 national coverage determination, or local coverage determination.

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. MACs have the discretion to use a letter similar to the letters in Exhibit 7 of the PIM when notifying providers of the probe review and requesting documentation. MACs have the discretion to advise providers of the probe sample at the same time that medical documentation or other documentation is requested.

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 as long as they will not constitute undue administrative burden.

<u>MACs</u>

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 postpayment 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.

Recovery Auditors

The Recovery Auditors are required to post a description of all approved new issues to the Recovery Auditor's Web site before correspondence is sent to the provider. After posting, the Recovery Auditor should issue an additional documentation request (ADR) to the provider, if warranted.

Zone Program Integrity Contractors

The Zone Program Integrity Contractors shall notify selected providers prior to beginning a provider-specific review by sending an individual written notice. ZPICs shall indicate whether the review will occur on a prepayment or postpayment basis. ZPICs 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, Recovery Auditors 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

Web site postings

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

Recovery Auditors

Before beginning widespread service-specific reviews, Recovery Auditors shall notify the provider community that the Recovery Auditor intends to initiate review of certain items/services through a posting on the Recovery Auditor Web site describing the item/service that will be reviewed. Additionally, for complex reviews, the Recovery Auditors shall send ADRs to providers that clearly articulate the items or services under review and indicate the appropriate documentation to be submitted.

Zone Program Integrity Contractors

The ZPICs 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 ZPICs 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 Web site 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 Web site, 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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 provider tracking system (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 ZPICs 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 postpayment 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. Recovery Auditor Case Files

The Recovery Auditor shall maintain case files following the guidelines in the Recovery Auditor SOW.

C. Provider Addresses

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

The MACs, CERT and Recovery Auditors 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 Web sites. 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 and ZPICs, as indicated.

When the MACs and ZPICs 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 health insurance claim numbers). This process is contingent on current automated system limits.

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

- The MAC and ZPIC 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 MACs and ZPICs 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 HICNs 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 Postpayment Review

(Rev. 568, Issued: 02-04-15, Effective: 03-01-15, Implementation: 03-01-15)

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

A. General

In certain circumstances, the MACs, CERT, Recovery Auditors, and ZPICs 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 postpayment review. MACs, CERT, Recovery Auditors, and ZPICs have the discretion to collect documentation related to the beneficiary's condition before and after a service in order to get a more complete picture of the beneficiary's clinical condition. The MAC, Recovery Auditor, and ZPIC 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 in order to conduct a review and reach a conclusion about the claim.

NOTE: Reviewers shall consider documentation in accordance with other sections of this manual.

The MAC and ZPIC have the discretion to deny other "related" claims submitted before or after the claim in question, subject to CMS approval as described below. If

documentation associated with one claim can be used to validate another claim, those claims may be considered "related." Approved examples of "related" claims that may be denied as "related" are in the following situations:

- When the Part A Inpatient surgical claim is denied as not reasonable and necessary, the MAC may recoup the surgeon's Part B services. For services where the patient's history and physical (H&P), physician progress notes or other hospital record documentation does not support the medical necessity for performing the procedure, postpayment recoupment may occur for the performing physician's Part B service.

- Reserved for future approved "related" claim review situations. The MAC shall report to their BFL and COR prior to initiating denial of "related" claims situations.

The MAC and ZPIC shall await CMS approval prior to initiating requested "related" claim(s) review. Upon CMS approval, the MAC shall post the intent to conduct "related" claim review(s) to their Web site within 1 month prior to initiation of the approved "related" claim review(s). The MAC shall inform CMS of the implementation date of the "related" claim(s) review 1 month prior to the implementation date.

If "related" claims are denied automatically, MACs shall count these denials as automated review. If the "related" claims are denied after manual intervention, MACs shall count these denials as routine review.

The Recovery Auditor shall utilize the review approval process as outlined in their SOW when performing reviews of "related" claims.

The MAC, Recovery Auditor, and ZPIC are not required to request additional documentation for the "related" claims before issuing a denial for the "related" claims.

Contactors shall process appeals of the "related" claim(s) separately.

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."

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." Postpayment medical review does not require an OMB control number.

C. PWK (Paperwork) Modifier

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. When the documentation is received, the contractor has 30 calendar days to make a determination on the claim. If the contractor cannot make a determination on the claim after reviewing the unsolicited documentation submitted, they shall request additional documentation using their normal business procedures for ADR that are outlined in Chapter 3 of the Program Integrity Manual.

3.2.3.1 - Additional Documentation Requests (ADR)

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

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

The MACs, CERT, Recovery Auditors, and ZPICs 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.

A. Outcome Assessment Information Set (OASIS)

Medicare's Home Health PPS Rate Update for CY 2010 final rule, published in the November 10, 2009 Federal Register, includes a provision to require the submission of the OASIS as a condition of payment, that is codified in regulations 42 CFR§484.210(e). Beginning January 1, 2010, home health agencies (HHAs) are required to submit an OASIS as a condition for payment. The MACs shall deny the claim if providers do not meet this regulatory requirement. The assessment must be patient specific, accurate and reflect the current health status of the patient. This status includes certain OASIS elements used for calculation of payment. These include documentation of clinical needs, functional status, and service utilization.

B. Plan of Care (POC)

Comprehensive care planning is essential to good patient care under the Medicare program. In fact, it is specifically written into the coverage and/or certification requirements for a number of healthcare settings. For purposes of the Part A benefit for home health, inpatient rehabilitation facility and hospice, the Social Security Act

describes criteria and standards used for covering these services. This includes establishing an individualized POC.

The POC identifies treatment goals and coordination of services to meet patient needs as set forth in CFR §418.200 requirement for coverage. The POC must be established by a physician(s). However, in the case of a hospice, in addition to the physician, an interdisciplinary group shall establish a POC.

Section 1814(a)(2)(C), Part B 1835(a)(2)(A) of the Act, and CFR §409.43 state that a POC established by a treating physician must contain all pertinent information, such as, the patient history, initial status, treatment goals, procedures/services duration, and progress notes.

CFR§412.622 requires an individualized POC by a rehabilitation physician that meets the requirements listed in the regulation. MACs shall deny the claim as not meeting statutory requirements under the Social Security Act when the provider of services fails to comply with the POC requirements.

Pursuant to 42 CFR §489.21, a provider of services shall not charge a beneficiary for services that have been denied for the reasons stated above.

3.2.3.2 - Time - Frames for Submission

(Rev. 628, Issued: 12-04-15, Effective: 11-16-15, Implementation: 01-06-16)

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

A. Prepayment Review Time Frames

When requesting documentation for prepayment review, the MAC and ZPIC shall notify providers that the requested documentation is to be submitted within 45 calendar days of the request. The reviewer should not grant extensions to providers who need more time to comply with the request. Reviewers shall deny claims for which the requested documentation was not received by day 46.

B. Postpayment Review Time Frames

When requesting documentation for postpayment review, the MAC, CERT and RAC shall notify providers that the requested documents are to be submitted within 45 calendar days of the request. ZPICS shall notify providers that requested documents are to be submitted within 30 calendar days of the request. Because there are no statutory provisions requiring that postpayment review of the documentation be completed within a certain timeframe, MACs, CERT, and ZPICs have the discretion to grant extensions to providers who need more time to comply with the request. The number of submission extensions and the number of days for each extension is solely within the discretion of the MACs, CERT and ZPICs. RACs shall follow the time requirements outlined in their SOW.

C. For esMD submissions

The esMD review contractor shall use the Enterprise File Transfer (EFT) system receipt date as the date the documentation was received. If the EFT 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 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 EFT system.

3.2.3.3 - Third-party Additional Documentation Request

(Rev. 500, Issued: 12-27-13, Effective; 07-11-08, Implementation: 01-28-14)

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

Unless otherwise specified, the MAC, Recovery Auditor and ZPIC shall request information from the billing provider/supplier. The treating physician, another clinician, provider, or supplier should submit the requested documentation. However, because the provider selected for review is the one whose payment is at risk, it is this provider who is ultimately responsible for submitting, within the established timelines, the documentation requested by the MAC, CERT, Recovery Auditor and ZPIC.

The CERT reviewer shall request medical record documentation from the referring provider as submitted/identified by National Provider Identifier/Unique Physician Identification Number on the claim when such information is not sent in by the billing supplier/provider initially and after a request for additional documentation fails to produce medical documentation necessary to support the service billed and supported by the Local and National Coverage Determinations.

The MAC, ZPIC and Recovery Auditor have the discretion to send a separate ADR to third-party entities involved in the beneficiary's care. They shall not solicit documentation from a third party unless they first or simultaneously solicit the same information from the billing provider or supplier. The following requirements also apply:

- The MACs, ZPICs and Recovery Auditors shall notify the third party and the billing provider or supplier that they have 30 calendar days to respond for a prepayment review or 45 calendar days for a postpayment review for MACs and Recovery Auditors and 30 calendar days for ZPICs.

- For prepayment review, the MACs and ZPICs shall pend the claim for 45 calendar days. This 45 day time period may run concurrently as the 45 days that the billing provider or supplier has to respond to the ADR letter;

- The MACs and ZPICs 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 30th or 45th calendar day , 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 and ZPICs shall deny the claim, in full or in part, using the appropriate denial code. Contractors shall count these denials as complex review.

- Contractors shall include language in the denial notice reminding 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.100-04, Medicare Claims Processing Manual, chapter 30.

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

3.2.3.4 - Additional Documentation Request Required and Optional Elements

(Rev. 557, Issued: 11-26-14, Effective: 12-29-14, Implementation: 12-29-14)

This section applies to Medicare Administrative Contractors (MAC), Recovery Auditors, Comprehensive Error Rate Testing (CERT), and Supplemental Medical Review Contractors (SMRC), as indicated.

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

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

- The MACs, CERT, SMRCs, and Recovery Auditors, 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, Recovery Auditors, and SMRCs have the discretion to issue as many reminder notices as they deem appropriate. Reminder notices can be issued via email, letter, or phone call.

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

- The MACs, Recovery Auditors, and SMRCs 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 postpayment medical review, the MACs, CERT, SMRCs and Recovery Auditors shall use the unified postpayment 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 postpayment 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, CERT, SMRCs and Recovery Auditors 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. 488, Issued: 09-20-13, Effective: 10-21-13 Implementation: 10-21-13)

This section applies to MACs, Recovery Auditors, CERT, and ZPICs, 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, and Recovery Auditors shall accept documents via paper, fax, CD/DVD, and electronic submission of medical documentation (esMD).

A. Paper

The MACs, CERT, and Recovery Auditors 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 and Recovery Auditors should provide a physical mailing address instead of a P.O. Box.

B. Fax

If the MACs, CERT, or Recovery Auditors 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 and CERT shall state in the ADR that imaged medical documentation files on CD/DVD may be mailed by any means. Recovery Auditor ADRs shall provide a Web site link or phone number that provides information regarding the requirements for submitting imaged documentation on CD or DVD.

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

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

MACs 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 (Web posting, list serve, tweet, etc.) the contractor must clear the announcement with CMS.

3.2.3.6 - Reimbursing Providers and HIHs for Additional Documentation

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

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

- The MACs, CERT and ZPICs are not required to pay for medical documentation for either prepayment or postpayment review.

- The Recovery Auditors performing postpayment review of hospital inpatient prospective payment system (PPS) and long term care facilities are required to pay the providers for photocopying and submitting hard copy documents sent via mail. Recovery Auditors shall follow the payment rate methodology established in 42 CFR§476.78.

- The Recovery Auditors shall pay the same per-page rate established in 42 CFR§476.78 for the submission of imaged or electronic documentation sent via the esMD mechanism or on CD/DVD.

- The Recovery Auditors that accept esMD transactions shall pay a transaction fee of $2.00/case in lieu of postage.

- The Recovery Auditors performing postpayment review of any other provider types are not required to pay providers for photocopying and submitting documentation.

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

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

3.2.3.7 - Special Provisions for Lab Additional Documentation Requests

(Rev. 657, Issued; 06-17-16, Effective: 07-18-16, Implementation: 07-18 - 16)

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

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

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

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

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

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

3.2.3.8 - No Response or Insufficient Response to Additional Documentation Requests

(Rev. 663, Issued: 07-15-16, Effective: 08-16-16, Implementation: 08-16-16)

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

A. Additional Documentation Requests

If information is requested from both the billing provider or supplier and a third party and no response is received from either within 45 calendar days for MACs and Recovery Auditors or 30 calendar days for ZPICs after the date of the request (or within a reasonable time following an extension), the MACs, Recovery Auditors and ZPICs shall deny the claim, in full or in part, as not reasonable and necessary. 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.

Contractors shall count these denials as automated review or manual review depending on the method of development. For claims that had a PWK modifier, and the unsolicited documentation was reviewed, the review shall be counted as complex review.

B. No Response

During prepayment review, if no response is received within 45 calendar days after the date of the ADR, the MACs, and ZPICs shall deny the claim.

During postpayment review, if no response is received within 45 calendar days after the date of the ADR (or extension), the MACs and Recovery Auditors shall deny the claim as not reasonable and necessary and count these denials as non-complex reviews. ZPICs shall deny the claim as not meeting reasonable and necessary criteria if no response is received within 30 calendar days. Recovery Auditors shall report these denials as "No Response Denials." Recovery Auditors shall not count these as complex or non-complex reviews. Ambulance claims may be denied based on §1861(s) (7) of the Act.

C. Insufficient Response

If the MAC, CERT, Recovery Auditor, or ZPIC 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. 663, Issued: 07-15-16, Effective: 08-16-16, Implementation: 08-16-16)

If the MACs and CERT 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 and CERT who choose to reopen shall notify the provider or supplier of their intent to reopen, make a 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. Processing claims with additional information follows these general provisions:

- For claims originally selected for postpayment 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., postpayment complex);

In cases where the MAC or ZPIC 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 (AC, MAC, PSC, or ZPIC) who initiated the prepayment edit shall be responsible for conducting the reopening.

- The MACs and CERT 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 Recovery Auditor receives requested documentation from a supplier after a denial has been issued they shall not reopen the claim.

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

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

3.2.3.10 - Record Retention and Storage

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

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

3.2.4 - Use of Claims History Information in Claim Payment Determinations

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

A. Contractors to Which This Section Applies

This section applies to ACs, MACs, CERT and Recovery Auditors.

B. General

In general, AC, MAC, CERT and Recovery Auditor reviewers shall not use claims history information to make a payment determination on a claim. However, this policy does not prevent contractors from using claims history for other purposes such as data mining.

The AC, MAC, CERT and Recovery Auditor reviewers shall use claims history information as a supplement to the medical record only in the following circumstances when making complex review determinations about payment on a claim.

1. AC, MAC, CERT and Recovery Auditor 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. AC, MAC, CERT and Recovery Auditor 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. AC, MAC, CERT and Recovery Auditor 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. Claims history information shall be used only to validate specific events; not as a substitute for the medical record.

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. AC, MAC, CERT and Recovery Auditor 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. AC, MAC, CERT and Recovery Auditor reviewers shall use claims history information to make a determination of the quantity of items to be covered based on policy guidelines. Information obtained on a claim being reviewed may be applied to a prior paid claim to make a determination of how long the quantity of items provided/billed on the paid claim should last. If a new quantity of items is billed prior to the projected end date of the previously paid claim (based on policy guidelines), the new quantity should be denied.

Example: Twice per day testing of blood sugars is ordered for a non-insulin treated beneficiary with diabetes. A 3 month quantity of supplies (for twice per day testing) is provided on July 1 and is paid without review. Another 3 month quantity of

supplies is provided on 10/1. That claim is developed and reviewed and a determination is made that the medically necessary frequency of testing is once per day. Therefore, the 10/1 claim should be denied because the quantity of supplies paid for on 7/1 was sufficient to last beyond 10/1 if testing was done once per day.

5. AC, MAC, CERT and Recovery Auditor reviewers shall use claims history information to identify duplication and overutilization of services.

3.3 – Policies and Guidelines Applied During Review

(Rev. 608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs, CERT, Recovery Auditors, Supplemental Medical Review Contractors (SMRCs) and ZPICs, 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, Recovery Auditors, SMRCs, and ZPICs 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
Regulatio
ns 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, Recovery Auditors, and ZPICs 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-4 (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, Recovery Auditor, and ZPIC 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. Recovery Auditors are required to develop written review guidelines in accordance with their SOW. The MACs, CERT, Recovery Auditors, and ZPICs 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: Complex and Non-Complex

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

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

For Recovery Auditors, non-complex and automated reviews are synonymous.

A. General

Most of the claim review activities completed for the purpose of identifying inappropriate billing and avoiding improper payments are divided into two distinct types: Complex Review and Non-Complex Review. Each can occur on either a prepayment or postpayment basis.

The chart below indicates which contractors perform which types of review:

	Prepayment		**Postpayment**	
	Complex	Non-Complex	Complex	Non-Complex
MACs	Yes	Yes	Yes	Yes
CERT	No	No	Yes	Yes
Recovery Auditors	No	No	Yes	Yes
ZPICs	Yes	Yes	Yes	Yes

Complex reviews involve requesting, receiving, and medical review of additional documentation associated with a claim.

3.3.1.1 - Complex Medical Review

(Rev. 613, Issued: 09-25-15, Effective: 10-26-15, Implementation: 10-26-15)

This section applies to MACs, CERT, Recovery Auditors, Supplemental Medical Review Contractor(s) and ZPICs, as indicated.

A. Credentials of Reviewers

The MACs, CERT, and ZPICs shall ensure that complex reviews for the purpose of making coverage determinations are performed by licensed nurses (RNs and LPNs) or physicians, unless this task is delegated to other licensed health care professionals. Recovery Auditors and the Supplemental Medical Review Contractor(s) shall ensure that the credentials of their reviewers are consistent with the requirements in their respective SOWs.

During a complex review, nurse and physician reviewers may call upon other health care professionals (e.g., dieticians or physician specialists) for advice. The MACs, CERT, and ZPICs 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). Recovery Auditors and the Supplemental Medical Review Contractor(s) shall follow guidance related to calling upon other healthcare professionals as outlined in their respective SOWs.

Recovery Auditors shall ensure that complex reviews for the purpose of making coding determinations are performed by certified coders. CERT and MACs are encouraged to make coding determinations by using certified coders. ZPICs have the discretion to make coding determinations using certified coders.

B. Credential Files

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

C. Quality Improvement (QI) Process

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

D. Advanced Beneficiary Notice (ABN)

The MACs, CERT, Recovery Auditors, ZPICs, and Supplemental Medical Review Contractor(s) shall request as part of the ADR, during a complex 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.

E. MAC Funding Issues

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

F. Review Timeliness Requirements

<u>Prepayment Review Requirements for MACs</u>

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 routine reviews, prepayment complex reviews and prepayment documentation compliance 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.

<u>Postpayment Review Requirements for MACs</u>

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, provided the documentation is received within 45 calendar days of the date of the ADR.

For claims associated with any referrals to the ZPIC 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 ZPIC or is notified by the ZPIC 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.

Postpayment Review Requirements for Recovery Auditors

When a Recovery Auditor receives requested documentation for review within 45 calendar days of the date of the ADR, the Recovery Auditor 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.

Counting the 30 Calendar Day Timeframe

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

Prepayment Review Requirements for ZPICs

When a ZPIC receives all documentation requested for prepayment review within 45 calendar days of the date of the ADR, the ZPIC shall make and document the review determination and notify the MAC of its determination within 60 calendar days of receiving all requested documentation.

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.

G. Auto Denial of Claim Line Item(s) Submitted with a GZ Modifier

Effective for dates of service on and after July 1, 2011, all MACs, PSCs and ZPICs shall automatically deny claim line(s) items submitted with a GZ modifier. Contractors shall not perform complex medical review on claim line(s) items submitted with the GZ modifier. The GZ modifier indicates that an ABN was not issued to the beneficiary and signifies that the provider expects denial due to a lack of medical necessity based on an informed knowledge of Medicare policy. All MACs shall make all language published in educational outreach materials, articles, and on their Web sites, consistent to state all claim line(s) items submitted with a GZ modifier shall be denied automatically and will not be subject to complex medical review. See Pub. 100-04, Medicare Claims Processing Manual, chapter 23, section

20.9.1.1. under paragraph F “GZ Modifier” for codes and the MSN to be used when automatically denying claim line(s) items submitted with a GZ modifier.

3.3.1.2 - Non-Complex Review

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

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

A. Terminology

Non-complex reviews occur when the MAC, CERT, Recovery Auditor, or ZPIC makes a claim determination without clinical review of medical documentation submitted by the provider. Appropriate non-complex reviews increase the efficiency and consistency of payment decisions. MACs shall implement automated prepayment review whenever appropriate.

The MACs and ZPICs refer to two categories of non-complex reviews:

1. “Routine review” requires some human intervention (e.g., for instance, to verify durable medical equipment [DME] delivery dates)

2. “Automated review” requires no human intervention.

The Recovery Auditors refer to all reviews where no documentation was requested as “automated review.”

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

The MAC, Recovery Auditor, CERT, and ZPIC shall ensure that automated prepayment and postpayment denials are based on clear policy that serves as the basis for denial; or a medically unlikely edit (MUE); or occurs when no timely response is received to an ADR.

When a clear policy exists (or in the case of a MUE), MACs, Recovery Auditors, and ZPICs have the discretion to automatically deny the services without stopping the claim for human 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. The term “clear policy” means a statute, regulation, NCD, coverage provision in an interpretive manual, coding guideline, LCD or MAC article that specifies the circumstances under which a service will always be considered non-covered, incorrectly coded, or improperly billed.

A Medically Unlikely Edit (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.

C. Basis for Reviews that Involve Utilization Parameters

The MACs, Recovery Auditors, and ZPICs shall base utilization denials on one of the following:

- Clear policy that contains utilization guidelines;
- Apparent typographical errors (e.g., 10,000 blood cultures for the same beneficiary on the same day);
- MUEs;
- The ADR response failed to support the coverage or coding of the claim; or,
- The ADR response was not received in a timely manner.

D. Basis for Documentation Compliance Reviews

Documentation Compliance Reviews are nonclinical, technical reviews to evaluate the presence or absence of particular pieces of documentation. MACs, Recovery Auditors, and ZPICs have the discretion to conduct documentation compliance reviews as they deem appropriate. MACs, Recovery Auditors and ZPICs may find this type of review to be an efficient way to review claims where there is a pattern of insufficient documentation.

3.3.1.3 - Basis for Clinical Review Judgment

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

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

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 to make a reviewer determination on whether the clinical requirements in the relevant policy have been met. MAC, CERT, Recovery Auditor, and ZPIC clinical review staff shall use clinical review judgment when making complex 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, Recovery Auditors and ZPICs 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.

3.3.2 - Medical Review Guidance
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

This section describes the requirements that MACs, CERT, Recovery Auditors, and ZPICs shall follow when reviewing submitted documentation. Additional requirements for ZPICs are located in PIM chapter 4. When ZPIC staff is performing benefit integrity reviews, their focus is different than that of MACs, CERT, and Recovery Auditors. For example, ZPIC 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

The MACs, CERT, Recovery Auditors, and ZPICs shall review any information necessary to make a prepayment and/or postpayment 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. Reviewers also have the discretion to consider 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. 455, Issued: 03-15-13, Effective: 12-10-12, Implementation: 03-21-13)

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.

"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.

CMS does not prohibit the use of templates to facilitate record-keeping. CMS also does not endorse or approve any particular templates. A physician/LCMP may choose any template to assist in documenting medical information.

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 <u>selected</u> information focused primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. This is often because these documents generally do not provide sufficient information to adequately show that the medical necessity criteria for the item/service are met.

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

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

C. Financial Liability

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

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

3.3.2.2 - Absolute Words and Prerequisite Therapies

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

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

The MACs, CERT, Recovery Auditors, and ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs, Recovery Auditors, CERT and ZPICs, 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 and ZPICs 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. The selected line does not need to be completely reviewed. 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 ZPICs shall use discretion in notifying the provider.

3.3.2.4 - Signature Requirements

(Rev. 604, Issued: 07-24-15, Effective: 08-25-15, Implementation: 08-25-15)

This section is applicable for MACs, CERT, SMRC, and ZPICs. This section does not apply to Recovery Auditors.

For medical review purposes, Medicare requires that services provided/ordered be authenticated by the author. The method used shall be a handwritten or electronic signature. Stamped signatures are not acceptable.

EXCEPTION 1: Facsimiles of original written or electronic signatures are acceptable for the certifications of terminal illness for hospice.

EXCEPTION 2: There are some circumstances for which an order does not need to be signed. For example, orders for some clinical diagnostic tests are not required to be signed. The rules in 42 CFR 410 and Pub.100-02 chapter 15, §80.6.1 state that if the order for the clinical diagnostic test is unsigned, there must be medical documentation (e.g., a progress note) by the treating physician that he/she intended the clinical diagnostic test be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature.

EXCEPTION 3: Other regulations and the CMS' instructions regarding conditions of payment related to signatures (such as timeliness standards for particular benefits) take precedence. For medical review purposes, if the relevant regulation, NCD, LCD and CMS manuals are silent on whether the signature needs to be legible or present and the signature is illegible/missing, the reviewer shall follow the guidelines listed below to discern the identity and credentials (e.g., MD, RN, etc.) of the signator. In cases where the relevant regulation, NCD, LCD and CMS manuals have specific signature requirements, those signature requirements take precedence.

EXCEPTION 4: CMS would permit 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.

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

If MAC and CERT reviewers find reasons for denial unrelated to signature requirements, the reviewer need not proceed to signature authentication. If the criteria in the relevant Medicare policy cannot be met but for a key piece of medical

documentation that contains a missing or illegible signature, the reviewer shall proceed to the signature assessment.

Providers should not add late signatures to the medical record, (beyond the short delay that occurs during the transcription process) but instead should make use of the signature authentication process. The signature authentication process described below should also be used for illegible signatures.

A. Handwritten Signature

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

- If the signature is illegible, MACs, ZPICs, SMRC, and CERT shall consider evidence in a signature log, attestation statement, or other documentation submitted to determine the identity of the author of a medical record entry.

- If the signature is missing from an order, MACs, SMRC, and CERT **shall disregard the order** during the review of the claim (e.g., the reviewer will proceed as if the order was not received).

- If the signature is missing from any other medical documentation (other than an order), MACs, SMRC, and CERT shall accept a signature attestation from the author of the medical record entry.

B. 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.

C. Signature Attestation Statement

Providers will sometimes include an attestation statement in the documentation they submit. In order 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. However, since no form for signature attestation has been approved by the Office of Management and Budget (OMB), the contractors should not give the providers any standard format on which to submit the attestation. Once the OMB has assigned an OMB Paperwork Reduction Act number to this attestation form, its use will be mandatory.

Note: The MACs and CERT 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 policy 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.

D. Signature Guidelines

The guidelines below will assist in determining whether to consider the signature requirements met:

- In the situations where the guidelines indicate **"signature requirements met,"** the reviewer shall consider the entry.

- In situations where the guidelines indicate **"contact billing provider and ask a non-standardized follow up question,"** the reviewer shall contact the person or organization that billed the claim and ask if the billing entity would like to submit an attestation statement or signature log within 20 calendar days. The 20 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. If the biller submits a signature log or attestation, 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 days. This extension starts upon receipt of the signature attestation or log.

- The MACs, CERT and ZPICs shall document all contacts with the provider and/or other efforts to authenticate the signature.

Note: The MACs, CERT and ZPICs shall **NOT** contact the **biller when the claim should be denied for reasons unrelated** to the signature requirement.

		Signature Requirement Met	Contact billing provider and ask a non-standardized follow up question
1	Legible full signature	X	
2	Legible first initial and last name	X	
3	Illegible signature over a typed or printed name Example : John Whigg, MD	X	
4	Illegible signature where the letterhead, addressograph or other information on the page indicates the identity **o**f the signatory. Example: An illegible signature appears on a prescription. The letterhead of the prescription lists (3) physicians' names. One of the names is circled.	X	
5	Illegible signature NOT over a typed/printed name and NOT on letterhead, but the submitted documentation **is accompanied** by: a signature log, or an attestation statement	X	
6	Illegible signature NOT over a typed/printed name, NOT on letterhead and the documentation is **UNaccompanied** by: a signature log, or an attestation statement Example:		X
7	Initials over a typed or printed name	X	
8	Initials NOT over a typed/printed name but **accompanied** by: a signature log, or an attestation statement	X	
9	Initials NOT over a typed/printed name **UNaccompanied** by: a signature log, or an attestation statement		X
10	Unsigned typed note with provider's typed name Example: John Whigg, MD		X
11	Unsigned typed note without providers typed/printed		X

	name		
12	Unsigned handwritten note, the only entry on the page		X
13	Unsigned handwritten note where other entries on the same page in the same handwriting are signed.	X	
14	“signature on file”		X

E. Electronic Signatures

Providers using electronic systems need to recognize that 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.

F. Electronic Prescribing

Electronic prescribing (e-prescribing) is the transmission of prescription or prescription-related information through electronic media. E-prescribing takes place between a prescriber and dispenser, pharmacy benefit manager (PBM), or health plan. It can take place directly or through an e-prescribing network. With e-prescribing, health care professionals can electronically transmit both new prescriptions and responses to renewal requests to a pharmacy without having to write or fax the prescription. E-prescribing can save time, enhance office and pharmacy productivity, and improve beneficiary safety and quality of care.

A “qualified” e-prescribing system is one that meets the Medicare Part D requirements described in 42 CFR 423.160 (Standards for Electronic Prescribing).

1. E-Prescribing for Part B Medications (Other than Controlled Substances)

The MAC, CERT and ZPIC reviewers shall accept as a valid order any Part B medications, other than controlled substances, ordered through a qualified e-prescribing system. For Medicare Part B medical review purposes, a qualified e-prescribing system is one that meets all 42 CFR §423.160 requirements. When Part B medications have been ordered through a qualified e-prescribing system, the reviewer shall NOT require the provider to produce hardcopy pen and ink signatures as evidence of a medication order.

2. E-Prescribing for Part B Controlled Substance Medications

Historically, the Drug Enforcement Agency (DEA) has not permitted the prescribing of controlled substance medications through e-prescribing systems. Therefore, when reviewing claims for controlled substance medications, MAC, CERT and ZPIC reviewers shall only accept hardcopy pen and ink signatures as evidence of a medication order. However, the DEA is in the process of establishing requirements

for electronic prescriptions for controlled substances. Refer to 21 CFR§§1300, 1304, 1306 and 1311 for further information.

3. E-Prescribing for Medications Incident to DME

The MAC, CERT and ZPIC reviewers shall accept as valid any e-prescribed order for medications incident to Durable Medical Equipment (DME), other than controlled substances. For the purpose of conducting Medicare medical review of medications incident to DME, a qualified e-prescribing system is one that meets all §42 CFR 423.160 requirements. When medications incident to DME have been ordered through a qualified e-prescribing system, the reviewer shall NOT require the provider to produce hardcopy pen and ink signatures as evidence of a medication order.

G. Additional Signature Requirements for Durable Medical Equipment, Prosthetics, Orthotics, & Supplies (DMEPOS)

Refer to PIM chapter 5 for further details regarding additional signature requirements for DMEPOS.

H. Signature Dating Requirements

For medical review purposes, if the relevant regulation, NCD, LCD and other CMS manuals are silent on whether the signature must be dated, the MACs, CERT and ZPICs 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. The ADR response is one page from the hospital medical record containing three (3) entries. The first entry is dated October 4 and is a physical therapy note. The second entry is a physician visit note that is undated. The third entry is a nursing note dated October 4. The reviewer should conclude that the physician visit was conducted on October 4.

I. Additional Documentation Request Language Regarding Signatures

The CERT contractor shall use language in its ADR letters reminding providers that the provider may need to contact another entity to obtain the signed version of a document. For example, a hospital discharge summary in the physician's office files may be unsigned, whereas the version of the discharge summary in the hospital files should be signed and dated. MACs are encouraged to use such language in their letters. In addition, MACs, CERT and ZPICs have the discretion to add language to their ADRs stating that the provider is encouraged to review their documentation prior to submission, to ensure that all services and orders are signed appropriately. In cases where a reviewer finds a note with a missing or illegible signature, the ADR may inform the provider that it should submit a signature log or signature attestation as part of the ADR response.

The following is sample language that reviewers may choose to use in certain ADRs:

> "Medicare requires that medical record entries for services provided/ordered be authenticated by the author. The method used shall be a handwritten or

electronic signature. Stamp signatures are not acceptable. Beneficiary identification, date of service, and provider of the service should be clearly identified on the submitted documentation.

The documentation you submit in response to this request should comply with these requirements. This may require you to contact the hospital or other facility where you provided the service and obtain your signed progress notes, plan of care, discharge summary, etc.

If you question the legibility of your signature, you may submit an attestation statement in your ADR response.

If the signature requirements are not met, the reviewer will conduct the review without considering the documentation with the missing or illegible signature. This could lead the reviewer to determine that the medical necessity for the service billed has not been substantiated."

J. Potential Fraud Referrals

At any time, suspected fraud shall result in a referral to the ZPIC for development. If MAC, Recovery Auditor or CERT reviewers identify a pattern of missing/illegible signatures, the reviewer shall refer to the appropriate ZPIC for further development.

3.3.2.5 - Amendments, Corrections and Delayed Entries in Medical Documentation

(Rev. 615, Issued: 10-02-15, Effective: 10-02-15, Implementation: 11-02-15)

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

A. Amendments, Corrections and Delayed Entries in Medical Documentation

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 are not properly documented. In this event, the documentation will need to be amended, corrected, or entered after rendering the service. When making review determinations the MACs, CERT, Recovery Auditors, and ZPICs shall consider all submitted entries that comply with the widely accepted Recordkeeping Principles described in section B below. The MACs, CERT, Recovery Auditors, and ZPICs shall NOT consider any entries that do not comply with the principles listed in section B below, even if such exclusion would lead to a claim denial. For example, they shall not consider undated or unsigned entries handwritten in the margin of a document. Instead, they shall exclude these entries from consideration.

B. Recordkeeping Principles

Regardless of whether a documentation submission originates from a paper record or an electronic health record, documents submitted to MACs, CERT, Recovery Auditors, and ZPICs containing amendments, corrections or addenda must:

1. Clearly and permanently identify any amendment, correction or delayed entry as such, and

2. Clearly indicate the date and author of any amendment, correction or delayed entry, and

3. Clearly identify all original content, without deletion.

Paper Medical Records: When correcting a paper medical record, these principles are generally accomplished by:

1. Using a single line strike through so the original content is still readable, and

2. The author of the alteration must sign and date the revision.

Amendments or delayed entries to paper records must be clearly signed and dated upon entry into the record. Amendments or delayed entries to paper records may be initialed and dated if the medical record contains evidence associating the provider's initials with their name.

Electronic Health Records (EHR): Medical record keeping within an EHR deserves special considerations; however, the principles specified above remain fundamental and necessary for document submission to MACs, CERT, Recovery Auditors, and ZPICs. Records sourced from electronic systems containing amendments, corrections or delayed entries must:

a. Distinctly identify any amendment, correction or delayed entry, and

b. Provide a reliable means to clearly identify the original content, the modified content, and the date and authorship of each modification of the record.

C. If the MACs, CERT or Recovery Auditors identify medical documentation with potentially fraudulent entries, the reviewers shall refer the cases to the ZPIC and may consider referring to the RO and State Agency.

3.3.2.6 - Psychotherapy Notes

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

This section applies to MACs, CERT, Recovery Auditors or ZPICs, 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, Recovery Auditors or ZPICs 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, Recovery Auditors, CERT or ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

Financial limitations on therapy services (therapy caps) were originally initiated by the Balanced Budget Act of 1997 and have been implemented at times without an exceptions process. During a time when no exceptions process exists, contractors shall deny claims for Part B occupational, physical, and speech-language pathology therapy services, except for hospital outpatient therapy services, which exceed the therapy cap. There is no therapy cap for hospital outpatient therapy services.

Automatic Process for Exception from the Therapy Cap

Section 1833(g)(5) of the Social Security Act provides that contractors shall, at the request of the individual enrolled under the Part B benefit or a person acting on behalf of that individual, grant an exception to the therapy cap in certain circumstances.

For therapy services provided during a time when a therapy cap exceptions process is in effect, the contractor shall presume the beneficiary to be excepted from the therapy cap without submission of request for exception or supporting documentation if:

- The beneficiary meets specific conditions listed in CMS Pub.100-04, chapter 5, §10.2 for exception from the therapy cap, or

- The beneficiary does not meet the specific criteria in CMS Pub.100-04, chapter 5, §10.2, but has a need for medically necessary therapy services above the therapy cap.

In both of these situations, the contractor shall require that the therapist maintain on file, necessary documentation to support the medical necessity of therapy services.

Documentation requirements are found in CMS Pub.100-02, chapter 15, section 230.3.

Request for Exception from Therapy Caps

Contractors shall not require providers to submit written requests for exception from the therapy cap. Instead, the placement of the KX modifier on the claim shall be interpreted as a request for exception from the cap. For beneficiaries who the clinician believes will require therapy treatment days in excess of those payable under the therapy cap, and who meet the above bulleted criteria for automatic exception, the Medicare contractor shall require the provider to maintain sufficient documentation on file to support the medical necessity for this service. Use of the KX modifier shall be interpreted as the therapist's attestation that services provided above the cap are medically necessary.

The contractor shall require the provider to maintain on file documentation in accordance with CMS Pub.100-02, chapter 15, section 220.3 and CMS Pub.100-04, chapter 5, sections 10.2 and 20 with the request for treatment days in excess of those payable under the therapy cap.

If the clinician attests that the requested services are medically necessary by using a KX modifier on the claim line, the contractor may make the determination that the claim is medically necessary. That determination is binding on the contractor in the absence of:

- potential fraud; or
- evidence of misrepresentation of facts presented to the contractor, or
- A pattern of aberrant billing by a provider.

Should such evidence of potential fraud, misrepresentation, or aberrant billing patterns by a provider be found, claims are subject to medical review regardless of whether the KX modifier was used on the claim.

Progressive corrective action (PCA) and medical review have a role in the therapy exception process. Although the services may meet the criteria for exception from the cap due to condition or complexity, they are still subject to review to determine that the services are otherwise covered and appropriately provided. The exception is granted on the clinician's assertion that there is documentation in the record justifying that the services meet the criteria for reasonable and necessary services. For example, the documentation must accurately represent the facts, and there shall be no evidence of patterns of aberrant billing of the services by the provider/supplier. Services deemed medically necessary are still subject to review related to fraud or abuse. An example of inappropriate use of the process is the routine use of the KX modifier on every claim for a patient that has an excepted condition or complexity, regardless of the impact of the condition on the need for services above the cap.

3.3.2.8 - MAC Articles

(Rev. 608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

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.

- 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 ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The MACs, CERT, Recovery Auditors, and ZPICs 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. 489, Issued: 10-18-13, Effective: 11-19-13, Implementation: 11-19-13)

This section applies to MACs.

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% 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% 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% Prepayment Review

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

MACs have the discretion to conduct 100 % prepayment review of providers. CMS considers 100 % 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 % prepayment review shall inform the CMS COR, Regional Office TM, and BFL in advance about any provider being placed on 100 % 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% prepayment review.
- The length of time the provider is expected to be on 100 % 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 % prepayment review.

3.4.1 - Electronic and Paper Claims

(Rev. 608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

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 complex medical 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).

A. Supporting Documentation Submitted with Claims

The MACs shall not require or request providers to submit supporting documentation with the initial claim(s) through MAC-developed forms, local policies, or any other communications with providers. The MACs shall only request supporting documentation through the ADR process or an alternate MAC process that permits matching the claim number to the submitted documentation.

The MACs shall match supporting documentation with claims as part of the ongoing medical review process. The MACs have the discretion to consider unsolicited documentation, but are not required to. The MACs shall inform providers in their jurisdiction if they allow supporting paper documentation to be submitted with the claim for medical review purposes.

The MACs may choose to suspend for medical review claims for lab services coded with one of the laboratory-negotiated rulemaking diagnosis "Codes that Do Not Support Medical Necessity (where documentation could result in payment)" only if identified as a prioritized problem in their medical review strategy, and consistent with PIM chapter 11, §11. In these cases, MACs shall continue to use the documentation submitted with the claim in order to determine whether the lab service was reasonable and necessary for that particular diagnosis code.

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. 608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs and ZPICs, 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 ZPICs 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 ZPICs 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 ZPICs 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 ZPICs 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 ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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 complex 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 complex 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 – Complex Prepayment Review Edits

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

This section applies to MACs.

The MACs shall focus complex prepayment 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 complex prepayment 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 Review of Claims

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

The MACs shall initiate targeted provider-specific postpayment review only when there is the likelihood of a sustained or high level of payment error. MACs are encouraged to initiate targeted service-specific postpayment review to recoup improper payments. Recovery Auditors shall perform postpay review of claims as outlined in their SOW.

3.5.1 - Re-opening Claims

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

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

The MACs, CERT, Recovery Auditors, and ZPICs shall adhere to the rules found in CFR 405.980 through 986 when conducting automated or complex postpayment 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. 674, Issued: 09-02-16, Effective: 11-04-16, Implementation: 11-04-16)

This section applies to MACs, CERT, Recovery Auditors, SMRC, and ZPICs, 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, Recovery Auditors, SMRC, and ZPICs have the discretion to select cases for postpayment review on a claim-by-claim basis or use statistical sampling for overpayment estimation.
    - When MACs, Recovery Auditors, SMRC, and ZPICs conduct claim-by-claim postpayment review, they shall only collect or refund the actual overpayment or underpayment amount.
    - When MACs, Recovery Auditors, SMRC, and ZPICs 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, CERT, Recovery Auditors, SMRC, and ZPICs have the discretion to conduct the postpayment review offsite at the provider or supplier's location.
- The MAC staff shall review their provider tracking system (PTS) and consult with the ZPIC to ensure non-duplication during the process of selecting providers for postpayment review.
- The MAC, SMRC, and Recovery Auditor shall not perform a duplicate review for any claim previously reviewed 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 ZPIC 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, Recovery Auditors, SMRC and ZPICs 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, Recovery Auditors, SMRC and ZPICs make coverage, coding, limitation of liability, waiver of recoupment, and/or other determinations when re-adjudicating claims.

- The MACs, CERT, Recovery Auditors, SMRC and ZPICs 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, Recovery Auditors, SMRC and ZPICs shall document the rationale for denial and include the basis for revisions in each case (important for provider appeals). MACs, CERT, and ZPICs should include copies of the NCD, coverage provisions from interpretive manuals, or LCD and any applicable references needed to support individual case determinations. Recovery Auditors 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. 174, Issued: 11-17-06; Effective: 10-01-2006; Implementation: 10-06-06)

In past years, CMS created mandated edits that suspend certain claims for manual 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 manual 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

It is not a SNF (excluding swing beds) or HHA demand bill (these demand bills must be reviewed).

3.5.3 - CMS Mandated Edits

(Rev. 174, Issued: 11-17-06; Effective: 10-01-2006; Implementation: 10-06-06)

In past years, CMS created mandated edits that suspend certain claims for manual 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 manual coverage and coding review without performing review if one or more of the following conditions apply:

3. The contractor does not have MR responsibility for the claim, or

4. The contractor's data analysis/priority setting/ MR strategy does not indicate this service is a problem in their jurisdiction, or

It is not a SNF (excluding swing beds) or HHA demand bill (these demand bills must be reviewed).

3.5.4 - Tracking Medicare Contractors' Postpayment Reviews

(Rev. 496, Issued: 12-12-13, Effective: 10-03-13, Implementation: 10-03-13)

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 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 MACs shall use the attached file layout for claims uploaded to the Recovery Audit Data Warehouse. Claims shall be submitted to the Recovery Audit Data Warehouse by the 20th day of every month for the previous month.

MAC staff who need access to the Data Warehouse shall contact RAC@cms.hhs.gov.

Header Layout

Field Name	Location	Length	Attributes	Sample	Valid Values and Notes
File Type	1	10	AN-10	CLAIM	Value: "Claim" Left justified, space fill
Filler	11	1	AN-1		Space fill
File Format Version	12	3	AN-3	4	Value: 004
Filler	15	1	AN -1		Space fill
Record Count	16	6	Num-6	102	Number of records contained in file. Right justified, zero fill
Filler	22	1	AN-1		Space fill
Record Length	23	3	Num-3	188	188
Filler	26	1	AN -1		Space fill
Create Date	27	8	Num-8	20090617	File Creation Date Format = YYYYMMDD
Filler	35	7	AN -7		Space fill
Source ID	42	5	AN-5		Values = Contractor ID of the user who created the file. Left Justified
Filler	47	1	AN-1		Space fill
MAC Jurisdiction	48	1	AN-1	F	A-N

Claim Record Layout

Field Name	Start	End	Length / Attributes	Required / Situational	Description - Valid Values and Notes
Record Type	1	1	1-AN	R	Claim Record-C
Claim Type	2	2	1-A	R	NCH MQA Record Identification Code 1 = Inpatient 2 = SNF 3 = Hospice

					4 = Outpatient 5 = Home Health Agency 6 = Carrier 7 = Durable Medical Equipment
Out-of-Jurisdiction Flag	3	3	1-A	S	Use "Z" for claims from out-of-jurisdiction providers. All other cases, use space.
State Code	4	5	2-A	R	State Codes: ME, CA
Place of Service ZIP Code	6	10	5-AN	R	US Postal Code where service rendered.
Workload ID	11	15	5-AN	R	Claims processing contractor ID number
Original Claim ID	16	38	23-AN	R	Unique identifier number assigned by Carrier, Fiscal Intermediary, A/B MAC or DME MAC to claim For Claim Type 1 through 5 - length must be equal to or greater than 14. For Claim Type 6 - length must be 15. For Claim Type 7 - length must be 14.
Type of Bill	39	42	4-AN	R/S	* Required for Claim Type 1 - 5.
Provider Legacy Number	43	55	13-AN	S	Unique Provider Legacy Number of the provider that performed the service and filed the claim.
Provider NPI	56	65	10-AN	R	Unique Provider NPI of the provider that performed the service and filed the claim
DME Ordering Provider NPI	66	75	10-AN	S	NPI of Provider that prescribed the supplies.
Original Claim Paid Amount	76	84	9.2-N	R	Amount of original payment made from Medicare fund ex: 999999.99
Original Claim Paid Date	85	92	8-N	R	Date claim was paid YYYYMMDD
Date of Service Start	93	100	8-N	R	Date service started/performed

					YYYYMMDD
Date of Service End	101	108	8-N	R	Date service ended YYYYMMDD
Provider Type	109	110	2-AN	R	Type of Provider or Supplier Valid Values: 1 = Lab/Ambulance 2 = Outpatient Hospital 3 = Home Health (HHA) 4 = Hospice 5 = Professional Services (physician/non-physician practitioner) 6 = DME by Supplier 7 = Skilled Nursing (SNF) 8 = Inpatient Hospital 9 = Inpatient Rehabilitation (IRF) 10 = Critical Access Hospital (CAH) 11 = Long Term Care Hospital (LTCH) 12 = DME by Physician 13 = Ambulatory Surgery Center (ASC) 14 = Other
CMS Provider Specialty Code	111	112	2-AN	S	CMS Provider Specialty Code in Carrier/DME files; no equivalent in institutional files
Review Type	113	114	2-AN	R	Automated Review-AR Complex Review-CR Semi-Automated Review-SA
Review Status	115	116	2-AN	S	Valid Values: UP = Underpayment Reimbursed in Full; OP = Overpayment Paid in Full; AP = Appealed Claim;

					RC = Review Concluded without identification of improper payment; CR = Debt Resolved by Contractor. Example: MAC notifies RAC that provider has declared bankruptcy or has disappeared. PR = Debt Resolved by Provider. Example: Provider supplies new evidence in discussion period; RAC agrees and reverses improper payment finding. TR = Terminated by CMS. Example: Claim was excluded while under review. ER = Closed due to error in record (can be reloaded as new corrected record) RE = Reopen claim(to activate a closed claim)
Adjustment ID	117	139	23-AN	R*	Unique identifier number assigned by Carrier, Fiscal Intermediary, A/B MAC or DME MAC to claim
Date Code A	140	141	2-AN	R*	Type of date: 01-Initial selection of record for audit 02-Request for medical records 03-Received medical records from provider 04-Results letter sent to provider (complex review) 05-Demand letter sent. 06-Claim closed 07-No findings letter sent.

					* Date Code 01 is always required.
Date A	142	149	8-N	R	Date format YYYYMMDD
Date Code B	150	151	2-AN	S	Type of date:
Date B	152	159	8-N	S	Date format YYYYMMDD
Date Code C	160	161	2-AN	S	Type of date:
Date C	162	169	8-N	S	Date format YYYYMMDD
Date Code D	170	171	2-AN	S	Type of date:
Date D	172	179	8-N	S	Date format YYYYMMDD
Demand Letter Amount	180	188	9.2-N	R*	ex: 999999.99 * Submit negative amounts for underpayments

Claim Line Item Record Layout

Field Name	Start	End	Length / Attributes	Required / Situational	Description - Valid Values and Notes
Record Type	1	1	1-AN	R	Line-L
Line item number	2	4	3-AN	R	Claim line item number; 000 for institutional claims. If line number = 000, then no other lines are acceptable for that claim

Original Diagnosis Code Version Indicator	5	5	1-N	R	9 for ICD-9 or 0 for ICD-10;
Original Principal Diagnosis Code (institutional) or line-specific Diagnosis Code (non-institutional)	6	12	7-AN	R	Original ICD-9 or ICD-10. Decimal point(.) is not allowed.
Final Diagnosis Code Version Indicator	13	13	1-N	S	9 for ICD-9 or 0 for ICD-10;
Final Principal Diagnosis Code (institutional) or line-specific Diagnosis Code (non-institutional)	14	20	7-AN	S	Final diagnosis code after audit. Decimal point(.) is not allowed.
Original DRG	21	23	3-AN	S	Original DRG on claim. It must be three digit numbers. Line 000 only
Final DRG	24	26	3-AN	S	Final DRG after audit. It must be three digit numbers. Line 000 only
Original ICD Procedure Code	27	33	7-AN	S	Original ICD9/ICD10 Procedure Code on RAC identified claim. Decimal point(.) is not allowed.
Final ICD Procedure Code	34	40	7-AN	S	Final ICD9/ICD10 Procedure Code after audit. Decimal point(.) is not allowed.
Original Non-DRG PPS/Hospice LOC Code	41	45	5-AN	S	Original HOPPS code for outpatient hospitals (APCs), HIPPS code for SNFs (RUG/AIs), HHAs (HHRGs) or IRFs (CMG/RICs), or Level of Care code for hospice claims.
Final Non-DRG PPS/Hospice LOC Code	46	50	5-AN	S	Final APC/HIPPS/LOC after audit
Original HCPCS	51	55	5-AN	S	Original HCPCS on claim. Not generally used for inpatient claims (exceptions do exist)
Final HCPCS	56	60	5-AN	S	Final HCPCS after audit. Not generally used for inpatient claims
Original Units of Service	61	63	3-N	S	Original units of service on claim
Final Units of Service	64	66	3-N	S	Final units of service on claims

Original BETOS Code	67	69	3-AN	S	Original Berenson-Eggers type of service (BETOS) code for the given HCPCS
Final BETOS Code	70	72	3-AN	S	Final BETOS code for the given HCPCS
Filler	73	188	116-AN	R	Spaces

3.6 - Determinations Made During Review
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

A. General

The MACs, CERT, Recovery Auditors, and ZPICs 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 ZPICs 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 ZPIC.

3.6.1 - Determining Overpayments and Underpayments
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs, and ZPICs. 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 ZPICs shall develop projection methodologies in conjunction with their statisticians that are consistent with the requirements found in PIM chapter 8, §8.4. MACs and ZPICs 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) (l) 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(l) 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 ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs, CERT, and ZPICs, 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The MACs, CERT, Recovery Auditors, and ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs, CERT, Recovery Auditors, and ZPICs, 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 ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs, CERT, Recovery Auditors, and ZPICs, 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 ZPICs 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 ZPICs 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. 608, Issued: 08-14-15, Effective: 01-01-12, Implementation: 09-14-15)

This section applies to MACs, CERT, SMRC, Recovery Auditors, and ZPICs, 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 ZPICs 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, ZPICs and Recovery Auditors shall not deny the entire claim but instead shall adjust the code and adjust the payment. The MACs, SMRC, CERT, ZPICs 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, ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

The MACs, CERT, Recovery Auditors, and ZPICs 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 ZPICs shall use the guidelines listed below in selecting the appropriate denial reason. Recovery Auditors 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 ZPICs 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 ZPICs 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 ZPICs 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 routine 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, Recovery Auditors, and ZPICs 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, Recovery Auditors, and ZPICs 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 Recovery Auditors shall only deny items or services for which they have accurately determined that the provider is liable for the improper payment. The Recovery Auditor SOW does not allow the Recovery Auditors to review items or services for which the beneficiary is liable. If, in the course of claims review, a Recovery Auditor determines that payment for an item or service should be denied and the beneficiary is liable, these claims should be referred to the MAC to recoup/refund. The Recovery Auditors will not receive a contingency for these claims.

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 HICN 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.

B. Denial Reasons

The ZPICs shall deny payment on claims either partially (e.g., by denying one line item on a multi-line claim) or in full whenever there is evidence that a service:

- Was furnished in violation of the self referral prohibition, which prohibits physicians from referring beneficiaries to entities in which the physician has a financial interest; or
- Was furnished, ordered or prescribed on or after the effective date of exclusion by a provider excluded from the Medicare program and that provider does not meet the exceptions identified below in PIM, chapter 4, §4.19.2.6.

The ZPICs shall deny payment whenever there is evidence that an item or service was not furnished, or not furnished as billed. The denial should occur even while developing the case for referral to OIG or if the case has been accepted by the OIG. In cases where there is apparent fraud, ZPICs shall deny the claim(s) and identify the overpayment where there is potential fraud after notifying law enforcement. It is necessary to document each denial thoroughly to sustain denials in the appeals process. MACs shall make adjustments in cost reports, as appropriate.

The MACs, CERT, Recovery Auditors, and ZPICs shall deny claims, in full or in part, and recoup the overpayment (MACs recoup the overpayment for ZPICs and Recovery Auditors) under the circumstances listed above. MACs shall not "Return to Provider" or reject claims under these circumstances. Unless the denied claims were the basis for an overpayment extrapolation, MACs shall reverse the claims denied on postpayment review in the claims processing system so they do not appear on the Provider Statistical and Reimbursement Report.

3.6.3 - Beneficiary Notification

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

This section applies to MACs, CERT, Recovery Auditors, and ZPICs, 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, Recovery Auditors, and ZPICs are not required to issue beneficiary notices for claims they deny. Instead, CERT, Recovery Auditors, and ZPICs 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, routine, or complex 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 Recovery Auditor cases, the Recovery Auditor and MAC Joint Operating Agreement (JOA) shall specify what information the Recovery Auditor 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. 663, Issued: 07-15-16, Effective: 08-16-16, Implementation: 08-16-16)

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

A. General

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 Recovery Auditors shall issue a Review Results Letter for complex audits as outlined in their SOW requirements. ZPICs 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 Recovery Auditors or ZPICs);
- The provider's or supplier's right to request an extended repayment schedule (not applicable to Recovery Auditors or ZPICs);
- The MACs and ZPICs 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 ZPICs 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 Recovery Auditor shall notify the provider by issuing a notification letter to meet this requirement. The ZPIC 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 complex 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. Recovery Auditors

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

For overpayments detected through **non-complex** review, the Recovery Auditor shall notify the provider as indicated in the Recovery auditor SOW and will communicate sufficient information to the MAC so that the MAC can send a Remittance Advice to the provider.

For underpayments, the Recovery Auditor shall notify the provider as indicated in the Recovery Auditor SOW. In addition, the Recovery Auditor 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. ZPICs

For overpayments detected through **complex** review, and after coordination between the ZPIC and OIG, the ZPIC shall send a review results letter (the MAC sends the demand letter). In addition, the ZPIC shall communicate sufficient information to the MAC so that the MAC can send a demand letter to the provider and collect the overpayment. The ZPIC 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 ZPIC 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 complex 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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 ZPIC.

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

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

For each claim denied, in full or in part, the MACs, CERT, and ZPICs 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 ZPICs 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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 complex medical 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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 ZPICs.

3.7.1.1 - Provider Error Rate

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

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

$$\frac{\text{Dollar amount of allowable** charges for services billed in error as determined by MR***}}{\text{Dollar amount of allowable** charges for services medically reviewed}}$$

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

$$\frac{\text{Dollar amount of services paid in error as determined by MR***}}{\text{Dollar amount of services medically reviewed}}$$

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

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 ZPICs to ensure contacts are not in conflict with fraud related activities.

3.7.3.1 - Evaluation of Prepayment Edits
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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
- Routine or complex review edits shall be evaluated quarterly.

The edit evaluations are to determine their effectiveness on the provider or service area while assessing the affect 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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 ZPIC to evaluate the effectiveness of edits implemented at ZPIC request. The MACs shall provide this report on a monthly basis by the 15th business day of each month. This requirement could also be met by the ZPICs 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 ZPIC just specific to ZPIC 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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 ZPIC. 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 ZPIC 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. 617, Issued: 10-09-15, Effective: 11-10-15, Implementation: 11-10-15)

A. General

This section applies to MACs.

The CMS will provide information to the MACs regarding CMS Recovery Auditor, 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 Recovery Audit program, 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 email the Excel file back to CMS.

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 have the discretion to readjust the format for use in Excel, but all fields shall be completed. The Excel file and email shall be named with the TDL number, jurisdiction number or letter, jurisdiction name, and response due date (e.g., TDL 12345 JX, Contractor Inc. due 05302014). The MACs shall email the Excel file to the CMS contact indicated in the TDL, their Contracting Officer's Representative (COR) or Contractor Manager, Business Function Lead (BFL), and Technical Monitor (TM).

The MACs shall attach the Excel file and submit their responses via email to CMS by the date specified in the TDL. If the due dates fall on a weekend or a federal holiday, the MAC shall submit the report 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 included 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 was 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs and Recovery Auditors. ZPICs 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, (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. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

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

The MAC shall assign a physician to participate or take party status at Administrative Law Judge (ALJ) hearings, and oversee the ALJ hearing support process established in this section. This applies only to their own claim determinations or claim determinations over which they have responsibility. For claims that are reviewed by other entities, the MAC should participate only in a supporting role. Further rules and procedures related to the ALJ hearing process begin at 42 CFR 405.1000. Physicians overseeing and/or taking party or participant status shall be a current CMD, a MAC employed physician or any combination thereof.

The MAC shall establish a process for assessing the notices of hearing received to determine which cases should be selected for participation at the ALJ level of appeal. Factors to be examined should include, but not be limited to policy implications, dollars at issue, source of the denial, program integrity matters, and the extent to which a particular issue is, or has been, a recurring issue at the ALJ level of appeal. MACs should be proactive in evaluating potential participation cases and redetermination cases that are expected to continue through to an ALJ hearing and, in some cases, should prepare a letter to include in the case file to indicate that they intend on participating if the case goes to a hearing.

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/participant status, a contractor may elect to have an attorney or clinician take party or participant status, or another qualified individual if approved by the COR.

The MACs shall capture and report the ALJ participation and party data in their monthly status report to CMS.

3.9.1 - Collaboration

(Rev. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

A notice of an ALJ hearing issued by Office of Medicare Hearings and Appeals (OMHA) will be sent to the appropriate QIC. The MAC shall coordinate with the QIC to ensure timely notification of all ALJ hearings, as the election to participate must be made no later than 10 calendar days after QIC receipt of the notice of hearing. The MAC shall add procedural details involved with the coordination of representation at ALJ hearings into the existing joint operating agreement with the QIC.

Since the QIC may also elect to participate in the ALJ hearing process, the MAC shall also collaborate with the QIC regarding 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. MACs should obtain all relevant case file information, including information from other MACs regarding the claims at issue, when electing to participate in the hearing as a participant or as a party. There may be cases in which testimony from another contractor is necessary. The MAC should call those entities as a witness only if the MAC has declared party status. However, if the MAC submits a position paper as a participant, the MAC should collaborate with other contractors and document their views on the case in the paper.

The MAC 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 MACs. The MAC shall provide contact information and updates to the AdQIC for dissemination to CMS, OMHA Headquarters, and OMHA ALJ field offices.

The MAC shall copy all other relevant CMS entities and parties to the hearing (i.e., Recovery Auditor, ZPIC, QIC) when sending their response to the notice of hearing. If multiple CMS entities intend to participate and the QIC is not participating, the MAC shall coordinate the roles and responsibilities of the participants.

3.9.2 - Participation in the ALJ Hearing

(Rev. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

The MAC shall make the election to participate in the hearing consistent with the rules at 42 CFR 405.1010, and shall provide such notice in writing to the ALJ, appellant, and all parties identified, within 10 calendar days of receipt of the notice of hearing (by the QIC). Participation may include filing position papers and providing testimony to clarify

factual and policy issues involved in a case. The MAC shall be adequately prepared to respond to questioning by the ALJ (and by the appellant if the contractor is willing) regarding all issues related to the claims under appeal.

Because participation status does not include the same rights as full party status, the MAC may not call witnesses, or cross-examine witnesses, of another party. The MAC shall coordinate with other contractors in advance to solicit their participation should testimony from the other contractors be necessary.

3.9.3 - Party in the ALJ Hearing

(Rev. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

The MAC shall obtain approval from CMS prior to electing party status in an ALJ hearing. High priority will be given to cases involving program integrity matters and/or overpayment cases involving significant dollar amounts. The MAC shall obtain approval from CMS prior to advising the ALJ and other parties of the intention to participate as a party. In the event that CMS does not approve the MAC's request for party status, the MAC may elect to proceed as a participant.

The MAC shall make the election for party status consistent with the rules at 42 CFR 405.1012, and shall provide such notice in writing to the ALJ, appellant, and all parties identified, within 10 calendar days of receipt of the notice of hearing (by the QIC). As a party, the MAC can file position papers, call witnesses, and/or cross-examine witnesses of other parties, and/or request discovery, subject to the limitations of 42 CFR 405.1037(b). The MAC shall submit any position paper or additional evidence requested by the ALJ within timeframes established by the ALJ, and provide copies of any written statements to the other parties to the hearing at the same time they are submitted to the ALJ. The MAC shall be adequately prepared to respond to questioning by the ALJ or other parties regarding all issues related to the claims under appeal.

3.9.4 - The ALJ Hearing

(Rev. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

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.

Notice of the hearing will be sent to all parties and to the QIC. If the MAC intends to be either a participant or a party, the MAC shall send the acknowledgement notice to the ALJ, the appellant, and all other parties identified in the notice of hearing within 10 calendar days of the date that the QIC received the notice of hearing. A party may object in writing to the time and place of the hearing, as soon as possible before the originally scheduled time, 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).

The MAC shall actively participate in the ALJ hearing as appropriate based on participation status (participant or party). In either situation, the MAC shall 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 extrapolation cases, the MAC shall 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 process.

3.10 – Prior Authorization

(Rev. 698; Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

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 number, 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 expediently 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. 698; Issued: 01-20-17; Effective: 02-21-17; Implementation: 02-21-17)

A prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization is described in 42 C.F.R. 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, administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other data analysis.

The Prior Authorization Master List is the list of DMEPOS items that have been identified using the inclusion criteria described in 42 C.F.R. 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.

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.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R698PI	01/20/2017	The Process of Prior Authorization	02/21/2017	9940
R674PI	09/02/2016	Duplicate Postpayment Claim Reviews	11/04/2016	9665
R663PI	07/15/2016	Denial Codes for Missing or Insufficient Documentation	08/16/2016	9690
R657PI	06/17/2016	Special Provisions for Lab Additional Documentation Requests (ADRs)	07/18/2016	9670
R634PI	01/22/2016	Reviewers' Credentials, Notifying the Provider, CARC Code Update	04/22/2016	9333
R628PI	12/04/2015	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.2 (Time Frames for Submission)	01/06/2016	9438
R620PI	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
R617PI	10/09/2015	Update to Chapter 3 of Pub. 100-08	11/10/2015	9303
R615PI	10/02/2015	Signature Requirements	11/02/2015	9332
R613PI	09/25/2015	Postpayment Review Requirements	10/26/2015	9323
R608PI	08/14/2015	Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	09/14/2015	8747
R604PI	07/24/2015	Signature Requirements	08/25/2015	9225
R585PI	04/03/2015	Coding Determinations	05/04/2015	8937
R568PI	02/04/2015	Review Timeliness Requirements for Complex Review	03/01/2015	8443
R567PI	02/04/2015	New Timeframe for Response to Additional Documentation Requests	04/06/2015	8583
R566PI	01/07/2015	New Timeframe for Response to Additional Documentation Requests – Rescinded and replaced by Transmittal 567	04/06/2015	8583
R565PI	12/31/2014	Update to CMS Publication 100-08, Chapter 3, Section 3.2.3.2 (Time Frames for Submission)	02/02/2015	9012
R557PI	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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R554PI	11/14/2014	New Timeframe for Response to Additional Documentation Requests – Rescinded and replaced by Transmittal 566	04/06/2015	8583
R547PI	10/17/2014	Review Timeliness Requirements for Complex Review – Rescinded and replaced by Transmittal 566	02/24/2015	8443
R543PI	09/26/2014	Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings	10/27/2014	8501
R541PI	09/12/2014	Claims that are Related	09/08/2014	8802
R540PI	09/04/2014	Claims that are Related – Rescinded and replaced by Transmittal 541	09/08/2014	8802
R534PI	08/08/2014	Claims that are Related – Rescinded and replaced by Transmittal 540	09/08/2014	8802
R527PI	07/03/2014	Provider Notice on MAC Web sites	09/05/2014	8690
R523PI	04/20/2014	Update to CMS Pub. 100-08, Chapter 3 – Rescinded and not replaced	07/22/2014	8791
R512PI	04/18/2014	Revision to the Program Integrity Manual, Chapter 3 Section 3.3	05/19/2014	8716
R505PI	02/05/2014	Removing Prohibition - Rescinded	03/06/2014	8425
R501PI	01/09/2014	Complex Medical Review	10/07/2013	8429
R500PI	12/27/2013	Third-party Additional Documentation Request CERT Update	01/28/2014	8547
R498PI	12/27/2013	Notifying the Provider of Postpayment Review Results	01/28/2014	8541
R496PI	12/12/2013	Tracking Medicare Contractors' Postpayment Reviews	10/03/2013	8362
R489PI	10/18/2013	100% Prepayment Review and Random Review Instructions	11/19/2013	8427
R488PI	09/20/2013	Acceptable Submission Methods for Responses to ADRs	10/21/2013	8436
R487PI	09/13/2013	Tracking Medicare Contractors' Postpayment Reviews	10/03/2013	8362
R486PI	09/06/2013	Complex Medical Review – Rescinded and replaced by Transmittal 501	10/07/2013	8429
R485PI	08/21/2013	Program Safeguard Contractor (PSC) and Zone Program Integrity Contractor (ZPIC) Provider Notification	01/29/2013	8079
R484PI	08/21/2013	OMB Collection Number	05/21/2012	7750

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R477PI	08/02/2013	Tracking Medicare Contractors' Postpayment Reviews – Rescinded and replaced by Transmittal 487	10/03/2013	8362
R465PI	05/17/2013	Use of a Rubber Stamp for Signature	06/18/2013	8219
R464PI	05/17/2013	Reopening Claims with Additional Information or Denied due to Late or No Submission of Requested Information	06/18/2013	8267
R458PI	04/12/2013	EsMD RC Public Announcement	05/13/2013	8208
R455PI	03/15/2013	Progress Notes and Forms	12/10/2012	8033
R453PI	03/13/2013	Progress Notes and Forms – Rescinded and replaced by Transmittal 455	12/10/2012	8033
R447PI	01/18/2013	Medical Review Timeliness Requirements	02/19/2013	8131
R446PI	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
R442PI	12/07/2012	Update for Amendments, Corrections and Delayed Entries in Medical Documentation	01/08/2013	8105
R438PI	11/09/2012	Progress Notes and Forms – Rescinded and replaced by Transmittal 453	12/10/2012	8033
R426PI	06/15/2012	Process for Handling Electronic Submission of Medical Documentation (esMD)	07/16/2012	7835
R422PI	05/25/2012	Request Records Related to the Claim Being Reviewed	06/26/2012	7837
R418PI	04/20/2012	OMB Collection Number – Rescinded and replaced by Transmittal 484	05/21/2012	7750
R399PI	11/04/2011	Revision of PIM Chapter 3, Section 3.2.1 Setting Priorities and Targeting Reviews	12/05/2011	7622
R398PI	11/04/2011	Revision of PIM Chapter 3, Section 3.7.5, Part B, Corrective Action Reporting on CMS and OIG Identified Vulnerabilities Spreadsheet Submission Instructions	12/05/2011	7479
R396PI	11/02/2011	Medical Review of PWK (paperwork)	04/02/2012	7330
R383PI	08/26/2011	Update to Pub. 100-08, Medicare Program Integrity Manual-Chapter 3	09/26/2011	7536
R377PI	05/27/2011	Program Integrity Manual Reorganization of Chapters 3 and 8	06/28/2011	6560
R367PI	02/25/2011	Use of Claims History Information in Claim Payment Determination	03/25/2011	7305

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R366PI	02/04/2011	Auto Denial of Claim Line(s) Items Submitted with a GZ Modifier	07/05/2011	7228
R360PI	12/10/2010	Corrective Action Reporting	01/12/2011	7241
R343PI	06/18/2010	Medical Review Resolutions in the Absence of a Plan of Care (POC) and the Outcome Assessment Information Set (OASIS)	07/19/2010	6982
R338PI	05/14/2010	Clinical Review Judgment (CRJ)	06/15/2010	6954
R327PI	03/16/2010	Signature Guidelines for Medical Review Purposes	04/16/2010	6698
R303PI	09/25/2009	Local Coverage Determinations (LCD) Exceptions - Rescinded	10/13/2009	6586
R302PI	09/11/2009	Local Coverage Determinations (LCD) Exceptions - Rescinded and replaced by Transmittal 303	10/13/2009	6586
R282PI	01/08/2009	Zone Program Integrity Contractor (ZPIC) Updates	01/26/2009	6170
R278PI	12/19/2008	Zone Program Integrity Contractor (ZPIC) Updates - Rescinded and replaced by Transmittal 282	01/26/2009	6170
R264PI	08/07/2008	Transition of Responsibility for Medical Review From Quality Improvement Organizations (QIOs)	08/15/2008	5849
R248PI	03/28/2008	Signature Requirements Clarification	04/28/2008	5971
R245PI	02/29/2008	Processing Part B Therapy Claims While the Therapy Cap Exceptions Process is in Effect	03/31/2008	5945
R220PI	08/24/2007	Various Medical Review Clarifications	09/03/2007	5550
R185PI	01/26/2007	Updating Financial Reporting Requirements for Workload and Cost Associated With the Return of Demand Bills	02/26/2007	4378
R184PI	01/26/2007	Revisions for MACs and PSCs	02/26/2007	5399
R181PI	12/29/2006	Outpatient Therapy Cap Exceptions Process for Calendar Year (CY) 2007	01/29/2007	5478
R179PI	12/15/2006	Revised Medical Review Timeliness and Reopening Requirements for Medical Review	01/16/2007	5252
R174PI	11/17/2006	Transition of Medical Review Educational Activities	10/06/2006	5275
R171PI	11/09/2006	Outpatient Therapy Cap Clarifications	12/09/2006	5271
R170PI	11/03/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 174	10/06/2006	5275

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R167PI	10/27/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFS) for Claims Processing	10/01/2006	4296
R163PI	09/29/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 170	10/06/2006	5275
R159PI	09/22/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFS) for Claims Processing - Replaced by Transmittal 167	10/02/2006	4296
R149PI	06/30/2006	Notification to Providers, Suppliers, and Beneficiaries of Postpayment Review Results	07/31/2006	5115
R142PI	03/02/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFS) for Claims Processing – Replaced by Transmittal 159	10/02/2006	4296
R140PI	02/15/2006	Therapy Caps Exception Process	03/13/2006	4364
R139PI	02/13/2006	Therapy Caps Exception Process - Replaced by Transmittal 140	03/13/2006	4364
R138PI	02/10/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFS) for Claims Processing - Replaced by Transmittal 142	10/03/2006	4296
R135PI	01/06/2006	Changes to the GTL Titles	02/06/2006	4228
R131PI	10/10/2005	Medical Review Matching of Electronic Claims and Additional Documentation in the Medical Review Process	02/10/2006	4052
R125PI	09/30/2005	Medical Review Additional Documentation Requests	12/30/2005	4022
R123PI	09/23/2005	MMA Section 935	10/24/2005	3703
R122PI	09/16/2005	Medical Review Collection Number Requirements	10/17/2005	4091
R120PI	08/25/2005	Correction to Change Request (CR) 3222: Local Medical Review Policy/ Local Coverage Determination Medicare Summary Notice (MSN) Message Revision	N/A	3880
R118PI	08/12/2005	Various Benefit Integrity (BI) Clarifications	09/12/2005	3896
R114PI	06/10/2005	Change in Statistical Sampling Instructions	05/31/2005	3734
R108PI	04/29/2005	Change in Statistical Sampling Instructions	05/31/2005	3734

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R100PI	01/21/2005	Review of Documentation During Medical Review	02/22/2005	3644
R098PI	01/21/2005	Psychotherapy Notes	02/22/2005	3457
R096PI	01/14/2005	Consent Settlements	02/14/2005	3626
R094PI	01/14/2005	Informing Beneficiaries About Which Local Medical Review Policy (LMRP) and/or Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) is Associated with Their Claim Denial	07/05/2005	3602
R091PI	12/10/2004	Revision of Program Integrity Manual (PIM), Section 3.11.1.4	01/03/2005	3560
R090PI	12/10/2004	Prepayment Review of Claims for MR Purposes	01/10/2005	3569
R087PI	11/05/2004	Informing Beneficiaries About Which Local Medical Review Policy (LMRP) and/or Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) is Associated with Their Claim Denial	04/04/2005	3363
R086PI	11/05/2005	Payment for Emergency Medical Treatment and Labor Act (EMTALA) - Mandated Screening and Stabilization Services	11/22/2004	3437
R85PI	10/22/2004	Informing Beneficiaries About Which Local Medical Review Policy (LMRP) and/or Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) is Associated with Their Claim Denial - Replaced by Transmittal 87	04/04/2005	3363
R084PI	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
R079PI	07/09/2004	Local Medical Review Policy/ Local Coverage Determination Medicare Summary Notice (MSN) Message Revision; Denial Notices	08/09/2004	3222
R076PI	05/28/2004	Clarification of Complex Medical Review	06/28/2004	3211
R075PI	05/14/2004	Informing Beneficiaries About Which Local Medical Review Policy (LMRP) and/or Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) is Associated with Their Claim Denial	10/04/2004	3089

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R072PI	04/16/2004	Automated Prepayment Review	05/01/2004	3088
R071PI	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
R070PI	04/09/2004	New Requirements for Self-Administered Drug (SAD) Exclusion List Articles in the Medicare Coverage Database (MCD)	05/10/2004	3136
R066PI	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
R064PI	01/30/2004	Role Conditions of Participation (COPs) Requirements When Making a Payment Decision	03/02/2004	3042
R059PI	11/28/2003	Documentation Specifications for Areas Selected for Prepayment or Postpayment MR	01/05/2004	2937
R054PI	10/31/2003	Denial Notices	04/05/2004	2936
R053PI	10/31/2003	Prepayment Edits	04/05/2004	2916
R049PI	09/26/2003	Changing the Use of Remittance Advice Code N109 From Mandatory to Contractor's Discretion	10/10/2003	2873
R047PI	07/25/2003	CMS Mandated Edits	08/08/2003	2517
R046PI	07/25/2003	Prepayment Edits	08/01/2003	2681
R039PI	03/14/2003	MR Review and Documentation	04/01/2003	2417
R038PI	02/03/2003	When Contractors May Publish Coverage/Coding Articles In Their Bulletins And Web Sites	02/14/2003	2120
R035PI	11/29/2002	Types of Prepayment and Postpayment Review	01/01/2003	2418
R033PI	11/01/2002	FY 2003 Budget Performance Requirements	11/01/2002	2407
R032PI	10/25/2002	Consent Settlements, CMPs Delegated to CMS and Referrals to OIG	10/25/2002	2333
R031PI	10/25/2002	Revised Prepayment Edits	09/01/2002	1793
R017PIM	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 citations instead.	04/01/2002	1891
R016PIM	11/28/2001	Adds Various Program Memoranda for BI Requests for Information, Organizational Requirements, Unsolicited Voluntary Refund	11/28/2001	1732

Rev #	Issue Date	Subject	Impl Date	CR#
		Checks, Anti-Kickback Statute Implications		
R013PIM	09/26/2001	Administrative Relief from Medical Review and Benefit Integrity in Disaster Situations	09/26/2001	1879
R003PIM	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292
R001PIM	06/2000	Initial Release of Manual	NA	931

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