CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-08 Medicare Program Integrity	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 377	**Date: May 27, 2011**
	Change Request 6560

SUBJECT: Program Integrity Manual Reorganization of Chapters 3 and 8

I. SUMMARY OF CHANGES: The CR will relocate and delete sections of Chapter 3 for better flow of information and ease of use. Some of the sections in Chapter 3 will be moved to a new Chapter - Chapter 8 Administrative Actions and Statistical Sampling for Overpayment Estimates.

EFFECTIVE DATE: June 28, 2011
IMPLEMENTATION DATE: June 28, 2011

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3.1/Introduction
D	3.1.1/Provider Tracking System (PTS)
D	3.1.2/Evaluating Effectiveness of Corrective Actions
N	3.2/Overview of Prepayment and Postpayment Reviews
N	3.2.1/Setting Priorities and Targeting Reviews
N	3.2.2/Provider Notice
N	3.2.2.1/Maintaining Provider Information
N	3.2.3/Requesting Additional Documentation During Prepayment and Postpayment Review
N	3.2.3.1/Additional Documentation Requests (ADR)
N	3.2.3.2/Time Frames for Submission
N	3.2.3.3/Third-Party Additional Documentation Request
N	3.2.3.4/Additional Documentation Request Required and Optional Elements
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N	3.2.3.10/Record Retention and Storage
N	3.3/Policies and Guidelines Applied During Review
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N	3.3.1.1/Complex Medical Review
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N	3.3.2/Medical Review Guidance
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N	3.3.2.2/Absolute Words and Prerequisite Therapies
N	3.3.2.3/Mandatory Policy Provisions
N	3.3.2.4/Signature Requirements
N	3.3.2.5/Late Entries in Medical Documentation

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D	3.4.1.1.1/Exception From the Uniform Dollar Limitation ("Therapy Cap")
N	3.4.1.2/Not Otherwise Classified (NOC) Codes
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D	3.4.6/Spreading Workload Evenly
D	3.4.7/New Provider/New Benefit Monitoring
D	3.4.8/Review That Involves Utilization Parameters
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N	8.4.10/Resources

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N	8.4.11.1/Stratified Sampling
N	8.4.11.2/Cluster Sampling

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-08	Transmittal: 377	Date: MAY 27, 2011	Change Request: 6560

SUBJECT: Program Integrity Manual Reorganization of Chapters 3 and 8

Effective Date:
June 28, 2011

Implementation Date:
June 28, 2011

I. GENERAL INFORMATION

A. Background:

The Office of Financial Management is reorganizing the Program Integrity Manual. This process will delete duplications and relocate sections within the PIM chapter 3 for improved flow of information and ease of use. A new chapter 8 has been created. The information in this chapter has not been changed. The information was moved intact from chapter 3 to Chapter 8.

B. Policy:

Clarifies and updates sections of PIM chapter 3.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6560.1	In an effort to identify the claims most likely to contain improper billing, contractors are encouraged to use prepayment and postpayment screening tools or natural language coding software.	X	X	X	X	X					RAC
6560.2	Reviewers 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.	X	X	X	X	X					RAC
6560.3	Reviewers have the discretion to post the screening tools in use to their Web sites or otherwise disclose to the provider community.	X	X	X	X	X					RAC
6560.4	RACs perform targeted reviews consistent with their SOWs.										RAC
6560.5	RACs are required to post a description of all approved										RAC

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	new issues to the RACs Web site before correspondence is sent to the provider. After posting, the RAC should issue an Additional Documentation Request (ADR) to the provider, if warranted.										
6560.6	Contractors shall provide notification prior to beginning a service-specific review by either posting a review description on the MAC Web site, or sending individual written notices, such as an Additional Documentation Request, to the affected providers.	X	X	X	X	X					
6560.7	MACs have the discretion to issue the notice separately or include it in the ADR.	X	X	X	X	X					
6560.8	When contractor data analysis confirms that an improper payment can be prevented through service-specific complex review, the contractor shall install service-specific complex review edits as soon as feasible under their MR strategy. The contractors are not required to conduct an error validation review prior to installing these edits.	X	X	X	X	X					
6560.9	Before beginning widespread service-specific review, RACs shall notify the provider community that the RAC intends to initiate review of certain items/services through a posting on the RAC Web site describing the item/service that will be reviewed.										RAC
6560.10	RAC shall maintain case files following the guidelines of the RAC SOW.										RAC
6560.11	Contractors shall mail the Additional Documentation Request (ADR) to the best known address for the provider.	X	X	X	X	X					CERT, RAC
6560.12	Contractors are encouraged to indicate the procedure a provider can follow to update address information.	X	X	X	X	X					
6560.13	If a provider wishes to have ADRs sent to one address but demand letters sent to a different address, contractors are encouraged to accommodate this request.	X	X	X	X	X					
6560.14	When contractors are aware that the provider or supplier no longer occupies a physical address, any future correspondence shall only reference the claim control numbers and not list the individual beneficiary data (e.g., names and health insurance claim numbers),contingent on current automated system limits.	X	X	X	X	X					PSC, ZPIC
6560.15	RACs shall issue ADRs in accordance with limits established by their Project Officer for each calendar year.										RAC
6560.16	Contractors shall request records related to the claim(s)	X	X	X	X	X					RAC,

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	being reviewed and have the discretion to collect documentation related to the beneficiary's condition before and after a service, but shall never request documentation dating from more than 12 months prior to the Date of Service unless required to do so by a NCD, LCD, CMS ruling or regulation.										CERT
6560.17	Contractors have the discretion to issue as many reminder notices as they deem appropriate.	X	X	X	X	X					RAC PSC, ZPIC
6560.18	Contractor shall issue reminder notices in accordance with their SOW.										CERT
6560.19	Contractors shall not use OMB #0938-0969 on their ADRs or any other type of written request for additional documentation for medical review.	X	X	X	X	X					RAC, PSC, ZPIC
6560.20	Should contractors receive a fax that does not include the disclaimer, they shall process the incoming fax as usual.	X	X	X	X	X					RAC, CERT
6560.21	If contractor has the capability to offer fax confirmation, they are encouraged to send such confirmations with every successfully received fax.	X	X	X	X	X					RAC, CERT
6560.22	Contractors that accept imaged medical documentation file(s) sent on CD/DVD from providers/HIHs shall state in the ADR that imaged medical documentation files on CD/DVD are to be permitted to be mailed through any means.	X	X	X	X	X					RAC, CERT
6560.23	RAC ADRs shall provide a Web site link or phone number that provides information regarding the requirements for submitting imaged documentation on CD or DVD.										RAC,
6560.24	Contractors will be encouraged to post a statement to their Web sites indicating whether they do or do not accept esMD transactions along with a link to a Web site about how a provider/(HIH) can submit medical documentation via the esMD mechanism.	X	X	X	X	X					RAC, CERT
6560.25	Contractors that accept this form of documentation submission from providers/ HIHs will be encouraged to state in their ADRs how providers can get more information about submitting medical documentation via the esMD mechanism.	X	X	X	X	X					CERT
6560.26	Contractors are not required to pay for medical documentation for either prepayment or postpayment review.	X	X	X	X	X					CERT, PSCs

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
											, ZPIC
6560.27	RACs 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. Contractors shall follow the payment rate methodology established in 42 CFR §476.78.										RAC
6560.28	RACs 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.										RAC
6560.29	RACs that accept esMD transactions shall pay a transaction fee of $2.00/case in lieu of postage.										RAC
6560.30	RACs performing postpayment review of any other provider types are not required to pay providers for photocopying and submitting documentation.										RAC
6560.31	RACs shall honor all requests from providers to issue photocopying payments to HIHs.										RAC
6560.32	RACs shall issue photocopying payments on at least a monthly basis and shall issue all photocopying payments within 45 calendar days of receiving the documentation.										RAC
6560.33	Contractors shall abide by all documentation retention requirements listed in all litigation holds issued via Joint Signature Memoranda or Technical Direction Letters (JSM/TDL).	X	X	X	X	X					PSC, ZPIC , RAC, CERT
6560.34	RACs shall comply with the record retention requirements in their SOWs.										RAC
6560.35	All complex review work performed by contractors shall: involve activities defined under the Medicare Integrity Program (MIP) at Section 1893(b)(1) of the Act; be articulated in their medical review strategy; and be designed in such a way as to reduce their Comprehensive Error Rate Testing (CERT) error rate or prevent the contractor's error rate from increasing.	X	X	X	X	X					
6560.36	Contractors shall follow requirements for prerequisite therapies when deciding whether to cover a service if listed in coverage provisions in interpretive manuals.	X	X	X	X	X					PSC, ZPIC , RAC,

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
											CERT
6560.37	Contractor reviewers shall review every line on the randomly selected claim. The reviewer shall review each line on the claim that affects payment to determine if the following requirements are met: coding requirements; benefit category and the reasonable and necessary requirements of the NCD and LCDs, among others.										CERT
6560.38	Contractors shall give less weight to documentation created more than 30 days following the date of service when making review determinations.	X	X	X	X	X					PSC, ZPIC, RAC, CERT
6560.39	If contractors identify providers with patterns of making late entries in the medical documentation, the reviewers shall refer the case to PSC or ZPIC.	X	X	X	X	X					RAC, CERT
6560.40	Contractors are encouraged to initiate targeted service-specific prepayment review to prevent improper payments for services identified by CERT or RACs as problem areas.	X	X	X	X	X					
6560.41	RAC staff shall check the RAC Data Warehouse to ensure they do not choose claims for review that have been reviewed by another entity.										RAC
6560.42	The results of the re-adjudication are used to determine the over- or underpayment amount for each claim. Re-adjudicating claims may not result in a payment correction. For claims paid under PPS rules, contractors shall develop projection methodologies in conjunction with their statisticians that are consistent with the requirements found in PIM 8. §8.4. Reviewers shall net out the dollar amount of claims underpaid during the cost accounting period, meaning that amounts owed to providers are balanced against amounts owed from providers.	X	X	X	X	X					PSC, ZPIC, RAC,
6560.43	Contractors shall consider an item or service to be reasonable and necessary if it is safe and effective; not experimental or investigational and appropriate.	X	X	X	X	X					PSC, ZPIC, RAC, CERT

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6560.44	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), Coding Clinic for ICD-9 or ICD-10, Coding Clinic for HCPCS and any coding requirements listed in CMS manuals, AC articles, or MAC articles.	X	X	X	X	X					PSC, ZPIC, RAC, CERT
6560.45	For overpayments detected through non-complex review, the RAC shall send a demand letter to the provider and communicate sufficient information to the MAC so that the MAC can send a remittance advice to the provider.										RAC
6560.46	For underpayments, the RAC shall send a review results letter to the provider.										RAC
6560.47	For overpayments detected through complex review, and after coordination between the ZPIC and the OIG, the ZPIC shall send a review results 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.										PSC, ZPIC
6560.48	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).	X	X	X	X	X					RAC, CERT, PSC, ZPIC

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	None.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

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X-Ref Requirement Number	Recommendations or other supporting information:
	None.

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Deborah Ricker, 410-786-0970, Deborah.ricker@cms.hhs.gov

Post-Implementation Contact(s):
Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers,* use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs),* include the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

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

Table of Contents

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.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. 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), a provider's identification number (PIN/UPIN) or 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[ICD]-9 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.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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).

3.2.2 Provider Notice

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

This section applies to MAC and Recovery Auditors, 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. The ZPICs are also not required to notify providers before beginning a review.

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 the same problem 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 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.

MACs
The MACs shall notify selected providers prior to beginning a provider-specific review by sending an individual written notice. MACs shall indicate whether the review will occur on a prepayment or 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.

B. Notice of Service-Specific Review

This section applies to MACs and Recovery Auditors, 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
The MACs shall provide notification prior to beginning a service-specific review by either posting a review description on its Web site, or by sending individual written notices, such as an

ADR, to the affected providers. MACs have the discretion to issue the notice separately or include it in the ADR.

When MAC data analysis confirms that an improper payment can be prevented through service-specific complex review, the MAC shall install service-specific complex review edits as soon as feasible under their MR Strategy. The MAC is not required to conduct an error validation review prior to installing these edits.

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.

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.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

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). 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

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."

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.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.

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 30 calendar days of the request. The reviewer has the discretion to 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 45.

B. Postpayment Review Time Frames

When requesting documentation for postpayment review, the Recovery Auditor shall notify providers that the requested documents are to be submitted within 45 calendar days of the request. MACs, CERT and ZPICs shall notify providers that requested documents are to be submitted within 30 calendar days of the request. 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. Recovery Auditors shall follow the time requirements outlined in their SOW.

3.2.3.3 Third-party Additional Documentation Request

(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.

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 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. IOM 100-04, 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.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 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 ADRs in accordance with limits established by their Contract Officer Technical representative (COTR) for each calendar year.*
- *The MACs, CERT ,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, but shall not request documentation dating from more than 12 months prior to the Date of Service unless an exception exists.*
- *The MACs, Recovery Auditors, and ZPICs have the discretion to issue as many reminder notices as they deem appropriate. Reminder notices can be issued via email or letter.*
- *The CERT shall issue reminder notices in accordance with its SOW.*
- *MACs, Recovery Auditors, and ZPICs shall not target their ADRs to providers based solely on the provider's electronic health record status or chosen method of submitting records.*

3.2.3.5 Acceptable Submission Methods
(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.

Reviewers shall be clear in their ADR letters about what documentation submission methods they will accept from a provider or HIH. The table below indicates for each contractor type whether it shall or has the discretion to include in their ADRs various documentation submission options.

	MAC MR Units	***CERT***	***Recovery Auditors***
Paper	***Shall give provider the option***	***Shall give provider the***	***Shall give provider the option***

		option	
Fax	***Have the discretion to give provider the option***	***Shall give provider the option***	***Shall give provider the option***
CD/DVD	***Have the discretion to give provider the option***	***Shall give provider the option***	***Shall give provider the option***
Electronic Submission of Medical Documentation (esMD)	***Have the discretion to give provider the option***	***Will have the discretion to give provider the option***	***Have the discretion to give provider the option***

Table 1: Acceptable submission methods for providers/HIHs when responding to ADRs from MACs, CERT, and Recovery Auditors.

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, CERT and Recovery Auditors should provide a physical mailing address instead of a P.O. Box. MACs are encouraged to use physical mailing addresses.

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 or CERT that accept this form of documentation submission from providers/HIHs shall state in the ADR that imaged medical documentation files on CD/DVD are permitted to 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 will allow providers/HIHs to submit medical documentation over secure electronic means. Information about the esMD system can be found at www.cms.gov/esMD.

All MACs, CERT and Recovery Auditors are encouraged to post a statement to their Web sites indicating whether they do or do not accept esMD transactions along with a link to a Web site about how a provider HIH can submit medical documentation via the esMD mechanism.

MACs, and CERT that accept this form of documentation submission from providers/HIHs are encouraged to state in their ADRs how providers can get more information about submitting medical documentation via the esMD mechanism.

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.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.

Use ICD-9 until such time as ICD-10 is in effect. Further instructions will be issued regarding claims containing ICD-9 codes with dates of service prior to the ICD-10 implementation that are submitted after ICD-10 is in effect.

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 ICD-9 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.

The MACs, CERT and Recovery Auditors shall implement these requirements to the extent possible without shared systems changes.

3.2.3.8 No or Insufficient Response to Additional Documentation Requests

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

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. These claims denials are issued with Remittance Advice Code N102/56900 that reads "This claim has been denied without reviewing the medical record because the requested records were not received or were not received timely." Contractors shall count these denials as automated review or manual review depending on the method of development.

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

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 under Remittance Advice Code N102 56900 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 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.)

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.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. 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. The MACs, CERT, Recovery Auditors, and ZPICs shall use Medicare policies in the form of regulations, CMS rulings, national coverage determinations (NCDs), coverage provisions in interpretive Medicare manuals, local coverage determinations (LCDs) and MAC policy articles attached to an LCD or listed in the Medicare Coverage Database to apply the provisions of the Act. Coverage provisions in interpretive Medicare manuals are instructions that are used to further define when and under what circumstances services are or are not covered.

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, ICD-9, HCPCS and CMS 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.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. 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 shall ensure that the credentials of their reviewers are consistent with the requirements in the Recovery Auditor SOW.

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 shall follow guidance related to calling upon other healthcare professionals as outlined in the Recovery auditor SOW.

The CERT and Recovery Auditors shall ensure that complex reviews for the purpose of making coding determinations are performed by certified coders. 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
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The MACs, CERT, and ZPICs shall establish a Quality Improvement (QI) process that verifies the accuracy of MR decisions made by licensed health care professionals. This includes contractor-developed annual training on clinical review judgment and inter-rater reliability assessments.

D. Advanced Beneficiary Notice (ABN)

The MACs, CERT, Recovery Auditors and ZPICs shall request as part of the ADR, during a complex medical record review, a copy of any mandatory ABNs, as defined in IOM 100-04, Medicare Claims Processing Manual Chapter 30 §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 IOM 100-04 Medicare Claims Processing Manual chapter 30 § 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 § 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 Requirement

For Prepayment Reviews

When a MAC receives requested documentation for prepayment review within 45 calendar days, the MAC shall do the following within 60 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).

For prepayment reviews, the MAC shall count day one as the date each new medical record is received in the mailroom. Each new medical record received would have an independent 60-day review time period associated with it.

For Postpayment Reviews

The MAC or Recovery Auditor 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.

The MAC has the option to either:

- *Begin counting the 60 days at the receipt of each medical record in the mailroom. Each new medical record would have an independent 60 day time period associated with it; or*
- *Wait until all requested medical documentation is received in the mailroom. The date on which the last of the requested medical documentation is received would represent the beginning of the 60 day time period.*

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.

3.3.2.2 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.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section is applicable for MACs, CERT, 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. 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 and CERT shall consider evidence in a signature log or attestation statement to determine the identity of the author of a medical record entry.*
- *If the signature is missing from an order, MACs 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 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 **of** the signatory.*	*X*	

	Example: An illegible signature appears on a prescription. The letterhead of the prescription lists (3) physicians' names. One of the names is circled.		
5	*Illegible signature NOT over a typed/printed name and NOT on letterhead, but the submitted documentation **is accompanied** by:* *a) a signature log, or* *b) an attestation statement*	*X*	
6	*Illegible signature NOT over a typed/printed name, NOT on letterhead and the documentation is **UNaccompanied** by:* *a) a signature log, or* *b) 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) a signature log, or* *b) an attestation statement*	*X*	
9	*Initials NOT over a typed/printed name **UNaccompanied** by:* *a) a signature log, or* *b) 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 name*		*X*
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 Late Entries in Medical Documentation

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

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

A provider may discover that certain documents were misfiled or needed to be filed in the medical documentation during the process of responding to an ADR. Providers are encouraged to add to the medical record or notes file all relevant documents that were created at the time of service or within a few days of the date of service.

The MACs, CERT, Recovery Auditors, and ZPICs shall give less weight when making review determinations to documentation, including a provider's internal query responses, created more than 30 calendar days following the date of service. If the MACs, CERT, or Recovery Auditors identify providers with patterns of making late (more than 30 calendar days past the date of service) entries in the medical documentation, including the query responses, the reviewers shall refer the cases to ZPIC and may consider referring to the RO and State Agency.

A query is a communication tool used between facility coding personnel and the physician and/or other health care practitioners whereby the coder obtains additional documentation to improve the specificity and completeness of the data used to assign diagnosis and procedure codes in a beneficiary's health record. The process may take place concurrently (while the beneficiary is in the facility) or retrospectively (after discharge).

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

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 ICD-9 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.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs.

A. General

The MACs shall initiate targeted provider-specific prepayment review only when there is the likelihood of a 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.

3.4.1 Electronic and Paper Claims

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

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 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 ICD-9 "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 ICD-9 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.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

This section applies to MACs and ZPICs, as indicated.

Use ICD-9 until such time as ICD-10 is in effect. Further instructions will be issued regarding claims containing ICD-9 codes with dates of service prior to the ICD-10 implementation that are submitted after ICD-10 is in effect.

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 ICD-9 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 ICD-9 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-9 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 ICD-9 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 ICD-9 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.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

Case review and development provisions:
The MACs 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, 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, and ZPICs conduct claim-by-claim postpayment review, they shall only collect or refund the actual overpayment or underpayment amount.*
    - *When MACs, Recovery Auditors, 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, 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 Recovery Auditor staff shall check the Recovery Auditor Data Warehouse to ensure they do not choose claims for review that have been reviewed by another entity.*
- *When the MACs, CERT, Recovery Auditors, 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, and ZPICs make coverage, coding, limitation of liability, waiver of recoupment, and/or other determinations when re-adjudicating claims.*
- *The MACs, CERT, Recovery Auditors, and ZPICs shall document all incorrectly paid, denied, or under-coded (e.g., billed using a HCPCS 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, 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 shall include detailed rationale as outlined in their SOW.

- *The MACs have the discretion to deny payment without the review of the claim with a medically unlikely service edit.*

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.*

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(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.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.

Use ICD-9 until such time as ICD-10 is in effect. Further instructions will be issued regarding claims containing ICD-9 codes with dates of service prior to the ICD-10 implementation that are submitted after ICD-10 is in effect.

The MACs, CERT, 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-9, Coding Clinic for HCPCS, and any coding requirements listed in CMS manuals or MAC articles.

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

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

A. General

The MACs shall send a Review Results Letter to the provider. 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 findings for each claim in the sample, including a specific explanation of why any services were determined to be non-covered, or incorrectly coded;*
- *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 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, using remittance advice code N102/56900, 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.

For claims where the reviewer makes a denial following complex review, the reviewer has the discretion to indicate in the denial notice, using remittance advice code N109 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. 360, Issued: 12-10-10, Effective: 12-01-10, Implementation: 01-12-11)

A. General

This section applies to MACs.

The MACs shall submit their first reports for both corrective actions and overpayment recovery on March 1, 2011.

The CMS will provide information to the MACs regarding CMS and OIG- identified vulnerabilities via Joint Signature Memoranda/Technical Direction Letters (JSM/TDLs). The JSM/TDLs will be sent to the MACs each quarter on or around January 1, April 1, July 1 and October 1.

B. Corrective Action Reporting on CMS and OIG Identified Vulnerabilities

The CMS will provide the MACs with a list of errors/vulnerabilities on a quarterly basis. These errors/vulnerabilities may be uncovered by the CERT program, the Recovery Auditor program, OIG audits, through internal CMS analysis or other means. The MACs shall review the list and provide detailed comments back to the CMS. The detailed comments shall include any corrective actions1) taken by the MAC 2) in progress by the MAC 3) planned by the MAC for future action, or 4) suggested by the MAC for CMS to undertake in the future. Detailed comments may also include any pertinent background or other information deemed important by the MAC.

The MACs shall submit their response, including detailed comments 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 JSM/TDL from CMS which includes the list of errors/vulnerabilities. The MACs shall use the format "Corrective Actions Taken on CMS and OIG-Identified Vulnerabilities Format" located in Exhibit 18 for reporting purposes. The MAC has the discretion to readjust the format for use in Excel but all fields shall be completed.

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 JSM/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 JSM/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

<u>Providers Directly Affected By Disaster</u>

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."

<u>Providers Indirectly Affected By Disaster</u>

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.

Medicare Program Integrity Manual

Chapter 8 – Administrative Actions and Statistical Sampling for Overpayment Estimates

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

8.1 - Appeal of Denials

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

A claimant dissatisfied with a contractor's initial determination is entitled by law and regulations to specified appeals. The appeals process allows a provider and/or a beneficiary (or representative) the right to request a review or reconsideration of the determination to deny a service in full or in part. In this process, Hearing Officers (HOs) and ALJs look to the evidence of record and must base their decision upon a preponderance of the evidence. If the appeal is of a claim reviewed by a PSC, then the PSC forwards its records on the case to the AC so that it can handle the appeal.

As conclusory statements may be considered of little or questionable value, it is important that reviewers include clearly articulated rationale for their findings. Such clearly articulated rationale will continue to be of importance if a denial is appealed beyond the ALJ level to the Appeals Council or eventually to federal court. Contractors must include a copy of the policy underlying denial in the case file.

A. Use of Medical Specialist

Reviewers may also use medical specialists to lend more weight and credibility to their rationale or findings. When an adjudicator must weigh the statements and rationale furnished by the appellant provider against the statements and rationale of the reviewer (and any information used by the reviewer), the opinion of a specialist in the same area as the provider may carry greater weight than the opinion of a non-specialist.

Consequently, PSCs are required to have a medical specialist involved in denials that are not based on the application of clearly articulated policy with clearly articulated rationale. A review or reconsideration involving the use of medical judgment should involve consultation with a medical specialist. Additionally, contractors are encouraged to use specialists whenever possible since providers are more likely to accept the opinion (and any resulting overpayment) of a specialist in their own area.

B. Documenting Reopening and Good Cause

Reopening occurs when a PSC conducts a review of claims at any time after the initial/review determination (see 42 CFR 405.980, (b).) If reopening and conducting a postpayment review occurs within 12 months of the initial/review determination, the PSC does not need to establish good cause. However, the PSC should document the date so there is no confusion about whether good cause should have been established. After 12 months, but within 4 years from the date of the initial/review determination, contractors must establish good cause. (See Medicare Claims Processing Manual Pub 100-04, chapter 34 and 42 CFR 405.986. Documenting the date a claim was reopened (regardless of the demand letter issue date) and the rationale for good cause when claims are reopened more than 12 months from the initial/review determination will lend credibility to contractor documentation if the determination is appealed.

8.2 – Overpayment Procedures
(Rev.)

The PSCs and the ZPICs shall refer all identified overpayments to the AC or MAC who shall send the demand letter and recoup the overpayment.

Contractors should initiate recovery of overpayments whenever it is determined that Medicare has erroneously paid. In any case involving an overpayment, even where there is a strong likelihood of fraud, request recovery of the overpayment. PSC or ZPIC BI units shall notify law enforcement of their intention to collect outstanding overpayments in cases in which they are aware of a pending investigation. There may be situations where OIG/OI or other law enforcement agencies might recommend that overpayments are postponed or not collected; however, this must be made on a case-by-case basis, and only when recovery of the overpayment would undermine the specific law enforcement actions planned or currently taking place. PSCs or ZPICs shall refer such requests to the Primary GTL, Associate GTL, and SME. If delaying recoupment minimizes eventual recovery, delay may not be appropriate. PSCs or ZPICs shall forward any correspondence received from law enforcement requesting the overpayment not be recovered to the Primary GTL, Associate GTL, and SME. The Primary GTL, Associate GTL, and SME will decide whether or not to recover.

If a large number of claims are involved, contractors consider using statistical sampling for overpayment estimation to calculate the amount of the overpayment. (See PIM, chapter 8, §8.4.)

Contractors have the option to request the periodic production of records or supporting documentation for a limited sample of submitted claims from providers or suppliers to which amounts were previously overpaid to ensure that the practice leading to the overpayment is not

continuing. The contractor may take any appropriate remedial action described in this chapter if a provider or supplier continues to have a high level of payment error.

Offer the provider a consent settlement based on the potential projected overpayment amount.

8.2.1 – Overpayment Assessment Procedures
(Rev.)

After an overpayment determination is made concluding an incorrect amount of money has been paid, contractors must assess an overpayment. The assessment options vary depending upon the type of sample used when identifying beneficiary claims for inclusion in the postpay review. Whenever possible, CMS encourages contractors to report postpayment savings in terms of:

- Actual overpayment;
- Settlement based overpayment, or
- Statistically extrapolated overpayments.

A. Example Format of An Overpayment Worksheet (also see Exhibit 46)

Provider Name	
Provider UPIN or PIN:	
Reason for Review	
Type of Sample Reviewed: Statistical Sampling for Overpayment Estimation	
Explanation of Sampling Methodology:	
Number of Claims in Sample:	
Number of Claims in Universe:	
Amount of Overpayment (after allowance for deductible and coinsurance)	
Claims Reviewed	
Billed Amount	
Allowed Amount	

Rationale for Denial	
§1879 Determinations	
§1870 Determinations	
Total Actual Overpayment	
Overpayment extrapolated over the universe	

8.2.1.1 – Definition of Overpayment Assessment Terms
(Rev.)

A. Actual Overpayment

An actual overpayment is, for those claims reviewed, the sum of payments (based on the amount paid to the provider and Medicare approved amounts) made to a provider for services which were determined to be medically unnecessary or incorrectly billed.

B. Projected Overpayment

A projected overpayment is the numeric overpayment obtained by projecting an overpayment from statistical sampling for overpayment estimation to all similar claims in the universe under review.

C. Limited Projected Overpayment

A limited projected overpayment is the numeric overpayment obtained by projecting an overpayment from a limited sample or limited sub-sample to all similar claims in the universe under review.

8.2.2 – Assessing Overpayment When Review Was Based on Statistical Sampling for Overpayment Estimation
(Rev.)

If contractors use statistical sampling for overpayment estimation of claims, they follow instructions in Chapter 3, §3.10 to calculate the valid projected overpayment. They document the sampling methodology when review is based on statistical sampling for overpayment estimation. They notify the provider of the overpayment and refer the case to overpayment staff to make payment arrangements with the provider to collect the overpayment.

8.2.3 – Assessing Overpayment or Potential Overpayment When Review Was Based on Limited Sample or Limited Sub-sample
(Rev.)

If a limited sample or limited sub-sample of claims is chosen for review, there are three overpayment assessment options for contractors:

- Refer to overpayment staff for recoupment of the actual overpayment for the claims reviewed;

- Conduct an expanded review based on statistical sampling for overpayment estimation instructions in Chapter 8, §8.4 and recoup the projected overpayment; or

- Offer the provider a consent settlement based on the potential projected overpayment amount.

8.2.3.1 – Contractor Activities to Support Assessing Overpayment

(Rev.)

A. Step 1

The first step in assessing an overpayment is for contractors to document for each claim reviewed the following:

- The amount of the original claim;

- The allowed amount;

- The rationale for denial;

- The §1879 determination for each assigned claim in the sample denied because the service was not medically reasonable and necessary (or the §1842(1) provider refund determination on non-assigned provider claims denied on the basis of §1862 (a)(1)(A)) (see PIM Chapter 3 §3.6.7 and Exhibit 14.1);

- The §1870 determination for the provider for each overpaid assigned claim in the sample (see PIM Chapter 3 §3.6.7 and Exhibit 14.2); and

- The amount of overpayment (after allowance for deductible and coinsurance).

B. Step 2

Notify the provider of the preliminary overpayment findings and preliminary review findings.

C. Step 3

If the provider submits additional documentation, review the material and adjust the preliminary overpayment findings, accordingly.

D. Step 4

Calculate the final overpayment.

E. Step 5

Refer to the overpayment recoupment staff.

8.2.3.2 – Conduct of Expanded Review Based on Statistical Sampling for Overpayment Estimation and Recoupment of Projected Overpayment by Contractors

(Rev.)

The ACs and MACs shall perform the actual recoupment identified by the PSCs or the ZPICs.

A. If an expanded review of claims is conducted, contractors shall follow the sampling instructions found in PIM chapter 8, §8.4 obtain and review claims and medical records, and document for each claim reviewed:

- The amount of the original claim;
- The allowed amount;
- The rationale for denial;
- The §1879 determination for each assigned claim in the sample denied because the service was not medically reasonable and necessary (or the §1842(1) provider refund determination on non-assigned provider claims denied on the basis of §1862(a)(1)(A)) (see PIM chapter 3, §3.6.7 and exhibit 14.1);
- The §1870 determination for the provider for each overpaid assigned claim in the sample (see PIM chapter 3, §3.6.7 and exhibit 14.2); and
- The amount of overpayment (after allowance for deductible and coinsurance).

B. Contractors calculate the projected overpayment by extrapolating from the actual overpayment to the universe that excludes those claims determined that the provider did not have knowledge that the service was not medically necessary;

C. Notify the provider of the preliminary projected overpayment findings and review findings;

D. If the provider submits additional documentation, review the material and adjust the preliminary projected overpayment findings, accordingly;

E. Calculate the final overpayment; and

F. Refer to the overpayment recoupment staff.

8.2.3.3 - Consent Settlement Instructions

(Rev.)

8.2.3.3.1 - Background on Consent Settlement
(Rev.)

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines consent settlement as an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved. The PSC and ZPIC BI units and the contractor medical review units shall submit via secure email the consent settlement to the Primary and Associate GTLs before offering a consent settlement to the provider or supplier. If the PSC or the ZPIC BI units or the contractor medical review units do not have secure email, the consent settlement shall be sent to the Primary GTL and the Associate GTL via hard copy. Upon receipt, GTLs will forward the consent settlement to the Director of the Division of Benefit Integrity Management Operations. The PSC or the ZPIC BI units and the contractor medical review units may contact the provider upon approval of the consent settlement. Consent settlement documents carefully explain, in a neutral tone, what rights a provider waives by accepting a consent settlement. The documents shall also explain in a neutral tone the consequences of not accepting a consent settlement. A key feature of a consent settlement is a binding statement that the provider agrees to waive any rights to appeal the decision regarding the potential overpayment. The consent settlement agreement shall carefully explain this, to ensure that the provider is knowingly and intentionally agreeing to a waiver of rights. Consent settlement correspondence shall contain:

A complete explanation of the review and the review findings

A thorough discussion of §1879 and §1870 determinations, where applicable

The consequences of deciding to accept or decline the consent settlement offer

It is rare that a PSC or ZPIC BI unit will offer and develop a consent settlement. However, when the PSC or ZPIC offers and develops a consent settlement, the AC or MAC shall administer the settlement.

8.2.3.3.2 - Opportunity to Submit Additional Information Before Consent Settlement Offer
(Rev.)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, section 935(a)(5) states the provider has the opportunity to submit additional information before being offered a consent settlement. Based on a postpayment review of the medical records, the contractor shall communicate in writing to the provider or supplier that:

- The preliminary evaluation of the records indicates there would be an overpayment;
- The nature of the problems in the billing and practice patterns identified in the evaluation;

- The steps that the provider or supplier can take to address the problems; and

- The provider or supplier has forty-five (45) days to furnish additional information concerning the medical records for the claims that have been reviewed.

If after forty-five (45) days, it is determined that there is still an overpayment, then the provider or supplier shall receive a consent settlement offer. If an overpayment is not warranted after additional review, then a follow-up letter shall be sent to the provider or supplier stating that no additional action is deemed necessary.

8.2.3.3.3. - Consent Settlement Offer
(Rev.)

After the additional information concerning the medical records for the claims reviewed have been assessed and if it is still determined that there was an overpayment, the contractor shall offer the provider or supplier the opportunity to proceed with statistical sampling for overpayment estimation or a consent settlement. The PSC or the ZPIC BI units and the contractor medical review units may choose to present the consent settlement letter to the provider or supplier in a face-to-face meeting. The consent settlement correspondence shall describe the two options available to the provider or supplier. The provider or supplier is given 60 days from the date of the correspondence to choose an option. If there is no response, Option 1 shall be selected by default.

8.2.3.3.4 - Option 1 - Election to Proceed to Statistical Sampling for Overpayment Estimation
(Rev.)

If a provider or supplier fails to respond, this option shall be selected by default. For providers or suppliers who select this option knowingly or by default, thereby rejecting the consent settlement offer and retaining their full appeal rights, PSC BI units and the contractor medical review units shall;

- Notify the provider or supplier of the actual overpayment and refer to overpayment recoupment staff; and

- Initiate statistical sampling for overpayment estimation of the provider's or supplier's claims for the service under review following instructions in the Program Integrity Manual, chapter 8, §8.4

If the review results in a decision to recoup the overpayment, the overpayment collection shall be initiated within 12 months of the decision.

8.2.3.3.5 - Option 2 - Acceptance of Consent Settlement Offer
(Rev.)

A provider or supplier accepting Option 2 waives any appeal rights with respect to the alleged overpayment. Providers or suppliers selecting Option 2 that have any additional claims shall not be audited for the service under review within the same time period.

Model language for the consent settlement documents can be found in PIM Exhibit 15.

8.2.3.3.6 - Consent Settlement Budget and Performance Requirements for ACs

(Rev.)

When supporting PSCs or ZPICs in consent settlements, the ACs shall report these costs in the PSC support activity code 23201.

8.2.4 - Coordination With Audit and Reimbursement Staff

(Rev.)

Intermediary MR staff must work closely with their Audit/Reimbursement staff from the beginning of the postpay process to ensure that the universe selected is appropriate and that overpayments and underpayments are accurately determined and reflected on the provider's cost report. They furnish the Audit/Reimbursement staff the following information upon completion of the postpayment review:

- The sample documentation contained in the PIM Chapter 3, §3.6.3;
- The identification of incorrectly paid or incorrectly denied services; and
- All other information required by the Cost Report Worksheets in PIM Chapter 3, §3.6.1 and applicable Exhibits.

They also furnish the above information if adjustments are made as a result of appeals.

In most instances, the Audit/Reimbursement staff will:

- Determine the overpayment to be recovered based on MR findings and pursue the recovery of the overpayment; and
- Use the information MR provides on their postpayment review findings to ensure an accurate settlement of the cost report and/or any adjustments to interim rates that may be necessary as a result of the MR findings. To preserve the integrity of Provider Statistical and Reimbursement Report (PS&R) data relative to paid claims and shared systems data relative to denied claims, and to ensure proper settlement of costs on provider cost reports, the same data must be used when the projection is made as was used when the sample was selected. Individual claims will not be adjusted. In the event that a cost report has been settled, Audit/Reimbursement staff will determine the impact on the settled cost report and the actions to be taken.

Projections on denied services must be made for each discipline and revenue center when PPS is not the payment method.

When notifying the provider of the review results for cost reimbursed services, MR must explain that the stated overpayment amount represents an interim payment adjustment. Indicate that subsequent adjustments may be made at cost report settlement to reflect final settled costs.

Information from the completed Worksheets 1 - 7 must be routed to the Audit and Reimbursement staff. In addition to the actual and projected overpayment amounts, the information must provide the number of denied services (actual denied services plus projected denied services) for each discipline and the amounts of denied charges (actual denied amounts plus projected denied amounts) for supplies and drugs.

Upon completion of the review, furnish the Audit and Reimbursement staff with the information listed in the PIM.

8.3 – Suspension of Payment
(Rev.)

The process by which the PSC or ZPIC notifies and coordinates with the AC or MAC of a CMS-approved suspension of payment shall be documented in the JOA. PSCs and ZPICs shall advise and coordinate with the AC or MAC when payment suspension has been approved by CMS. The PSCs and ZPICs shall perform the necessary medical review for suspensions for which they have recommended and received CMS approval.

Medicare authority to withhold payment in whole or in part for claims otherwise determined to be payable is found in federal regulations at 42 CFR 405.370-377, which provides for the suspension of payments.

8.3.1 – When Suspension of Payment May Be Used
(Rev.)

Suspension may be used when there is reliable information that:

- Fraud or willful misrepresentation exists;
- An overpayment exists but the amount of the overpayment is not yet determined;
- The payments to be made may not be correct; or
- The provider fails to furnish records and other requested information needed to determine the amounts due the provider or supplier.

These four reasons for implementing a suspension of payment are described more fully below.

NOTE: For providers that file cost reports, suspension may have little impact. If the provider is receiving periodic interim payments (PIP), interim payments may be suspended. If the provider is not on PIP, suspension will affect the settlement of the cost report. When an overpayment is determined, the amount is not included in any settlement amount on the cost report. For example, if the intermediary has suspended $100,000, when the cost report is settled, the intermediary would continue to hold the $100,000. This means if the cost report shows CMS owing the provider $150,000, the provider would only receive $50,000 until the suspension action has been completed. If the provider owes CMS money at settlement, the amount of the suspended payment would increase the amount owed by the provider. In most instances, intermediaries should adjust interim payments to reflect projected cost reductions. Limit the adjustment to the percentage of potential fraud or the total payable amount for any other reasons. For example, if the potential fraud involved 5 percent of the interim rate, the reduction in payment is not to exceed 5 percent. Occasionally, suspension of all interim payments may be appropriate.

8.3.1.1 – Fraud or Willful Misrepresentation Exists - Fraud Suspensions
(Rev.)

Suspension of payment may be used when the contractor, MAC, PSC or ZPIC or CMS possesses reliable information that fraud or willful misrepresentation exists. For the purposes of this section, these types of suspensions will be called "fraud suspensions."

Fraud suspensions may also be imposed for reasons not typically viewed within the context of false claims. An intermediary example is that the QIO has reviewed inpatient claims and determined that the diagnosis related groups (DRGs) have been upcoded. As an example, contractors or MACs may find is that suspected violation of the physician self referral ban is cause for suspension since claims submitted in violation of this statutory provision must be denied and any payment made would constitute an overpayment. Forged signatures on Certificates of Medical Necessity (CMN), treatment plans, and other misrepresentations on Medicare claims and claim forms to obtain payment result in overpayments. Credible allegations of such practices are cause for suspension pending further development.

Whether or not the contractor, MAC, PSC or ZPIC recommends suspension action to CMS is a case-by-case decision requiring review and analysis of the allegation and/or facts. The following information is provided to assist the contractor, MAC, PSC or ZPIC in deciding when to recommend suspension action.

A. Complaints

There is considerable latitude with regard to complaints alleging fraud and abuse. The history, or newness of the provider, the volume and frequency of complaints concerning the provider, and the nature of the complaints all contribute to whether suspension of payment should be recommended. If there is a credible allegation(s) that a provider is submitting or may have submitted false claims, the contractor, MAC, PSC or ZPIC shall recommend suspension of payment to the CMS Central Office (CO) Division of Benefit Integrity Management Operations Fraud and Abuse Suspensions and Sanctions (DBIMO FASS) team.

B. Provider Identified in CMS Fraud Alert

Contractors, MACs, PSCs and ZPICs shall recommend suspension to the CO DBIMO FASS team if a provider in their jurisdiction is the subject of a CMS national Fraud Alert and the provider is billing the identical items/services cited in the alert or if payment for other claims must be suspended to protect the interests of the government.

C. Requests from Outside Agencies

Contractors, MACs, PSCs, and ZPICs shall follow the suspension of payment actions for each agency request indicated below.

- CMS -- Initiate suspension as requested.

- OIG/FBI – Contractors, MACs, PSCs, and ZPICs shall forward the written request to the CO DBIMO FASS team for its review and determination. The CO DBIMO FASS team will decide.

- AUSA/DOJ – Contractors, MACs, PSCs, and ZPICs shall forward the written request to the CO DBIMO FASS team for review and determination.

- Other – Other situations the contractor, MAC, PSC or ZPIC may consider recommending suspension of payment to the CO DBIMO FASS team are:

    - Provider has pled guilty to, or been convicted of, Medicare, Medicaid, CHAMPUS, or private health care fraud and is still billing Medicare for services;

    - Federal/State law enforcement has subpoenaed the records of, or executed a search warrant at, a health care provider billing Medicare;

    - Provider has been indicted by a Federal Grand Jury for fraud, theft, embezzlement, breach of fiduciary responsibility, or other misconduct related to a health care program;

        - Provider presents a pattern of evidence of known false documentation or statements sent to the contractor or the MAC; e.g., false treatment plans, false statements on provider application forms.

8.3.1.2 – Overpayment Exists But the Amount is Not Determined - General Suspensions

(Rev.)

Suspension of payment may be used when the contractor, MAC, PSC or ZPIC or CMS possesses reliable information that an overpayment exists but has not yet determined the amount of the overpayment. In this situation, the contractor, MAC, PSC, and ZPIC shall recommend

suspension to the CO DBIMO FASS team. For the purposes of this section, these types of suspensions will be called "general suspensions."

EXAMPLE: Several claims identified on post-pay review were determined to be non-covered or miscoded. The provider has billed this service many times before and it is suspected that there may be a number of additional non-covered or miscoded claims that have been paid.

8.3.1.3 – Payments to be Made May Not be Correct - General Suspensions
(Rev.)

Suspension of payment may be used when the contractor, MAC, PSC or ZPIC or CMS possesses reliable information that the payments to be made may not be correct. In this situation, the contractor, MAC, PSC, and ZPIC shall recommend suspension to the CO DBIMO FASS team. For the purposes of this section, these types of suspensions will be called "general suspensions".

8.3.1.4 –Provider Fails to Furnish Records and Other Requested Information - General Suspensions
(Rev.)

Suspension of payment may be used when the contractor, MAC, PSC or ZPIC or CMS possesses reliable information that the provider has failed to furnish records and other information requested or that is due, and which is needed to determine the amounts due the provider. In this situation, the contractor, MAC, PSC, and ZPIC shall recommend suspension to the CO DBIMO FASS team. For the purposes of this section, these types of suspensions will be called "general suspensions".

EXAMPLE: During a postpayment review, medical records and other supporting documentation are solicited from the provider to support payment. The provider fails to submit the requested records. The contractor determines that the provider is continuing to submit claims for services in question.

8.3.2 – Procedures for Implementing Suspension of Payment
(Rev.)

8.3.2.1 – CMS Approval
(Rev.)

The initiation (including whether or not to give advance notice), modification, or removal of any type of suspension requires the explicit prior approval of the CMS CO DBIMO FASS team. The contractor, MAC, PSC, ZPIC or the CO DBIMO FASS team will coordinate suspension action with law enforcement partners.

The contractor, MAC, PSC or ZPIC shall forward a draft of the proposed notice of suspension and a brief summary of the evidence upon which the recommendation is based to the CO DBIMO FASS team. The contractor, MAC, PSC, and ZPIC shall not take suspension action without the explicit approval of the CO DBIMO FASS team. In most cases, the PSC or ZPIC

will notify OIG and other law enforcement partners of its decision and will keep law enforcement apprised of any future decisions to modify the suspension. However, if a contractor, MAC, PSC or ZPIC, or CMS has been working with law enforcement on the case, immediately notify them of the proposed recommendation being submitted to the CO DBIMO FASS team. Notice may consist of a telephone call or a fax. If law enforcement wants more time to study or discuss the suspension, contractors, MACs, PSCs, and ZPICs shall discuss their request with the CO DBIMO FASS team. If law enforcement requests that suspension action should, or should not, be taken, contractors, PSCs, and ZPICs shall contact the CO DBIMO FASS team. Contractors, MACs, PSCs and ZPICs shall also advise law enforcement that the request must be in writing and must provide a detailed rationale justifying why payment should, or should not, be suspended.

8.3.2.2 – The Notice of Intent to Suspend
(Rev.)

8.3.2.2.1 – Prior Notice Versus Concurrent Notice
(Rev.)

Contractors, MACs, PSCs, and ZPICs shall inform the provider of the suspension action being taken. When prior notice is appropriate, give at least 15 calendar days prior notice. Day one begins the day after the notice is mailed.

A. Medicare Trust Fund would be harmed by giving prior notice: Contractors, MACs, PSCs or ZPICs shall recommend to the CO DBIMO FASS team, not to give prior notice if in the contractor's, MAC's, PSC's or ZPIC's opinion, any of the following apply:

1. Delay in suspension will cause the overpayment to rise at an accelerated rate (i.e., dumping of claims);

2. There is reason to believe that the provider may flee the contractor's or MAC's jurisdiction before the overpayment can be recovered; or

3. The contractor, MAC, PSC or ZPIC has first hand knowledge of a risk that the provider will cease or severely curtail operations or otherwise seriously jeopardize its ability to repay its debts.

If the CO DBIMO FASS team waives the advance notice requirement, contractors, MACs, PSCs and ZPICs shall send the provider notice concurrent with implementation of the suspension, but no later than 15 days, after suspension is imposed.

B. Suspension imposed for failure to furnish requested information: Contractors, MACs, PSCs or ZPICs shall recommend that the CO DBIMO FASS team waive prior notice requirements for failure to furnish information requested by the contractor, MAC, PSC or ZPIC that is needed to determine the amounts due the provider.

If the CO DBIMO FASS team waives the prior notice requirement, contractors, MACs, PSCs and ZPICs shall send the provider notice concurrent with implementation of the suspension, but no later than 15 days after the suspension is imposed.

C. Fraud suspension: With respect to fraud suspensions, contractors, MACs, PSCs and ZPICs shall recommend to the CO DBIMO FASS team that prior notice not be given. The CO DBIMO FASS team will decide whether to waive the notice. The CO DBIMO FASS team will also direct the content of the notice.

If the CO DBIMO FASS team waives the advance notice requirement, the contractor, MAC, PSC or ZPIC shall send the provider notice concurrent with implementation of the suspension, but no later than 15 days, after suspension is imposed.

8.3.2.2.2 – Content of Notice

(Rev.)

Contractors, MACs, PSCs and ZPICs shall prepare a "draft notice" and send it, along with the recommendation and any other supportive information, to the CO DBIMO FASS team for approval. The draft notice shall include, at a minimum:

- That suspension action will be imposed;
- The extent of the suspension (i.e., all claims, certain types of claims, 100 percent suspension or partial suspension);
- That suspension action is not appealable;
- That CMS has approved implementation of the suspension;
- When suspension will begin;
- The items or services affected;
- How long the suspension is expected to be in effect;
- The reason for suspending payment;
- That the provider has the opportunity to submit a rebuttal statement within 15 days of notification; and
- Where to mail the rebuttal.

In the notice, contractors, MACs, PSCs and ZPICs shall also state why the suspension action is being taken.

For fraud suspensions, the contractor, MAC, PSC or ZPIC shall do so in a way that does not disclose information that would undermine a potential fraud case. The rationale must be specific enough to justify the action being taken and allow the provider an opportunity to identify the problem. The CO DBIMO FASS team will direct the content of the notice. The notice does not need to specify that the provider is suspected of fraud or willful misrepresentation. The notice shall include a limited selection of claims received that indicate payment may not have been collected.

8.3.2.2.3 – Shortening the Notice Period for Cause
(Rev.)

At any time, the contractor, MAC, PSC or ZPIC may recommend to the CO DBIMO FASS team that the advance notice be shortened during the notice period. Such a recommendation would be appropriate if the contractor, MAC, PSC or ZPIC believes that the provider is intentionally submitting additional claims in anticipation of the effective date of the suspension. If suspension is imposed earlier than indicated in the notice, the contractor, MAC, PSC or ZPIC shall notify the provider in writing of the change and the reason.

8.3.2.2.4 – Mailing the Notice to the Provider
(Rev.)

After consultation with and approval from the CO DBIMO FASS team, contractors, MACs, PSCs and ZPICs shall send the notice of suspension to the provider. In the case of fraud suspensions, they send a copy to the OIG, FBI, or AUSA if they have been previously involved.

8.3.2.2.5 – Opportunity for Rebuttal
(Rev.)

The suspension notice gives the provider an opportunity to submit to the contractor, MAC, PSC or ZPIC a statement within 15 days indicating why suspension action should not be, or should not have been, imposed. However, this may be shortened or lengthened for cause (see 42 CFR 405.374(b)). A provider's reaction to suspension may include threats of court action to restore payment or to stop the proposed action. The CO DBIMO FASS team will consult with OGC and will advise the contractor, MAC, PSC or ZPIC before the contractor, MAC, PSC or ZPIC responds to any rebuttal statements.

Contractors, MACs, PSCs and ZPICs shall ensure the following:

- CMS Review – Contractors, MACs, PSCs and ZPICs shall immediately forward provider responses and a draft response to the CMS CO DBIMO FASS team.

- Timing – Implementation of suspension actions is not delayed by the receipt and/or review of the rebuttal statement. The suspension goes into effect as indicated in the notice.

- Review of Rebuttal – Because suspension actions are not appealable, the rebuttal is the provider's only opportunity to present information as to why suspension action should be non-initiated or terminated. Contractors, MACs, PSCs and ZPICs shall also carefully review the provider's rebuttal statement and consider all facts and issues raised by the provider. If the contractor, MAC, PSC or ZPIC is convinced that the suspension action should be non-initiated or terminated, they shall consult immediately with the CO DBIMO FASS team.

- Response – Respond to the provider's rebuttal within 15 days from the date the statement is received, following consultation and approval from the CO DBIMO FASS team.

8.3.2.3 – Claims Review During the Suspension Period
(Rev.)

8.3.2.3.1 – Claims Review
(Rev.)

A. Claims Review of Suspended Claims:

Once suspension has been imposed, contractors, MACs, PSCs and ZPICs shall follow normal claims processing and MR procedures. Contractors and MACs shall make every attempt within the MR budget to determine if suspended claims are payable. Contractors, MACs, PSCs and ZPICs shall ensure that the provider is not substituting a new category of improper billing to counteract the effect of the payment suspension. If the claim is determined to be not payable, it shall be denied. For claims that are not denied, the contractor or MAC shall send a remittance advice to the provider showing that payment was approved but not sent. Contractors, MACs, PSCs and ZPICs are not required to perform 100 percent pre-pay medical review of suspended claims. If 100 percent prepayment review is not conducted, a 100 percent postpayment review shall be performed on all claims adjudicated during the suspension, prior to the issuance of the overpayment determination. Contractors, MACs, PSCs and ZPICs shall consult with the CO DBIMO FASS team when resources may be better utilized employing statistical sampling procedures. Contractors, MACs, PSCs and ZPICs shall use the principles of statistical sampling found in the PIM, Chapter 8, §8.4, to determine what percentage of claims in a given universe of suspended claims are payable.

B. Review of Suspected Fraudulent or Overpaid Claims:

Contractors, MACs, PSCs and ZPICs shall follow procedures in the PIM Chapter 3, §3.8 in establishing an overpayment. The overpayment consists of all claims in a specific time period determined to have been paid incorrectly. Contractors, MACs, PSCs and ZPICs shall make all reasonable efforts to expedite the determination of the overpayment amount.

NOTE: Claims selected for postpayment review may be reopened within 1 year for any reason or within 4 years for good cause. Cost report determinations may be reopened within 3 years after the Notice of Program Reimbursement has been issued. Good cause is defined as new and material evidence, error on the face of the record, or clerical error. The regulations have open-

ended potential for fraud or similar fault. The exception to the 1-year rule is for adjustments to DRG claims. A provider has 60 days to request a change in an assignment of a DRG. (See 42 CFR 412.60(d).)

8.3.2.3.2 – Case Development – Benefit Integrity
(Rev.)

Even though suspension action was recommended and/or implemented, PSCs and ZPICs shall discuss the case with the OIG to ascertain their interest in working the case. If OIG declines the case, they shall discuss whether OIG referral to another law enforcement agency is appropriate. If law enforcement is not interested in the case, PSCs and ZPICs shall consider preparing the case for CMP or permissive exclusion. See PIM Chapter 4 §4.22. Whether the case is accepted by law enforcement or not, PSCs and ZPICs shall develop the overpayment as expeditiously as administratively feasible and shall keep law enforcement apprised of the dollars being withheld as well as any potential recoupment action if they are investigating the provider under suspension.

The PSC and the ZPIC shall enter the suspension into the FID, no later than 5 business days after the effective date of suspension. See PIM Chapter 4, §4.11 for FID entry and update requirements. In the Suspension Narrative field, the PSC or ZPIC shall enter the items/services affected (i.e., type of item/service and applicable HCPCS/CPT codes).

8.3.2.4 – Duration of Suspension of Payment
(Rev.)

A. Time Limits

The CO DBIMO FASS team will initially approve suspension for a period up to 180 days. The CO DBIMO FASS team may extend the period of suspension for up to an additional 180 days upon the written request of the contractor, MAC, PSC or ZPIC, OIG, or other law enforcement agency. The request shall provide:

- Name and address of the provider under suspension;
- Amount of additional time needed (not to exceed the 180 days); and
- Rationale explaining why the additional time is necessary.

B. Exceptions to Time Limits

The following exceptions may apply:

- Department of Justice (including U.S. Attorneys). The CO DBIMO FASS team may grant an additional 180-day extension (beyond the first extension referred to in Section 3.9.2.4.A above) if an overpayment has not yet been determined and the Department of Justice submits a written request for an extension. Requests must include: 1) the identity of the person or entity

under suspension, 2) the amount of time needed for continued suspension in order to implement an ongoing or anticipated criminal and/or civil proceeding, and 3) a statement of why and/or how criminal and/or civil actions may be affected if the suspension is not extended. This extension may be granted based on a request received by the CO DBIMO FASS team at any time before or during the period of suspension.

- OIG. The time limits in subsection A above do not apply if the case has been referred to and is being considered by OIG for administrative sanctions (e.g., CMPs). However, this exception does not apply to pending criminal investigations by OIG.

C. Provider Notice of the Extension

The contractor, MAC, PSC or ZPIC shall obtain the CO DBIMO FASS team decision about the extension request, and shall notify the provider if the suspension action has been extended.

8.3.2.5 – Removing the Suspension
(Rev.)

Contractors, MACs, PSCs, and ZPICs shall recommend to the CO DBIMO FASS team that suspension of payments be terminated when the time limit expires. No action associated with termination shall be taken without the approval by the CO DBIMO FASS team.

The contractor, MAC, PSC or ZPIC may recommend to the CO DBIMO FASS team that a suspension be terminated earlier if the basis for the suspension action was that an overpayment may exist, and the contractor, MAC, PSC, or ZPIC has determined the amount of the overpayment, if any.

B. If the basis for the suspension action was that fraud or willful misrepresentation existed, there is satisfactory evidence that the fraud activity has ceased, and the amount of suspended monies exceeds the estimated amount of the suspected overpayment.

C. If the basis for the suspension action was that payments to be made may not be correct, and the contractor, MAC, PSC or ZPIC has determined that payments to be made are correct.

D. If the basis for the suspension action was that the provider failed to furnish records, the provider has submitted all requested records, and the contractor, MAC, PSC or ZPIC believes the provider will comply with future requests for records.

When the suspension expires or is lifted early, the disposition of the suspension shall be achieved within a reasonable time period.

8.3.2.6 – Disposition of the Suspension
(Rev.)

Payments for appropriate Medicare claims that are withheld during a suspension should not exceed the suspected amount of overpayment. Contractors, MACs, PSCs and ZPICs shall

maintain an accurate, up-to-date record of the amount withheld and the claims that comprise the suspended amount. Contractors, MACs, PSCs and ZPICs shall keep a separate accounting of payment on all claims affected by the suspension. They shall keep track of how much money is uncontested and due the provider. The amount needs to be known as it represents assets that may be applied to reduce or eliminate any overpayment. (See PIM, chapter 8, §8.2.) Contractors, MACs, PSCs and ZPICs shall be able to provide, upon request, copies of the claims affected by the suspension. After the suspension has been removed, they shall apply the amount withheld first to the Medicare overpayment and then to reduce any other obligation to CMS or to DHHS. Contractors and MACs shall remit to the provider all monies held in excess of the amount the provider owes. If the provider owes more money than was held in suspension, the contractor or MAC shall initiate recoupment action.

8.3.2.7 – Contractor Suspects Additional Improper Claims
(Rev.)

A. Present Time

If the contractor, MAC, PSC or ZPIC believes that the provider will continue to submit non-covered, misrepresented, or potentially fraudulent claims, it shall consider implementing or recommending other actions as appropriate (e.g., prepayment review, a new suspension of payment.)

B. Past Period of Time

If the contractor, MAC, PSC or ZPIC believes there are past periods of time that may contain possible overpayments, contractors, MACs, PSCs and ZPICs shall consider recommending a new suspension of payment covering those dates.

C. Additional Services

During the time that a provider is under suspension of payment for a particular service(s), if it is determined there is reason to initiate suspension action for a different service, a new suspension of payment shall be initiated or incorporated into the existing payment suspension depending on the circumstances.

Anytime a new suspension action is initiated on a provider who is already under one or more suspension actions, contractors, MACs, PSCs and ZPICs shall obtain separate CMS approval, shall issue an additional notice to the provider, shall offer a new rebuttal period, etc.

Model Suspension of Payment Letters can be found in Exhibit 16.

8.3.3 – Suspension Process for Multi-Region Issues
(Rev.)

8.3.3.1 –DME MACs and DME PSCs, and ZPICs
(Rev.)

The DME MACs, DME PSCs and ZPICs shall initiate suspension action when one of the criteria listed above is identified. (See PIM Chapter 3 §3.9.1, When Suspension of Payment May Be Used.) The following details the process that shall be followed when one DME MAC, DME PSC, or ZPIC suspends payments.

A. The initiating DME MAC shall get approval from the CO DBIMO FASS team.

B. The initiating DME MAC, DME PSC, or ZPIC shall share the suspension of payment information with the other DME MACs and DME PSCs and ZPICs. Reliable information that payments should be suspended in one region is sufficient reason for suspension decisions to apply to the other regions.

C. The CO DBIMO FASS team will approve one suspension letter advising that payments will be held by all DME MACs and DME PSCs and ZPICs. This letter shall advise the supplier to contact the initiating DME MAC, DME PSC or ZPIC should the supplier have any questions.

D. Should the suspension action require an extension of time, the CO DBIMO FASS team will approve the extension letter to the supplier.

8.3.3.2 – Reserved for Future Use
(Rev.)

8.4 - Use of Statistical Sampling for Overpayment Estimation
(Rev.)

8.4.1 – Introduction
(Rev.)

8.4.1.1 – General Purpose
(Rev.)

The purpose of this section is to provide instructions for PSC and ZPIC BI units and contractor MR units on the use of statistical sampling in their reviews to calculate and project (i.e., extrapolate) overpayment amounts to be recovered by recoupment, offset or otherwise. These instructions are provided to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project an overpayment where the results of the review indicate that overpayments have been made. These guidelines are for reviews performed by the PSC or ZPIC BI units or contractor MR units. Reviews that are conducted by the PSC or ZPIC BI units or the contractor MR units to assist law enforcement with the identification, case development and/or investigation of suspected fraud or other unlawful activities may also use sampling methodologies that differ from those prescribed herein.

These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC or the ZPIC BI unit or the contractor MR unit to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of

the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. Failure by the PSC or ZPIC BI units or the contractor MR units to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.

Use of statistical sampling to determine overpayments may be used in conjunction with other corrective actions, such as payment suspensions and prepayment review.

8.4.1.2 - The Purpose of Statistical Sampling
(Rev.)

Statistical sampling is used to calculate and project (i.e., extrapolate) the amount of overpayment(s) made on claims. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), mandates that before using extrapolation to determine overpayment amounts to be recovered by recoupment, offset or otherwise, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error. By law, the determination that a sustained or high level of payment error exists is not subject to administrative or judicial review.

8.4.1.3 - Steps for Conducting Statistical Sampling
(Rev.)

The major steps in conducting statistical sampling are: (1) Selecting the provider or supplier; (2) Selecting the period to be reviewed; (3) Defining the universe, the sampling unit, and the sampling frame; (4) Designing the sampling plan and selecting the sample; (5) Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable, (6) Estimating the overpayment. Where an overpayment has been determined to exist, follow applicable instructions for notification and collection of the overpayment.

8.4.1.4 - Determining When Statistical Sampling May Be Used
(Rev.)

The PSC or ZPIC BI units and the contractor MR units shall use statistical sampling when it has been determined that a sustained or high level of payment error exists, or where documented educational intervention has failed to correct the payment error. A sustained or high level of payment error may be determined to exist through a variety of means, including, but not limited to:

- error rate determinations by MR unit, PSC, ZPIC or other area
- probe samples
- data analysis
- provider/supplier history
- information from law enforcement investigations
- allegations of wrongdoing by current or former employees of a provider or supplier

- audits or evaluations conducted by the OIG

Once a determination has been made that statistical sampling may be used, factors also to be considered for determining when to undertake statistical sampling for overpayment estimation instead of a claim-by-claim review include, but are not limited to: the number of claims in the universe and the dollar values associated with those claims; available resources; and the cost effectiveness of the expected sampling results.

8.4.1.5 - Consultation With a Statistical Expert

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

The sampling methodology used to project overpayments must be reviewed by a statistician, or by a person with equivalent expertise in probability sampling and estimation methods. This is done to ensure that a statistically valid sample is drawn and that statistically valid methods for projecting overpayments are followed. The PSC or ZPIC BI unit and the contractor MR unit shall obtain from the statistical expert a written approval of the methodology for the type of statistical sampling to be performed. If this sampling methodology is applied routinely and repeatedly, the original written approval is adequate for conducting subsequent reviews utilizing the same methodology. The PSC or ZPIC BI unit or the contractor MR unit shall have the statistical expert review the results of the sampling prior to releasing the overpayment demand letter. If questions or issues arise during the on-going review, the PSC or ZPIC BI unit or the contractor MR unit shall also involve the statistical expert.

At a minimum, the statistical expert (either on-staff or consultant) shall possess a master's degree in statistics or have equivalent experience. See section 3.10.10 for a list, not exhaustive, of texts that represent the minimum level of understanding that the statistical expert should have. If the PSC or ZPIC BI unit or the contractor MR unit does not have staff with sufficient statistical experience as outlined here, it shall obtain such expert assistance prior to conducting statistical sampling.

8.4.1.6 - Use of Other Sampling Methodologies

(Rev.)

Once it is has been determined that statistical sampling may be used, nothing in these instructions precludes the Centers for Medicare & Medicaid Services (CMS) or the PSC or the ZPIC BI unit or the contractor MR unit from relying on statistically valid audit sampling methodologies employed by other law enforcement agencies, including but not limited to the OIG, the DOJ, the FBI, and other authoritative sources.

Where it is foreseen that the results of a PSC or ZPIC BI unit's or the contractor MR unit's review may be referred to law enforcement or another agency for litigation and/or other enforcement actions, the PSC or ZPIC BI unit or the contractor MR unit shall discuss specific litigation and/or other requirements as they relate to statistical sampling with it's statistical expert prior to undertaking the review. In addition, the PSC or ZPIC BI unit or the contractor MR unit shall discuss sampling requirements with law enforcement or other authorities before

initiating the review (to ensure that the review will meet their requirements and that such work will be funded accordingly).

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

Regardless of the method of sample selection used, the PSC or ZPIC BI unit or the contractor MR unit shall follow a procedure that results in a probability sample. For a procedure to be classified as probability sampling the following two features must apply:

- It must be possible, in principle, to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Although only one sample will be selected, each distinct sample of the set has a known probability of selection. It is not necessary to actually carry out the enumeration or calculate the probabilities, especially if the number of possible distinct samples is large - possibly billions. It is merely meant that one could, in theory, write down the samples, the sampling units contained therein, and the probabilities if one had unlimited time; and

- Each sampling unit in each distinct possible sample must have a known probability of selection. For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.

For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid." Because of differences in the choice of a design, the level of available resources, and the method of estimation, however, some procedures lead to higher precision (smaller confidence intervals) than other methods. A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment as is discussed below.

8.4.3 - Selection of Period to be Reviewed and Composition of Universe
(Rev.)

8.4.3.1 - Selection of Period for Review
(Rev.)

Following selection of the provider or supplier, determine the time period and the number of days, weeks, months, or years, for which sampling units will be reviewed. The target universe shall be defined according to this period. The period of review is determined by considering several factors, including (but not limited to):

- How long the pattern of sustained or high level of payment error is believed to have existed;
- The volume of claims that are involved;
- The length of time that a national coverage decision or regional or local coverage policy has been in effect (i.e., should the provider or supplier have succeeded in adjusting their billing/utilization practices by now);
- The extent of prepayment review already conducted or currently being conducted;
- The dollar value of the claims that are involved relative to the cost effectiveness of the sample; and/or,
- The applicable time periods for reopening claims (see the Medicare Claims Processing Manual, chapter 34 §10.6

NOTE: When sampling claims that are paid through cost report (as opposed to claims paid under a PPS reimbursement methodology), all claims reviewed must be drawn from within a provider's defined cost reporting year. **If the period under review is greater than one year, select a separate sample for each cost-reporting year.**

8.4.3.2 - Defining the Universe, the Sampling Unit, and the Sampling Frame
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The universe and sampling frame will usually cover all relevant claims or line items for the period under review. The discussion that follows assumes that the sampling unit is the claim, although this is not required. The sampling unit may also be a cluster of claims, as, for example, the patient, a treatment "day", or any other sampling unit appropriate for the issue under review.

8.4.3.2.1 - Composition of the Universe
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

A. Part A Claims: For providers reimbursed through cost report, the universe of claims from which the sample is selected shall consist of fully and partially adjudicated claims obtained from the shared systems. For such claims, use the service date to match findings to the cost report.

For providers reimbursed under PPS, the universe of claims from which the sample is selected will consist of all fully and partially paid claims submitted by the provider for the period under review.

B. Part B Claims: The universe shall consist of all fully and partially paid claims submitted by the supplier for the period selected for review and for the sampling units to be reviewed. For example, if the review is of Physician X for the period January 1, 2002 through March 31, 2002, and laboratory and other diagnostic tests have been selected for review, the universe would include all fully and partially paid claims for laboratory and diagnostic tests billed by that physician for the selected time period. For some reviews, the period of review may best be defined in terms of the date(s) of service because changes in coverage policy may have occurred.

8.4.3.2.2 - The Sampling Unit

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

Sampling units are the elements that are selected according to the design of the survey and the chosen method of statistical sampling. They may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary). For example, possible sampling units may include specific beneficiaries seen by a physician during the time period under review; or, claims for a specific item or service. In certain circumstances, e.g., multi-stage sample designs, other types of clusters of payments may be used. In principle, any type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts.

Unlike procedures for suppliers, overpayment projection and recovery procedures for providers and non-physician practitioners who bill intermediaries, in a non-PPS environment, must be designed so that overpayment amounts can be accurately reflected on the provider's cost report. Therefore, sampling units must coincide with a projection methodology designed specifically for that type of provider to ensure that the results can be placed at the appropriate points on the provider's cost report. The sample may be either claim-based or composed of specific line items. For example, home health cost reports are determined in units of "visits" for disciplines 1 through 6 and "lower of costs or charges" for drugs, supplies, etc. If claims are paid under cost report, the services reviewed and how those units link to the provider's cost report must be known. Follow the instructions contained in section 3.10, but use the projection methodologies provided in PIM, Exhibits 9 through 12, for the appropriate provider type. PIM, Exhibits 9 through 12, are to be used only for claims not paid under PPS.

8.4.3.2.3 - The Sampling Frame

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

The sampling frame is the "listing" of all the possible sampling units from which the sample is selected. The frame may be, for example, a list of all beneficiaries receiving items from a selected supplier, a list of all claims for which fully or partially favorable determinations have been issued, or a list of all the line items for specific items or services for which fully or partially favorable determinations have been issued.

The ideal frame is a list that covers the target universe completely. In some cases the frame must be constructed by combining lists from several sources and duplication of sampling units may

result. Although duplicate listings can be handled in various ways that do not invalidate the sample, it is recommended that duplicates be eliminated before selecting the sample.

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

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

Identify the sample design to be followed. The most common designs used are simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these.

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

Simple random sampling involves using a random selection method to draw a fixed number of sampling units from the frame without replacement, i.e., not allowing the same sampling unit to be selected more than once. The random selection method must ensure that, given the desired sample size, each distinguishable set of sampling units has the same probability of selection as any other set - thus the method is a case of "equal probability sampling." An example of simple random sampling is that of shuffling a deck of playing cards and dealing out a certain number of cards (although for such a design to qualify as probability sampling a randomization method that is more precise than hand shuffling and dealing would be required.)

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

Systematic sampling requires that the frame of sampling units be numbered, in order, starting with the number one (1) and ending with a number equal to the size of the frame. Using a random start, the first sampling unit is selected according to that random number, and the remaining sampling units that comprise the sample are selected using a fixed interval thereafter. For example, if a systematic sample with size one-tenth of the frame size is desired, select a random number between one and ten, say that it is "6", and then select every tenth unit thereafter, i.e., "16, 26, 36, …etc." until the maximum unit number in the frame has been exceeded.

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

Stratified sampling involves classifying the sampling units in the frame into non-overlapping groups, or strata. The stratification scheme should try to ensure that a sampling unit from a particular stratum is more likely to be similar in overpayment amount to others in its stratum than to sampling units in other strata. Although the amount of an overpayment cannot be known prior to review, it may be possible to stratify on an observable variable that is correlated with the overpayment amount of the sampling unit. Given a sample in which the total frame is covered

by non-overlapping strata, if independent probability samples are selected from each of the strata, the design is called stratified sampling. The independent random samples from the strata need not have the same selection rates. A common situation is one in which the overpayment amount in a frame of claims is thought to be significantly correlated with the amount of the original payment to the provider or supplier. The frame may then be stratified into a number of distinct groups by the level of the original payment and separate simple random samples are drawn from each stratum. Separate estimates of overpayment are made for each stratum and the results combined to yield an overall projected overpayment.

The main object of stratification is to define the strata in a way that will reduce the margin of error in the estimate below that which would be attained by other sampling methods, as well as to obtain an unbiased estimate or an estimate with an acceptable bias. The standard literature, including that referenced in Section 3.10.10, contains a number of different plans; the suitability of a particular method of stratification depends on the particular problem being reviewed, and the resources allotted to reviewing the problem. Additional discussion of stratified sampling is provided in Section 8.4.11.1.

8.4.4.1.4 - Cluster Sampling

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

Cluster sampling involves drawing a random sample of clusters and reviewing either all units or a sample of units selected from each of the sampled clusters. Unlike strata, clusters are groups of units that do not necessarily have strong similarities, but for which their selection and review as clusters is more efficient economically than, for example, simple random sampling. For example, if the sampling unit is a beneficiary and the plan is to review each of the set of payments for each selected beneficiary, then the design is an example of cluster sampling with each beneficiary constituting a cluster of payments. The main point to remember (when sampling all the units in the cluster) is that the sample size for purposes of estimating the sampling error of the estimate is the number of clusters, not the total number of individual payments that are reviewed.

A challenge to the validity of a cluster sample that is sometimes made is that the number of sampling units in a cluster is too small. (A similar challenge to stratified sampling is also raised – i.e., that the number of sampling units in a stratum is too small). Such a challenge is usually misguided since the estimate of the total overpayment is a combination of the individual cluster (or, in the case of stratified sampling, stratum) estimates; therefore the overall sample size is important, but the individual cluster (or stratum) sample sizes are usually not critical. Additional discussion of cluster sampling is provided in Section 8.4.11.2.

Both stratification and cluster sampling involve the grouping of more elementary units. The former is frequently recommended when there is sufficient prior knowledge to group units that are similar in some aspect and potentially different from other units. The latter is frequently recommended when there are natural groupings that make a study more cost effective. When carried out according to the rules of probability sampling both of the methods, or a combination, are valid. The use of any of the methods described in this section will produce valid results when done properly.

8.4.4.1.5 - Design Combinations
(Rev.)

A sample design may combine two or more of the methods discussed above. For example, clusters may be stratified before selection; systematic selection rather than simple random sampling may be used for selecting units within strata; or clusters may be subsampled using either simple random sampling or systematic sampling, to cite some of the possible combinations of techniques.

The benefits of stratification by claim amount may be achieved without actually stratifying if the frame is arranged in ascending order by the original payment amount and systematic sampling applied with a random start. That is because the systematic selection "balances out" the sample over the different levels of original payment in a manner similar to the effect of formal stratification. Thus systematic selection is often used in the hope that it will result in increased precision through "implicit stratification."

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

The PSC or ZPIC BI unit or the contractor MR unit shall identify the source of the random numbers used to select the individual sampling units. The PSC or ZPIC BI unit or the contractor MR unit shall also document the program and its algorithm or table that is used; this documentation becomes part of the record of the sampling and must be available for review. The PSC or ZPIC BI unit or the contractor MR unit shall document any starting point if using a random number table or drawing a systematic sample. In addition, the PSC or ZPIC BI units or the contractor MR units shall document the known seed value if a computer algorithm is used. The PSC or ZPIC BI units or the contractor MR units shall document all steps taken in the random selection process exactly as done to ensure that the necessary information is available for anyone attempting to replicate the sample selection.

There are a number of well-known, reputable software statistical packages (SPSS, SAS, etc.) and tables that may be used for generating a sample. One such package is RAT-STATS, available (at time of release of these instructions) through the Department of Health and Human Services, Office of Inspector General Web Site. It is emphasized that the different packages offer a variety of programs for sample generation and do not all contain the same program features or the same ease in operation. For any particular problem, the PSC or ZPIC BI unit's or the contractor MR unit's statistician or systems programmer shall determine which package is best suited to the problem being reviewed.

8.4.4.3 - Determining Sample Size
(Rev.)

The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target

population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.

In addition to the above considerations, real-world economic constraints shall be taken into account. As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC or ZPIC BI unit or the contractor MR unit shall also consider their available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design.

8.4.4.4 - Documentation of Sampling Methodology

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

The PSC or ZPIC BI unit or the contractor MR unit shall maintain complete documentation of the sampling methodology that was followed.

8.4.4.4.1 - Documentation of Universe and Frame

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

An explicit statement of how the universe is defined and elements included shall be made and maintained in writing. Further, the form of the frame and specific details as to the period covered, definition of the sampling unit(s), identifiers for the sampling units (e.g., claim numbers, carrier control numbers), and dates of service and source shall be specified and recorded in your record of how the sampling was done. A record shall be kept of the random numbers actually used in the sample and how they were selected. Sufficient documentation shall be kept so that the sampling frame can be re-created, should the methodology be challenged. The PSC or ZPIC BI units or the contractor MR units shall keep a copy of the frame.

8.4.4.4.2 - Arrangement and Control Totals

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

It is often convenient in frame preparation to array the universe elements by payment amount, e.g., low to high values, especially when stratification is used. At the same time, tabulate control totals for the numbers of elements and payment amounts.

8.4.4.4.3 - Worksheets

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

The PSC or ZPIC BI units or the contractor MR units shall maintain documentation of the review and sampling process. All worksheets used by reviewers shall contain sufficient information that allows for identification of the claim or item reviewed. Such information may include, for example:

- Name and identification number of the provider or supplier;
- Name and title of reviewer;
- The Health Insurance Claim Number (HICN), the unique claim identifier (e.g., the claim control number), and the line item identifier;
- Identification of each sampling unit and its components (e.g., UB-92 or attached medical information)
- Stratum and cluster identifiers, if applicable;
- The amount of the original submitted charges (in column format);
- Any other information required by the cost report worksheets in PIM Exhibits 9 through 12;
- The amount paid;
- The amount that should have been paid (either over or underpaid amount); and,
- The date(s) of service.

8.4.4.4.4 - Overpayment/Underpayment Worksheets

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

Worksheets shall be used in calculating the net overpayment. The worksheet shall include data on the claim number, line item, amount paid, audited value, amount overpaid, reason for disallowance, etc., so that each step in the overpayment calculation is clearly shown. Underpayments identified during reviews shall be similarly documented.

8.4.4.5 - Informational Copies to Primary GTL, Associate GTL, SME or CMS RO

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

The PSC or ZPIC BI units or the contractor MR units shall send informational copies of the statistician-approved sampling methodology to their Primary GTL, Associate GTL, SME or CMS RO. The Primary GTL, Associate GTL, SME or CMS RO will keep the methodology on file and will forward to CO upon request. If this sampling methodology is applied routinely and

repeatedly, the PSC or ZPIC BI units or the contractor MR units shall not repeatedly send the methodology to the Primary GTL, Associate GTL, SME or CMS RO.

8.4.5 - Calculating the Estimated Overpayment

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

8.4.5.1 - The Point Estimate

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

In simple random or systematic sampling the total overpayment in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame. In this estimation procedure, which is unbiased, the amount of overpayment dollars in the sample is expanded to yield an overpayment figure for the universe. The method is equivalent to dividing the total sample overpayment by the selection rate. The resulting estimated total is called the point estimate of the overpayment, i.e., the difference between what was paid and what should have been paid. In stratified sampling, an estimate is found for each stratum separately, and the weighted stratum estimates are added together to produce an overall point estimate.

In most situations the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier. The details of the calculation of this lower limit involve subtracting some multiple of the estimated standard error from the point estimate, thus yielding a lower figure. This procedure, which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment, and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate. However, the PSC or ZPIC BI unit or the contractor MR unit is not precluded from demanding the point estimate where high precision has been achieved.

Other methods of obtaining the point estimate are discussed in the standard textbooks on sampling theory. Alternatives to the simple expansion method that make use of auxiliary variables include ratio and regression estimation. Under the appropriate conditions, ratio or regression methods can result in smaller margins of error than the simple expansion method. For example, if, as discussed earlier, it is believed that the overpayment for a sample unit is strongly correlated with the original paid amount, the ratio estimator may be efficient. The ratio estimator is the ratio of the sample net overpayment to the sample total original payment multiplied by the total of original paid dollars in the frame. If the actual correlation between the overpayment and the original paid amount is high enough, greater precision in estimation will be attained, i.e., the lower limit of the one-sided 90 percent confidence interval will be closer to the point estimate. Exercise caution about using alternatives such as ratio or regression estimation because serious biases can be introduced if sample sizes are very small. (The term bias is used here in a technical sense and does not imply a finding that treats the provider or supplier unfairly. A biased estimator is often used rather than an unbiased estimator because the advantage of its greater precision outweighs the tendency of the point estimate to be a bit high or low.)

8.4.5.2 - Calculation of the Estimated Overpayment Amount
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The results of the sampling unit reviews are used to project an estimate of the overpayment amount. Each result shall be recorded except that a sampling unit's overpayment shall be set to zero if there is a limitation on liability determination made to waive provider or supplier liability for that sampling unit (per provisions found in §1879 of the Social Security Act (the Act)) and/or there is a determination that the provider or supplier is without fault as to that sampling unit overpayment (per provisions found in §1870 of the Act). Sampling units for which the requested records were not provided are to be treated as improper payments (i.e., as overpayments). Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall also be used in calculating the estimated overpayment.

8.4.6 - Actions to be Performed Following Selection of Provider or Supplier and Sample
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

NOTE: The instructions in this section dealing with notification and determination of location of the review do not supersede instructions for PSC or ZPIC BI units or the contractor MR units that are using statistical sampling for overpayment estimation as part of an investigation, either planned or on-going, into potential Medicare fraud.

8.4.6.1 – Notification of Provider or Supplier of the Review and Selection of the Review Site
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The PSC or ZPIC BI unit or the contractor MR unit shall first determine whether it will be giving advance notification to the provider or supplier of the review. Although in most cases the PSC or ZPIC BI unit or the contractor MR unit shall give prior notification, the provider or supplier is not always notified before the start of the review. When not giving advance notice, the PSC or ZPIC BI unit or PSC MR unit shall obtain the advance approval of the Primary GTL; and the contractor MR unit shall obtain the advance approval of the CMS RO. When giving advance notice, provide written notification by certified mail with return receipt requested (retain all receipts).

Second, regardless of whether you give advance notice or not, you shall determine where to conduct the review of the medical and other records: either at the provider or supplier's site(s) or at your office (PSC or ZPIC BI units or contractor MR units).

8.4.6.1.1 - Written Notification of Review
(Rev.)

You shall include at least the following in the notification of review:

- an explanation of why the review is being conducted (i.e., why the provider or supplier was selected),

- the time period under review,

- a list of claims that require medical records or other supporting documentation,

- a statement of where the review will take place (provider/supplier office or contractor site),

- information on appeal rights,

- an explanation of how results will be projected to the universe if claims are denied upon review and an overpayment is determined to exist, and

- an explanation of the possible methods of monetary recovery if an overpayment is determined to exist.

When advance notification is given, providers and suppliers have 30 calendar days to submit (for PSC or ZPIC BI unit or contractor MR unit site reviews) or make available (for provider/supplier site reviews) the requested documentation. Advise the provider or supplier that for requested documentation that is not submitted or made available by the end of 30 calendar days, you will start the review and you will deny those claims for which there is no documentation. The time limit for submission or production of requested documentation may be extended at your discretion.

NOTE: You do not have to request all documentation at the time of notification of review. For example, you may decide to request one-half of the documentation before you arrive, and then request the other half following your arrival at the provider/supplier's site.

When advance notification is **not** given, you shall give the provider or supplier the written notification of review when you arrive at their site.

8.4.6.1.2 - Determining Review Site

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

A. Provider/Supplier Site Reviews

Provider/supplier site reviews are performed at the provider's or supplier's location(s). Considerations in determining whether to conduct the review at the office of the provider or supplier include, but are not limited to, the following:

- the extent of aberrant billing or utilization patterns that have been identified;

- the presence of multiple program integrity issues;

- evidence or likelihood of fraud or abuse; and/or,

- past failure(s) of the provider or supplier to submit requested medical records in a timely manner or as requested.

B. PSC or ZPIC BI Unit or Contractor MR Unit Site Reviews

The PSC or ZPIC BI unit or the contractor MR unit site reviews are performed at a location of the PSC or ZPIC BI unit or the contractor MR unit.

8.4.6.2 - Meetings to Start and End the Review
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

In-person meetings to start and end the review are encouraged, but are not required or always feasible. If you hold an in-person meeting at the start of the review, explain both the scope and purpose of the review as well as discuss what will happen once you have completed the review. Attempt to answer all questions of the provider or supplier related to the review.

During an exit meeting, you may discuss the basic or preliminary findings of the review. Give the provider or supplier an opportunity to discuss or comment on the claims decisions that were made. Advise the provider or supplier that a demand letter detailing the results of the review and the statistical sampling will be sent if an overpayment is determined to exist.

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

Following your receipt of the requested documentation (or the end of the period to submit or make available the requested documentation, whichever comes first), start your review of the claims. You may ask for additional documentation as necessary for an objective and thorough evaluation of the payments that have been made, but you do not have to hold up conducting the review if the documents are not provided within a reasonable time frame. Use physician consultants and other health professionals in the various specialties as necessary to review or approve decisions involving medical judgment. The review decision is made on the basis of the Medicare law, HCFA/CMS rulings, regulations, national coverage determinations, Medicare instructions, and regional/local contractor medical review policies that were in effect at the time the item(s) or service(s) was provided.

Document all findings made so that it is apparent from your written documentation if the initial determination has been reversed. Document the amount of all overpayments and underpayments and how they were determined.

You are encouraged to complete your review and calculate the net overpayment within 90 calendar days of the start of the review (i.e., within 90 calendar days after you have either received the requested documentation or the time to submit or make available the records has passed, whichever comes first). However, there may be extenuating circumstances or circumstances out of your control where you may not be able to complete the review within this

time period (e.g., you have made a fraud referral to the OIG and are awaiting their response before pursuing an overpayment).

Your documentation of overpayment and underpayment determinations shall be clear and concise. Include copies of the local medical review policy and any applicable references needed to support individual case determinations. Compliance with these requirements facilitates adherence to the provider and supplier notification requirements.

8.4.7 - Overpayment Recovery

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

8.4.7.1 - Recovery From Provider or Supplier

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

Once an overpayment has been determined to exist, proceed with recovery based on applicable instructions. (See Publication 100-6, Financial Management Manual, chapter 3.) Include in the overpayment demand letter information about the review and statistical sampling methodology that was followed. For PSCs and ZPICs, only ACs or MACs shall issue demand letters and recoup the overpayment.

The explanation of the sampling methodology that was followed shall include:

- a description of the universe, the frame, and the sample design;
- a definition of the sampling unit,
- the sample selection procedure followed, and the numbers and definitions of the strata and size of the sample, including allocations, if stratified;
- the time period under review;
- the sample results, including the overpayment estimation methodology and the calculated sampling error as estimated from the sample results; and
- the amount of the actual overpayment/underpayment from each of the claims reviewed.

Also include a list of any problems/issued identified during the review, and any recommended corrective actions.

8.4.7.2 - Informational Copy to Primary GTL, Associate GTL, SME or CMS RO

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

Send an informational copy of the demand letter to the Primary GTL, Associate GTL, SME or CMS RO. They will maintain copies of demand letters and will forward to CO upon request. If

the demand letter is used routinely and repeatedly, you shall not repeatedly send it to the Primary GTL, Associate GTL, SME or CMS RO.

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

Take or recommend other corrective actions you deem necessary (such as payment suspension, imposition of civil money penalties, institution of pre- or post-payment review, additional edits, etc.) based upon your findings during or after the review.

8.4.9 - Changes Resulting From Appeals
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

If the decision issued on appeal contains either a finding that the sampling methodology was not valid, and/or reverses the revised initial claim determination, you shall take appropriate action to adjust the extrapolation of overpayment.

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

If the decision issued on appeal contains a finding that the sampling methodology was not valid, there are several options for revising the estimated overpayment based upon the appellate decision:

A. If the decision issued on appeal permits correction of errors in the sampling methodology, you shall revise the overpayment determination after making the corrections. Consult with your Primary GTL, Associate GTL, SME or CMS RO to confirm that this course of action is consistent with the decision of the hearing officer (HO), administrative law judge (ALJ) or Departmental Appeals Board (DAB), or with the court order.

B. You may elect to recover the actual overpayments related to the sampled claims and then initiate a new review of the provider or supplier. If the actual overpayments related to the sampling units in the original review have been recovered, then these individual sampling units shall be eliminated from the sampling frame used for any new review. Consult with your Primary GTL, Associate GTL, SME or CMS RO to confirm that this course of action is consistent with the decision of the HO, ALJ or DAB, or with the court order.

C. You may conduct a new review (using a new, valid methodology) for the same time period as was covered by the previous review. If this option is chosen, you shall not recover the actual overpayments on any of the sample claims found to be in error in the original sample. Before employing this option, consult with your Primary GTL, Associate GTL, SME or CMS RO to verify that this course of action is consistent with the decision of the HO, ALJ or DAB, or with the court order.

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

If the decision on appeal upholds the sampling methodology but reverses one or more of the revised initial claim determinations, the estimate of overpayment shall be recomputed and a revised projection of overpayment issued.

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

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8.4.11 - Additional Discussion of Stratified Sampling and Cluster Sampling
(Rev.377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

Generally, one defines strata to make them as internally homogeneous as possible with respect to overpayment amounts, which is equivalent to making the mean overpayments for different strata as different as possible. Typically, a proportionately stratified design with a given total sample size will yield an estimate that is more precise than a simple random sample of the same size without stratifying. The one highly unusual exception is one where the variability from stratum

mean to stratum mean is small relative to the average variability within each stratum. In this case, the precision would likely be reduced, but the result would be valid. It is extremely unlikely, however, that such a situation would ever occur in practice. Stratifying on a variable that is a reasonable surrogate for an overpayment can do no harm, and may greatly improve the precision of the estimated overpayment over simple random sampling. While it is a good idea to stratify whenever there is a reasonable basis for grouping the sampling units, failure to stratify does not invalidate the sample, nor does it bias the results.

If it is believed that the amount of overpayment is correlated with the amount of the original payment and the universe distribution of paid amounts is skewed to the right, i.e., with a set of extremely high values, it may be advantageous to define a "certainty stratum", selecting all of the sampling units starting with the largest value and working backward to the left of the distribution. When a stratum is sampled with certainty, i.e., auditing all of the sample units contained therein, the contribution of that stratum to the overall sampling error is zero. In that manner, extremely large overpayments in the sample are prevented from causing poor precision in estimation. In practice, the decision of whether or not to sample the right tail with certainty depends on fairly accurate prior knowledge of the distribution of overpayments, and also on the ability to totally audit one stratum while having sufficient resources left over to sample from each of the remaining strata.

Stratification works best if one has sufficient information on particular subgroups in the population to form reasonable strata. In addition to improving precision there are a number of reasons to stratify, e.g., ensuring that particular types of claims, line items or coding types are sampled, gaining information about overpayments for a particular type of service as well as an overall estimate, and assuring that certain rarely occurring types of services are represented. Not all stratifications will improve precision, but such stratifications may be advantageous and are valid.

Given the definition of a set of strata, the designer of the sample must decide how to allocate a sample of a certain total size to the individual strata. In other words, how much of the sample should be selected from Stratum 1, how much from Stratum 2, etc.? As shown in the standard textbooks, there is a method of "optimal allocation," i.e., one designed to maximize the precision of the estimated potential overpayment, assuming that one has a good idea of the values of the variances within each of the strata. Absent that kind of prior knowledge, however, a safe approach is to allocate proportionately. That is, the total sample is divided up into individual stratum samples so that, as nearly as possible, the stratum sample sizes are in a fixed proportion to the sizes of the individual stratum frames. It is emphasized, however, that even if the allocation is not optimal, using stratification with simple random sampling within each stratum does not introduce bias, and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample.

8.4.11.2 - Cluster Sampling

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

Selecting payments in clusters rather than individually usually leads to a reduction in the precision of estimation. However, your reasons for using cluster sampling instead of simple

random sampling may be driven by necessity and/or cost-savings related to the location of records or the nature of a record. For example, for medical review to determine the appropriateness of certain charges for a beneficiary it may be necessary to examine the complete medical record of the patient. This then may allow for review of claims for several services falling within the selected review period. In another instance, the medical records that you must review may be physically located in a cluster (e.g., the same warehouse, the same file drawer, the same folder) with the medical records for other similar claims and it is cost effective to select units from the same location. Whenever the cost in time and other resources of selecting and auditing clusters is the same as the cost of simple random sampling the same number of payments, it is better to use simple random sampling because greater precision will be attained.

When reviewing all the units in each cluster, the sample size is the number of clusters, not the number of units reviewed. This is single-stage cluster sampling, a method frequently used when sampling beneficiaries. One may choose to review a sample of units within each cluster rather than all units. Textbooks that cover the topic of multi-stage sampling provide formulas for estimating the precision of such sample designs. One example for which multi-stage sampling might be an appropriate choice of design is the case of reviewing a supplier chain where records are spread out among many locations. The first-stage selection would be a sample of locations. At the second stage a subsample of records would be selected from each sampled location.