Medicare Program Integrity Manual

Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

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(Rev. 282, 01-08-09)

3.1 – Introduction

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

Contractors must analyze provider compliance with Medicare coverage and coding rules and take appropriate corrective action when providers are found to be non-compliant. MR staff should not expend resources analyzing provider compliance with other Medicare rules (such as claims processing rules, conditions of participation, etc.). If during a review it is determined that a provider does not comply with conditions of participation, do not deny payment solely for this reason. Refer to the applicable state survey agency. The overall goal of taking administrative action should be to correct the behavior in need of change, to collect overpayments once identified, and deny payment when payment should not be made. For repeated infractions, or infractions showing potential fraud or pattern of abuse, more severe administrative action should be initiated. In every instance, the contractor's priority is to minimize the potential or actual loss to the Medicare Trust Funds while using resources efficiently and treating providers and beneficiaries fairly.

Contractor medical review (MR) staff shall coordinate and communicate with their associated PSCs' BI units to ensure coordination of efforts and to prevent inappropriate duplication of review activities.

A variety of interventions may be necessary in order to correct inappropriate behaviors. Contractors should use feedback and/or education as part of their intervention. Contractors should make sure that administrative actions are commensurate with the seriousness of the problem identified, after a limited probe is done to understand the nature and extent of the problem. Serious problems should be dealt with using the most substantial administrative actions available, such as 100 percent prepayment review, payment suspension, and use of statistical sampling for overpayment estimation of claims. Small and isolated problems should be dealt with through provider notification or feedback and reevaluation after notification. When MR notification and feedback letters are issued, the contractor shall ensure that POE staff have ready access to copies of the letters so that POE staff will have this information available should a provider contact POE requesting education. At any time, evidence of fraud should result in referral to the PSC BI unit for development.

3.1.1 – Provider Tracking System (PTS)

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

Medicare contractors must have in place a PTS. The PTS will identify all individual providers and track all contacts made as a result of actions to correct identified problems such as eligibility and medical necessity issues and repeated billing abusers who frequently change the way they code their bills to their financial advantage. Contractors should use the PTS to coordinate contacts with providers (e.g., MR notifications, telephone calls directly related to probe or complex reviews, *and referrals to POE).* contractors should ensure that if a provider is to be contacted as a result of more than one problem, multiple contacts are necessary, timely and appropriate, not redundant.

Contractors should also coordinate this information with the PSC BI unit to assure contacts are not in conflict with benefit integrity related activities. The PTS should contain the date a provider is put on a provider specific edit. The contractor should reassess all providers on MR quarterly to determine whether the behavior has changed. The contractor must note the results of the quarterly assessment in the PTS. If the behavior has resolved sufficiently and the edit was turned off, note the date the edit was turned off in the PTS. When a provider appeals a medical review determination to an Administrative Law Judge (ALJ), the information in the PTS should be shared with the ALJ to demonstrate corrective actions have been taken by the contractor.

3.1.2 – Evaluating Effectiveness of Corrective Actions

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

Contractors who perform MR must evaluate the effectiveness of their corrective actions on targeted problem areas at least every 3 months until there is evidence that the problem is corrected. Contractors shall establish a method to determine the disposition of educational referrals made to POE to ensure coordination of efforts and resolution of identified problems. Contractors may utilize the PTS to perform this function, but are not mandated to do so. Contractors must use the PTS to coordinate contacts with providers regarding MR activities. Contractors must ensure that, if a provider is to be contacted as a result of more than one problem, multiple contacts by MR are necessary, timely and appropriate, not redundant. Contractors must also coordinate this information with their benefit integrity unit to assure contacts are not in conflict with fraud related activities.

3.2 – Verifying Potential Error and Setting Priorities

(Rev. 220, Issued: 08-24-07, Effective: 09-03-07, Implementation: 09-03-07)

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. Using claims data, contractors shall determine the degree to which a potential error is widespread and decide if the potential error meets the deviation indicators established. When services and/or providers appear outside of norms, the contractor must verify that the potential error represents an unacceptable practice. Further investigate the provider(s) identified as causing the potential error.

Some examples of possible legitimate explanations for potential error are listed below. This is not an all-inclusive list.

- The provider may be associated with a medical school, research center, or may be a highly specialized facility; and

- The community may have special characteristics such as economic level or a concentration of a specific age group that leads to the aberrancy;

A. Error Validation (Probe) Review

If no legitimate explanation exists for the potential error, the contractor should verify the cause of a potential error. The contractor shall not suspend large volumes of claims for review or use 100% prepayment review. Instead, the contractor shall select a sample of cases which is representative of the universe where the problem is occurring. The contractor shall request appropriate medical documentation and review cases for coverage and correct coding. MR staff should not be reviewing claims for compliance with other Medicare rules (i.e., claims processing, conditions of participation, etc.). Error validation reviews may be conducted on a prepayment or postpayment basis.

Where errors are verified, the contractor shall initiate appropriate corrective actions found in PIM, chapter 3, §§5, 6, and 8 through 13.

Where no corrective action is taken, the contractor must document findings and explanations for not pursuing the problem. If no problems are found, the contractor shall discontinue the review. Do not wait until the end of the quarterly reporting period to end the review process.

In all situations where errors have been verified, the MR unit must notify the provider (written or verbal) that the particular practice or behavior is inappropriate and should not continue.

Error validation (probe) reviews require the examination of the provider's medical documentation but do not require use of statistical sampling for overpayment estimation methodologies. It does not allow projection of overpayments to the universe of claims reviewed. In this type of review, contractors collect overpayments only on claims that are actually reviewed, determined to be non-covered or incorrectly coded, and the provider is liable or at fault for the overpayment.

It may be used to determine:

- The extent of a problem across multiple providers, or
- Whether an individual provider has a problem.

Contractors shall select providers for error validation (probe) reviews in, at a minimum, the following instances:

- The contractor has identified questionable billing practices, (i.e., noncovered or incorrectly coded services) through data analysis.
- Alerts from other intermediaries, carriers, QIOs, intermediary payment staff, or other internal components are received that warrant such review;

- Complaints.

Contractors must document their reasons for selecting the provider for the error validation (probe) review. In all cases, they must clearly document the issues cited and the applicable law or their Published national coverage policies or local coverage determinations, if applicable.

B. Setting Priorities

Contractors shall focus administrative resources to achieve the greatest dollars returned to the Medicare program for resources used. This requires establishing a priority setting process to assure MR focuses on areas with the greatest potential for fraud and abuse. Fraud and abuse may be demonstrated by high dollar payments, high volume of services, dramatic changes, or significant risk for negative impact on beneficiaries (e.g., low volume but unnecessary surgery).

Efforts to stem errors shall be targeted to those areas which pose the greatest financial risk to the Medicare program and which represent the best investment of resources. Contractors should focus where the services billed have significant potential to be noncovered, incorrectly coded, or misrepresented. Target areas may be selected because of:

- High volume;
- High cost;
- Dramatic change;
- Adverse impact on beneficiaries; and/or
- Problems which, if not addressed, may escalate.

Contractors have the authority to review any claim at any time, however, the claims volume of the Medicare program prohibits review of every claim. Resources dictate that in attempting to make only correct payments, contractors make deliberate decisions on the best uses of limited resources to maximize returns. For example, contractors may decide not to review claims for certain services or providers for extended periods of time. Medical review staff may decide to focus review on problem areas that demonstrate significant risk to the Medicare program as a result of inappropriate or potentially inappropriate payments. Contractors shall have in place a program of innovative, systematic, and ongoing analysis of claims and other relevant data to focus intervention efforts on the most significant errors.

3.2.1 – Determining Whether the Problem is Widespread or Provider Specific

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

For each verified priority problem, the contractor must determine whether the problem is widespread or provider specific. If the error is a widespread problem and evenly distributed among providers, contractors should validate the concern by following the instructions detailed in section 3.11.1.2 of this section. Take service-specific corrective actions:

- Ensure POE has access to findings which may warrant widespread education,
- Develop new/revised LCDs if needed, and
- Initiate service-specific prepay edits where appropriate.

If the error is limited to a small number of providers, contractors should validate the concern by following the instructions detailed in section 3.11.1.2 of this section.

3.2.2 - Administrative Relief from Medical Review in the Presence of a Disaster

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

When a disaster occurs, whether natural or man-made, contractors should anticipate both an increased demand for emergency and other health care services, and a corresponding disruption to normal health care service delivery systems and networks. In disaster situations, contractors should do whatever they can to assure that all Medicare beneficiaries have access to the emergency or urgent care they need. Contractors should let providers know (via website, 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. Contractors should assure providers that they will work with providers to ensure that they receive payment for all covered services. The administrative flexibility available to contractors is discussed below. These actions will prevent most inappropriate denials and subsequent appeals.

A. Definition of Disaster

"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:

1. Partially or completely destroy medical records and associated documentation that may be requested by the contractor in the course of a Medicare medical review audit,

2. Interrupt normal mail service (including US Postal delivery, overnight parcel delivery services etc.), or

3. 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 an area designated as a disaster by the Federal Emergency Management Act

(FEMA) 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.

B. Basis for Providing Administrative Relief

In the event of a disaster, contractors may 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 these providers on a case-by-case basis in accord with the following guidelines:

- Contractors must make every effort to be responsive to providers who are victims of the disaster and whose medical record documentation may be partially or completely destroyed.

- Providers must maintain and, upon contractor request, submit verification 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 obtain duplicates of lost records, or reconstruct partially destroyed records.

Verification of the disaster and the resultant damage may 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. Contractors should not routinely request providers to submit verification of damage or loss of medical record documentation.

C. Types of Relief

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

When a provider who has been selected for complex pre or postpay review is directly affected by a disaster, the contractor should consider shifting the time period of the claims being reviewed to a later time period (e.g., 6 months later). Additional Documentation Requests (ADRs) should be stopped for providers who have been directly affected for at least 60 days. These claims should not be denied as noncovered and may be tagged for later postpay review. Contractors should consult with their regional office prior to shifting the time period of review or suspend ADRs for certain providers.

Contractors should allow up to an additional 6 months beyond the original due date for the submission of requested records. Requests for extensions beyond this date may be granted with good cause at the discretion of the contractor.

In the case of complete destruction of medical records where backup records exist, contractors must accept reproduced medical record copies from microfiched,

microfilmed, or optical disk systems that may be available in larger facilities, in lieu of the original document. In the case of complete destruction of medical records where no backup records exist, contractors must accept an attestation that no medical records exist and consider the services covered and correctly coded. In the case of partial destruction, contractors should instruct providers to reconstruct the records as best they can with whatever original records can be salvaged. Providers should note on the face sheet of the completely or partially reconstructed medical record: "This record was reconstructed because of disaster."

Providers Indirectly Impacted By Disaster

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

- For prepay or postpay documentation requests, extend the parameter that triggers denial for non-receipt of medical records from 45 days to 90 days. ADR letters must reflect that the response is due in 90 days rather than 45 days. This action will prevent most inappropriate denials and unnecessary increases in appeals workload.

- If a contractor receives the requested documentation after a denial has been issued but within a reasonable number of days beyond the denial date, the contractor should REOPEN the claim and make a medical review determination. Many contractors believe that 15 days is a reasonable number of days although contractors should make these decisions on a case-by-case basis. The workload, costs and savings associated with this activity should be allocated to the appropriate MR activity code (e.g., prepay complex or postpay complex review). Contractors should conduct these reopenings retroactively back to the date of the disaster.

D. Impact on Data Analysis

Contractors' data analysis should take into consideration the expected increase in certain services in disaster areas.

E. Impact on Contractor Performance Evaluation (CPE)

During CPE and SAS-70 reviews, CMS will consider a waiver to all contractor MR requirements, as necessary, to allow contractors the flexibility where required to handle issues that arise in the presence of disaster. Examples of such requirements include workload targets and any other MR administrative rules. Contractors must retain documentation of how their MR operations were affected during the disaster and make it available to CPE and SAS-70 review teams, CCMO staff, and local regional office staff, upon request.

3.3 – Articles

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

Contractors may publish articles communicating certain information to providers. Articles may include any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy. Since 2003, contractors have been required to enter into the Medicare Coverage Database those articles that address local coverage, coding or medical review-related billing and claims considerations.

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, including an e-mailing, and printing in a hardcopy bulletin. MR is responsible for the development of articles associated with new or revised LCDs, containing related coverage and coding information. MR is also responsible for the entering of those articles into the Medicare Coverage Database. Other widespread educational articles shall NOT be charged to MR.

Medical review shall send articles to the appropriate department within the contractor for publishing. All newly created articles must be posted on the contractor's Web site where duplicate copies may be obtained by providers/suppliers.

When national coverage determinations (NCD) or other coverage instructions issued by CMS include specific conditions or parameters for which services may be covered, contractors may develop and publish a list of covered codes related to the coverage provision. Contractors may automate denials for codes not included on the list without the development of an LCD if the NCD indicates or states that no other condition or parameters will be covered.

- Contractors may 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.

- The contractor may 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.

- The contractor may explain which off-labeled uses of FDA approved drugs are considered reasonable and necessary with the ICD-9-CM codes that reflect such uses.

The contractor may explain benefit category decisions and publish a list of drugs/biologicals that are considered usually self-administered.

On a flow basis, contractors shall report those injectable drugs that are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered by the patient. Contractors must enter their self-administered drug exclusion list into the Medicare Coverage Database. This database can be accessed at www.cms.hhs.gov/mcd.

In order to ensure that the Self-Administered Drug (SAD) Exclusion List report in the Medicare Coverage Database functions correctly, contractors must:

- Ensure that all CPT code information in a SAD exclusion article is listed in field 22.

- Ensure that all SAD exclusion articles are entered with the "SAD article" type. Contractors must not use the "General Detailed," "General Basic," or "FAQ" article types for their SAD exclusion articles.

- Ensure that the "End Date" for each drug listed in field 22 is correct. The end date should reflect the date that the drug is no longer excluded as self-administered.

- Review their SAD articles annually to ensure that the following requirements are met:

Drugs that have never been SAD-excluded	**Not on the list**
Drugs that were once SAD-excluded, but now are not SAD-excluded	Either: - On the list with an accurate "End Date," or - Were deleted from the list with an accurate article "Effective Date"
Drugs that are currently SAD-excluded	On the list

- The contractor may explain which HCPCS code or group of codes properly describes a particular service.

- The contractor may publish State non-physician licensure information that governs services billed by the physician under the "incident to" provision.

Articles may not conflict with NCDs or coverage provisions in interpretive manuals. Although a comment and notice process is not required, contractors are encouraged to consult with stakeholders in the provider community when developing articles. Contractors must 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 contractors from making individual claim determinations, even in the absence of an article or LMRP.

3.4 - Overview of Prepayment and Postpayment Review for MR Purposes

(Rev. 220, Issued: 08-24-07, Effective: 09-03-07, Implementation: 09-03-07)

The instructions listed in this section (section 3.4) apply only to reviews conducted for MR purposes unless otherwise noted. When MR staff are performing BI-directed prepay

or postpay claims review, the MR staff should seek direction from the BI staff. For example, if the provider calls the MR staff and requests feedback on the review results pursuant to the requirements for progressive corrective action, the MR staff should seek guidance from the BI unit.

When MR departments make referrals to POE, they shall maintain communication with POE regarding educational interventions completed and must continue to deny non-covered and incorrectly coded services even while provider education is occurring.

Prepayment MR of claims requires that a benefit category review, statutory exclusion review, reasonable and necessary review, and/or coding review be made BEFORE claim payment. Prepayment MR of claims always results in an "initial determination." See Pub. 100-04, chapter 29, section 30.3, for a complete definition of "initial determination."

Postpayment MR of claims requires that a benefit category review, statutory exclusion review, reasonable and necessary review, and/or coding review be made AFTER claim payment. These types of review allow the contractor the opportunity to make a determination to either affirm payment of a claim (in full or in part), or deny payment and assess an overpayment. Postpayment MR of claims may result in no change to the initial determination or may result in a "revised determination." See 42 CFR 405.841 and 42 CFR 405.750 for a complete definition of "revised determination."

When initiating prepay or postpay review (provider specific or service-specific), contractors must notify providers of the following:

- That the provider has been selected for review and the specific reason for such selection. If the basis for selection is comparative data, contractors must provide comparative data on how the provider varies significantly from other providers in the same specialty payment area or locality. Graphic presentations may help to communicate the perceived problem more clearly;

- Whether the review will occur on a prepayment or postpayment basis*;*

- If postpayment, the list of claims that require medical records*; and*

- The OMB Paperwork Reduction Act collection number, which is 0938-0969. This number needs to be on every additional documentation request (ADR) or any other type of written request for additional documentation for medical review. It can be in the header, footer or body of the document. We suggest the information read “OMB #: 0938-0969” or “OMB Control #: 0938-0969.”

This notice must be in writing and may be issued separately or in the same letter that lists the additional documentation that is being requested. Contractors may (but are not required to) make this notification via certified letter with return receipt requested. In addition, the contractor may include information on its Web site explaining that service-specific review will be occurring and the rationale for conducting such review.

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 can review the claim and associated documentation (including documentation requested after the claim is submitted) in order to make a determination under Section 1862(a)(1)(A) of the Social Security Act (the Act). Namely: is the claim medically reasonable and necessary in order 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: 1) involve activities defined under the Medicare Integrity Program (MIP) at Section 1893(b)(1) of the Act; 2) be articulated in the contractor's medical review strategy; and 3) be designed in such a way as to reduce the contractor's Comprehensive Error Rate Testing (CERT) error rate or prevent the contractor's CERT error rate from increasing.

Edits which suspend a claim for manual review to check for completeness of claims, conditions of participation, adherence to prescribing standards, coding, pricing or other non-clinical issues are not medical review edits. These activities are not defined under 1893(b)(1) of the Act and cannot be funded by MIP. Therefore, edits which result in work other than that defined in 1893(b)(1), shall be charged to the appropriate Program Management activity cost center.

3.4.1 - Determinations Made During Prepayment and Postpayment MR
(Rev. 71, 04-09-04)

When contractors review claims, either on a prepayment or postpayment basis, they may make any or all of the determinations listed below.

Contractors must be able to differentiate the type of determination made to ensure that limitations on liability determinations are made when appropriate.

When MR staff are reviewing a medical record for MR purposes, their focus is on making a coverage and/or coding determination. However, when MR staff are performing BI-directed review, their focus may be different (e.g., looking for possible falsification, etc.)

A. Coverage Determinations

A claim may be covered, in full or in part, by a contractor if it meets all the conditions listed in PIM Chapter 13, Section 13.4.1

B. Limitation of Liability Determinations

In accordance with §1879 of the Act, contractors first consider coverage determinations based on the absence of a benefit category or based on statutory exclusion. If both these conditions are met, the next consideration should be whether the service was reasonable and necessary. Section 1862(a)(1) of the Act is the authority for denial because a service is not reasonable and necessary. When a claim is denied, in full or in part, because an

item or service is not reasonable and necessary, contractors make and document §§1879, 1870, and 1842(l) (limitation of liability) determinations as appropriate. Because these determinations can be appealed, it is important that the rationale for the determination be documented both initially and at each level of appeal. Limitation of Liability determinations do not apply to denials based on determinations other than reasonable and necessary. See PIM Exhibits 14 - 14.3 for further details.

C. Coding Determinations

See PIM, chapter 13, section 13.4.2, for a description of a coding determination.

D. Pricing Determinations for First Time Not Otherwise Classified (NOC) Codes

In addition, contractor MR staff may assist contractor claims processing staff in making pricing determinations on NOC HCPCS codes. The MR staff will provide information needed to the claims processing staff so that they can price the service in accordance with CMS pricing methodologies described in the MCM and MIM. For frequently billed services, to the extent possible, contractors should keep track of these pricing determinations so that for future claims, the claims processing staff can price the claim using established MR pricing guidelines for that service.

3.4.1.1 - Documentation Specifications for Areas Selected for Prepayment or Postpayment MR

(Rev. 248; Issued: 03-28-08; Effective Date: 09-03-07; Implementation Date: 04-28-08)

The contractor may use any information they deem necessary to make a prepayment or postpayment claim review determination. This includes reviewing any documentation submitted with the claim as well as soliciting documentation from the provider or other entity when the contractor deems it necessary and in accordance with PIM, chapter 3, §3.4.1.2.

A. Review of Documentation Submitted with the Claim

If a claim is targeted based on data for prepayment or postpayment medical review (including automated, routine, or complex) contractors may review unsolicited supporting documentation accompanying the claim, but are not required to do so.

There are two exceptions to this rule. Contractors may deny without reviewing attached or simultaneously submitted documentation (1) when clear policy serves as the basis for denial, and (2) in instances of medical impossibility (see PIM, chapter 3, §3.5.1).

NOTE: The term "clear policy" means a statute, regulation, NCD, coverage provision in an interpretive manual, or LCD that specifies the circumstances under which a service will always be considered non-covered or incorrectly coded. Clear policy that will be

used as the basis for frequency denials must contain utilization guidelines that the contractor considers acceptable for coverage.

If a contractor chooses to allow supporting paper documentation to be submitted with the claim for medical review purposes the contractor shall inform providers in their jurisdiction of that fact (see PIM, chapter 3, §3.5).

B. Signature Requirements

Medicare requires a legible identifier for services provided/ordered. The method used shall be hand written or an electronic signature (stamp signatures are not acceptable) to sign an order or other medical record documentation for medical review purposes.

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

Providers using electronic systems should recognize that there is a potential for misuse or abuse with alternate signature methods. Facsimile and hard copies of a physician's electronic signature must be in the patient's medical record for the certification of terminal illness for hospice. For example, providers need a system and software products which are protected against modification, etc., and should apply administrative procedures which are adequate and correspond to recognized standards and laws. The individual whose name is on the alternate signature method and the provider bears the responsibility for the authenticity of the information being attested to. Physicians should check with their attorneys and malpractice insurers in regard to the use of alternative signature methods.

All State licensure and State practice regulations continue to apply. Where State law is more restrictive than Medicare, the contractor needs to apply the State law standard. The signature requirements described here do not assure compliance with Medicare conditions of participation.

Note that this instruction does not supersede the prohibition for certificates of medical necessity (CMNs) and DME MAC information forms (DIFs). CMNs and DIFs are forms used to determine if the medical necessity and applicable coverage criteria for durable medical equipment, prosthetic, and orthotic supplies (DMEPOS) have been met.

C. Review of Documentation Solicited After Claim Receipt

The process whereby a contractor requests additional documentation after claim receipt is known as "development." Providers selected for review are responsible for submitting medical records requested of them by the contractor within established timeframes. Development requirements are listed below in section 3.4.2.1.

D. Requirements That Certain Tests Must Be Ordered By The Treating Physician

Effective November 25, 2002, 42 CFR 410.32(a) requires that when billed to any contractor, all diagnostic x-ray services, diagnostic laboratory services, and other diagnostic services must be ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.

E. Diagnosis Requirements

Section 1833(e) of the Act provides that no payment may 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 . . ."Contractors may require information, in accordance with the requirements below whenever they deem necessary to make a determination listed in section 3.4.1 and thus to 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 an LCD.

- Claims Submitted by Physicians or **§1842(b)(18)(C) of the Act** Practitioners Must Contain Diagnosis Codes.

Section 1842 (p)(1) of the Act states that each claim submitted by a physician or §1842(b)(18)(C) of the Act practitioner "shall include the appropriate diagnosis code (or codes)…". For services from physicians and §1842(b)(18)(C) of the Act practitioners submitted with an ICD-9 code that is missing, invalid, or truncated, contractors must return the billed service to the provider as unprocessable in accordance with MCM §3005.4(p) or MIM §3605.3.

- Claims Submitted By All Other Provider Types Must Contain Diagnosis Codes If Such Codes Are Required By An LCD (effective 7/1/02).

In order to address potential abuse or overutilization, contractors can require that ICD-9 diagnosis codes be submitted with each claim for the targeted service. This information is used in determining whether the services are covered and correctly coded. Effective April 1, 2002, contractors may require ICD-9 diagnosis codes to be submitted by all non-physician billers with every claim for a targeted service only if such a requirement appears in an LCD for that service. Contractors must educate providers about this requirement beginning no later than January 1, 2002. This outreach should occur via Web site bulletin articles, etc.

For individual non-physician providers who are identified due to unusual billing practices, fraud referrals, etc., contractors may also require ICD-9 diagnosis codes to support the medical necessity of all or some claims submitted by the targeted entities, even if no LCD exists requiring such codes.

For services submitted with an ICD-9 diagnosis code that is missing, incorrect or truncated as indicated above, contractors must return the billed service to the provider as unprocessable.

F. 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 or 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 new panel codes, contractors may review these claims. Should contractors determine the need to develop a LCD for laboratory panel codes, develop these policies at the panel code level. In some instances of perceived abuse of the new panel codes, you may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test.

3.4.1.1.1 - Exception From the Uniform Dollar Limitation ("Therapy Cap")

(Rev. 245; Issued: 02-29-08; Effective: 01-01-08; Implementation: 03-31-08)

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.

3.4.1.2 - Additional Documentation Requests (ADR) During Prepayment or Postpayment MR

(Rev. 179, Issued: 12-15-06; Effective: 11-29-06; Implementation: 01-16-07)

When contractors cannot make a coverage or coding determination based upon the information on the claim and its attachments, the contractors may solicit additional documentation from the provider or supplier by issuing an additional documentation request (ADR). Contractors shall request records related to the claim(s) being reviewed. Contractors may collect documentation related to the patient's condition before and after a service in order to get a more complete picture of the patient's clinical condition. The contractor shall not deny other claims related to the documentation of the patient's condition before and after the claim in question unless appropriate consideration is given to the actual additional claims and associated documentation.

Contractors shall specify in the ADR the specific pieces of documentation needed (and ONLY those pieces needed) to make a coverage or coding determination. When reviewing documentation during medical review, contractors shall review and give appropriate consideration to all documentation that is provided.

Documentation provided for pre- or post-payment medical review shall support the medical necessity of the item(s) or service(s) provided. The treating physician, another clinician or provider, or supplier may supply this documentation. This documentation may take the form of clinical evaluations, physician evaluations, consultations, progress notes, physician letters, or other documents intended to record relevant information about a patient's clinical condition and treatment(s).

The date that an individual document was created, or the creator of a document is not the sole deciding factor in determining if the documentation supports the services billed.

In instances where medical necessity is not supported by contemporaneous information in physician progress notes, physician progress notes shall be the determining factor. In instances where documentation is provided in lieu of contemporaneous physician progress notes, contractors shall determine if the documentation is sufficient to justify coverage. If it is not, the claim shall be denied.

A. Development of Non-Lab Claims for Additional Documentation

If, during pre- or post-pay review, a contractor chooses to send an Additional Documentation Request (ADR) regarding a non-lab targeted service, they shall solicit the documentation from the billing provider or supplier and may solicit documentation from other entities (third parties) involved in the beneficiary's care. If a contractor chooses to solicit documentation from a third party, they may send the third party ADR simultaneously with the billing provider or supplier ADR. Contractors shall send ADRs in accordance with the following requirements:

Billing Provider or Supplier ADRs

- Contractors who choose to request additional documentation shall solicit such information from the billing provider or supplier and shall notify them that they have 30 days to respond. Contractors have the discretion to grant an extension of the timeframe

upon request. The contractor shall pend the claim for 45 days. Contractors may cc a third party.

- Contractors have the discretion to issue no more than two (2) "reminder" notices via letter or phone call prior to the 45th day.

- If information is automatically requested only from the billing provider or supplier and no response is received within 45 days after the date of the request (or extension), the contractor shall deny the service as not reasonable and necessary (except for ambulance claims where the denial may be based on §1861(s)(7) or §1862(a)(1)(A) of the Act depending upon the reason for the requested information). These claims denials are issued with Remittance Advice Code N102/56900 (“This claim has been denied without reviewing the medical record because the requested records were not received or were not received timely.”). These denials count as automated review. Refer to PIM chapter 3, section 3.4.5 for definitions and examples of types of prepayment and postpayment review.

- If information is requested only from the billing provider or supplier and the information received fails to support the medical necessity of the service, in full or in part, the contractor shall deny the claim, in full or in part, using the appropriate denial code (see section 3.4.2). 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. These denials would count as complex review. Refer to PIM chapter 3, section 3.4.5 for definitions and examples of types of prepayment and postpayment review.

THIRD PARTY ADRs

A contractor shall NOT solicit documentation from a third party unless the contractor first or simultaneously solicits the same information from the billing provider or supplier. Some examples of third parties are a physician’s office (e.g., if claim is for lab, x-ray, or Part A service requiring medical documentation), or a hospital (e.g., if claim is for physician’s inpatient services), Beneficiaries are not third parties.

When a contractor solicits documentation from a third party:

- The contractor shall notify the third party that they have 30 days to respond and the billing provider or supplier. Contractors have the discretion to grant extensions copy of the timeframe upon request.

- For prepay review, the contractor shall pend the claim for 45 days. This 45 day time period may run concurrent with the 45 day time period for the billing provider or supplier ADR letter;

- Contractors have the discretion to issue no more than two (2) "reminder" notices via email, letter or phone call prior to the 45th day;

- If information is requested from both the billing provider or supplier and a third party and no response is received from either within 45 days after the date of the request (or extension), the contractor 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 ("This claim has been denied without reviewing the medical record because the requested records were not received or were not received timely."). These denials would count as automated review.

- If information requested from both the billing provider or supplier and a third party and a response is received from one or both, but the information fails to support the medical necessity of the service, the contractor shall deny the claim, in full or in part, using appropriate denial code (see section 3.4.2). These denials would count as complex review. 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.

B. Development of Lab Claims for Additional Documentation

If, during pre- or post-pay review, a contractor chooses to send an ADR regarding a targeted **lab** service, the contractor shall solicit the documentation from the billing provider or supplier, and under certain circumstances, as listed below, shall also solicit documentation from the ordering provider.

Contractors shall send ADRs in accordance with the following requirements:

Billing Or supplier ADRs

- Contractors who choose to request additional documentation shall solicit such information from the billing provider or supplier and shall notify them that they have 30 days to respond. Contractors have the discretion to grant an extension of the time frame upon request. For prepay review, the contractor shall pend the claim for 45 days. Contractors may solicit billing providers only for the following information:

    - Documentation of the order for the service billed (including information sufficient to allow the contractor to identify and contact the ordering provider);

    - Documentation showing accurate processing for the order and submission of the claim; and

    - Diagnostic or other medical information supplied to the billing provider or supplier by the ordering provider, including any ICD-9 codes or narratives supplied.

- Contractors have the discretion to issue no more than two (2) "reminder" notices via letter, e-mail, or phone call prior to the 45th day.

- If no response is received from the billing provider or supplier within 45 days after the date of the request (or extension), the contractor shall deny the service as not reasonable and necessary. These claims denials are issued with Remittance Advice Code N102/56900 ("This claim has been denied without reviewing the medical record because the requested records were not received or were not received timely."). These denials would count as automated review.

- If the documentation received does not demonstrate the medical necessity of the service, the contractor shall deny. These denials would count as complex review. 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.

- If the information requested from the billing provider or supplier fails to support the coverage or coding of the claim in full or in part, the contractor shall:

    - Deny the claim if a benefit category, statutory exclusion, or coding issue is in question, or;

    - Develop to the ordering provider in accordance with the requirements listed below if a reasonable and necessary issue is in question.

Ordering Provider ADRs

A contractor may NOT solicit documentation from the ordering provider unless the contractor meets the following provisions:

1) Solicits information from the billing provider or supplier,

2) Finds the ADR response from the billing provider or supplier insufficient or not provided, and

3) The issue in question is one of medical necessity. Contractors may implement these requirements to the extent possible without shared systems changes.

When a contractor solicits documentation from the ordering provider the contractor shall provide to the ordering provider information sufficient to identify the claim being reviewed.

- The contractor shall solicit from the ordering provider only those parts of the medical record that are relevant to the specific claim(s) being reviewed. The contractor shall notify the ordering provider that they have 30 days to respond and copy the billing provider or supplier. Contractors have the discretion to grant extensions of the time frame upon request.

- For prepay review, the contractor shall pend the claim for 45 days.

- Contractors have the discretion to issue no more than two (2) "reminder" notices via email, letter or phone call prior to the 45th day.

- If information is requested from the ordering provider and no response is received within 45 days after the date of the request (or extension), the contractor 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 (“This claim has been denied without reviewing the medical record because the requested records were not received or were not received timely.”). These denials would count as automated review.

- If the information requested from the ordering provider is received, but the information fails to support the coverage or coding of the claim, they shall deny the claim, in full or in part, using appropriate denial code (see section 3.4.2). These denials would count as a complex review.

C. Psychotherapy Notes

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 expressly **excludes** medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of diagnosis, functional status, treatment plan, symptoms, prognosis, progress, and progress to date. etc., and 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 a contractor request a provider submit notes defined in 45 CFR §164.501. The refusal of a provider to submit such information shall not result in the denial of a claim.

If the medical record includes any of the information excluded from the definition of psychotherapy notes in §164.501, as stated above, the provider is responsible for extracting the information required to support that the claim is reasonable and necessary. Contractors shall review the claim using all supporting documentation submitted by the provider. If the provider does not submit sufficient information to demonstrate that services were medically necessary, the claim will 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.

3.4.1.2.1 - Development of Non-Lab Claims for Additional Documentation
(Rev.)

3.4.1.2.2 - Development of Lab Claims for Additional Documentation
(Rev.)

3.4.1.3 – Completing Complex Reviews
(Rev. 179, Issued: 12-15-06; Effective: 11-29-06; Implementation: 01-16-07)

A. Medical Review Timeliness Requirement

When a contractor receives requested documentation associated within 45 days (or allowed extended timeframe- see section 3.4.1.2) in response to an ADR, the contractor must make a medical review determination AND do one of the following within 60 days of receiving documentation:

- For postpay review, mail the notification letter to the provider or supplier (see PIM, chapter 3, section 3.6.5); or

- For prepay review, enter the MR decision into the FISS, MCS, or VMS system.

B. How to Count the 60-Day Medical Review Time Period

- For prepay reviews (e.g., prepay probe, regular prepay review) the contractor shall count day one as the date each new medical record is received in the contractor's mailroom. Each new medical record received would have an independent 60-day time period associated with it.

- For postpay reviews, contractors have the option to either:

  - Begin counting with the receipt of each medical record in the contractor's mailroom. Each new medical record received would have an independent 60-day time period associated with it, or

  - Wait until all requested medical records are received in the contractor's mailroom. The date on which the last of the requested medical records is received would represent the beginning of the 60-day time period.

- For claims associated with any case that is referred to the program safeguard contractor (PSC) or BI unit at the DME PSC for BI investigation, contractors shall stop counting the 60-day time period on the date the referral is made. The 60-day time period

will be restarted on the date the contractor receives requested input from the PSC or is notified by the PSC that the case has been declined.

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

See PIM, chapter 3, section 3.4.2.C, for description of the notification requirements.

3.4.1.4 - Handling Late Documentation

(Rev. 179, Issued: 12-15-06; Effective: 11-29-06; Implementation: 01-16-07)

There are 2 sets of instructions for handling late documentation received by MR after a denial has been issued due to failure to respond to an ADR. Those instructions are detailed below.

1. If a contractor medical review department receives the requested information from a provider or supplier after a denial has been issued but within a reasonable number of days (generally 15 days after the denial date), the contractor may chose to reopen the claim.

- Contractors who choose to reopen must 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 days of receiving documentation in the contractor's mailroom (For information on how to count the 60 days, see section 3.4.1.3 B):

  - For claims originally selected for postpay review, issue a new letter containing the revised denial reason and the information required by PIM chapter 3, §3.6.5; or

  - For claims originally selected for prepay review, enter the revised MR determination into the FISS, MCS, or VMS system, generating a new MSN and remittance advice with the new denial reason and appeals information.

The workload, costs, and savings associated with this activity should be allocated to the appropriate MR activity code in CAFM and PIMR (e.g., postpay complex).

- Contractors Who Choose NOT to Reopen -- Contractors who choose not to reopen should not destroy the documentation but instead retain the information (hardcopy or electronic) in a location where it could be accessed by appeals staff and MR staff.

If a contractor medical review department receives the requested information forwarded from the appeals department, in accordance with CMS Pub. IOM 100-04, chapter 34, §10.3, MR shall conduct a reopening, following the processing and reporting instructions in PIM chapter 3, section 3.4.1.5.

3.4.1.5 - Re-openings of Claims Denied Due to Failure to Submit Necessary Medical Documentation (remittance advice code N102 or 56900)

(Rev. 179, Issued: 12-15-06; Effective: 11-29-06; Implementation: 01-16-07)

In cases where the contractor denies a claim with remittance advice code N102 or 56900 ("This claim has been denied without reviewing the medical record because the requested records were not received or were not received timely.") and the denial is appealed, the appeals department will send the claim to the MR department for reopening under certain conditions, listed in CMS Pub. IOM 100-04, chapter 34, §10.3. The medical review department shall conduct a reopening of claims sent by the appeals department, which meet the criteria described in that section.

In the situation described above, MR shall make a MR determination on the lines previously denied due to failure to submit requested documentation and do one of the following, within 60 days of receipt of the forwarded claim and requested documentation in the MR department:

- For claims originally selected for postpay review, issue a new letter containing the revised denial reason and the information required by PIM chapter 3, §3.6.5; or

- For claims originally selected for prepay review, enter the revised MR determination into the FISS, MCS, or VMS system, generating a new MSN and remittance advice with the new denial reason and appeals information.

Contractors who report in CAFM shall report the cost and workload for these re-openings in CAFM-II activity code 21210.

3.4.2 –Medical Review Denial Notices

(Rev. 220, Issued: 08-24-07, Effective: 09-03-07, Implementation: 09-03-07)

Contractors must deny claims, in full or in part, under the circumstances listed below. Contractors do not have the option to "Return to Provider" or reject claims under these circumstances. Contractors must deny the claim in full or in part. See IOM Pub.100-04, chapter 30, §20.1, for further information on partials denials (known as "down coding").

A. Denial Reasons Used for Reviews Conducted for MR or BI Purposes

Contractors must 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 and national coverage determination, coverage provision in 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. (Contractors shall use this denial reason for all non-responses to ADRs.); and

- Was not billed in compliance with the national and local coding requirements; or

- Does not meet reasonable and necessary criteria specified in an LCD.

Contractors must give the specific reason for denial. Repeating one of the above bullets is not a specific reason. An exception to this instruction may occur when a demand bill (condition code 20) is submitted with an administrative error, such as when the beneficiary has not selected the checkbox indicating he or she wants Medicare to be billed on the HHABN (see CMS Pub. IOM 100-08, chapter 11, §11.1.3.4 for instructions regarding appropriate intermediary processes when this situation occurs). In most cases, the contractor shall RTP such claims submitted in error, except in the case of dual-eligible beneficiaries where there is a state-specific policy, as described in IOM 100-04, chapter 30, §60.5 A.

B. Denial Reasons Used for Reviews Conducted for BI Purposes

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

- Was not rendered (or was not rendered as billed);

- Was furnished in violation of the self referral prohibition; 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.

Contractors must deny payment whenever there is evidence that an item or service was not furnished, or not furnished as billed 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, but the case has been refused by law enforcement, contractors deny the claim(s) and collect the overpayment where there is fraud- - after notifying law enforcement. It is necessary to document each denial thoroughly to sustain denials in the appeals process. Intermediaries must make adjustments in cost reports, as appropriate.

C. Denial Notices

If a claim is denied, in full or in part, the contractor must notify the beneficiary and/or the provider. The contractor shall include limitation of liability and appeals information. Notification can occur via Medicare Summary Notice (MSN) and remittance advice.

Beneficiary Notices

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

> "A local medical review policy (LMRP) or local coverage determination (LCD) was used when we made this decision. An LMRP/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 or carrier 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 LMRP/LCD to see whether additional information from your physician would change our decision."

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

> 15.19 - Una Política Local de Revisión Médica (LMRP, por sus siglas en inglés) o una Determinación de Cobertura Local (LCD, por sus siglas en inglés) fue utilizada cuando se tomó esta decisión. La Política Local de Revisión Médica y la Determinación de Cobertura Local proveen una guía que ayuda a determinar si un artículo o servicio en particular está cubierto por Medicare. Una copia de esta política está disponible en su intermediario o su empresa de seguros Medicare local al llamar al número que aparece en la sección de Servicios al Cliente en la página uno. Usted puede comparar los datos de su caso con las reglas establecidas en la Política Local de Revisión Médica y en la Determinación de Cobertura Local para ver si obteniendo información adicional de su médico pudiera cambiar nuestra decisión.

Use the above message in every instance of a prepayment denial where an LCD was used in reviewing the claim. Use this message, and message 15.20 (now for FISS FI's, 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. Do not use this message on denials not involving LCDs. For claims reviewed on a postpayment basis, use the above message 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 #(s) and NCD #(s)] were used when we made this decision."(Pub. 100-04, chapter 21). 15.19 must continue to be used in conjunction with the MSN message 15.20, where 15.19 is applicable. Contractors may combine these messages if necessary, but 15.19 must not be deleted.

Provider Notices

Prepay Denial Messages

Because the amount of space is limited, contractors need only provide high-level information to providers when informing them of a prepayment denial via a remittance advice. In other words, the shared standard system remittance advice messages are sufficient notices to the provider. However, for routine and complex review, the contractor must retain more detailed information in an accessible location so that upon written or verbal request from the provider, the contractor can explain the specific reason the service was considered non-covered or not correctly coded.

Post Pay Denial Messages

When notifying providers of the results of post pay medical review determinations, the contractor must explain the specific reason each service was considered non-covered or not correctly coded.

Indicate in the Denial Notice Whether Records Were Reviewed

Effective March 1, 2002, for claims where the contractor has sent an ADR letter and no timely response was received, contractors must make a §1862(a)(1) of the Act denial (except for ambulance claims where the denial may be based on §1861(s)(7) or §1862(a)(1)(A) of the Act depending upon the reason for the requested information) and indicate in the provider denial notice, using remittance advice code N102, that the denial was made without reviewing the medical record because the requested records were not received or were not received timely. This information will be useful to the provider in deciding whether to appeal the decision.

For claims where the contractor makes a denial following complex review, contractors may, at their discretion, indicate in the denial notice, using remittance advice code N109 that the denial was made after review of medical records. This includes those claims where the provider submits medical records at the time of claim submission and the contractor selects that claim for review.

D. Audit Trail

For reporting purposes, contractors need to differentiate automated, routine and complex prepayment review of claims. Contractor systems must maintain the outcome (e.g., audit trail) of prepayment decisions such as approved, denied, or partially denied. When downcoding, contractors must retain a record of the HCPCS codes and modifiers that appeared on the original claim as submitted.

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

Contractors must be very careful in choosing which denial type to use since beneficiaries' liability varies based on denial type. Benefit category denials take precedence over statutory exclusion and reasonable and necessary denials. Statutory exclusion denials take precedence over reasonable and necessary denials. Contractors should use HCFA Ruling 95-1 and the guidelines listed below in selecting the appropriate denial reason.

- If the contractor requests additional documentation from the provider or other entity (in accordance with PIM, chapter 3, section 4.1.2.) for any MR reason (benefit category, statutory exclusion, reasonable/necessary, or coding), and the information is not received within 45 days, the contractor should issue a reasonable and necessary denial, in full or in part.

- If the contractor requests additional documentation because compliance with a benefit category requirement is questioned and the contractor receives the additional documentation, but the evidence of the benefit category requirement is missing, the contractor should issue a benefit category denial.

- If the contractor requests additional documentation because compliance with a benefit category requirement is questioned and the contractor receives the additional documentation, which shows evidence that, the benefit category requirement is present but is defective, the contractor should issue a reasonable and necessary denial.

EXAMPLE: A contractor is conducting a review of partial hospitalization (PH) services on a provider who has a problem with failing to comply with the benefit category requirement that there be a signed certification in the medical record. In the first medical record, the contractor finds that there is no signed certification present in the medical record. The contractor must 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 contractor determines that a signed certification is present in the medical record, but the documentation does not support the physician's certification, the services must be denied under §1862(a)(1)(A) of the Act (a reasonable and necessary denial) because the certification is present but defective.

If a contractor performs routine review on a surgical procedure and determines that the procedure was cosmetic surgery 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.

3.4.2.1 Role of Conditions of Participation Requirements When Making a Payment Decision

(Rev. 71, 04-09-04)

The Conditions of Participation (COP) requirements cannot be used as a basis for denying payment. The COPs define specific quality standards that providers must meet to participate in the Medicare program. A provider’s compliance with the COPs is

determined by the regional office (RO) based on the State survey agency recommendation.

In cases where you believe that the COPs are not being met or when problems have been identified, you should notify your RO and the appropriate State survey agency so that they can initiate appropriate action.

3.4.3 - Documenting That A Claim Should Be Denied
(Rev. 71, 04-09-04)

For each claim denied, in full or in part, contractor MR or BI staff must carefully document the basis for the denial in the internal claim record. If there are several reasons for denial, effective 1/1/03, the contractor must document each basis in the internal claim record.

In establishing an overpayment, contractors 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.

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

As part of its process of reviewing claims, contractor MR staff may develop detailed written review guidelines ("Internal MR Guidelines.") Internal MR Guidelines, in essence, will allow the contractor to operationalize LCDs and NCDs. Internal MR Guidelines shall specify what information should be reviewed by routine reviewers and the appropriate resulting determination. Contractor MR staff must make their Internal MR Guidelines available to their internal staff (e.g., POE, the appeals unit), PSC, or BI unit, as needed. Internal MR Guidelines must not create or change policy.

3.4.5 - Types of Prepayment and Postpayment Review
(Rev. 174, Issued: 11-17-06; Effective: 10-01-2006; Implementation: 10-06-06)

Claim review activities are divided into three distinct types of review:

A. Automated Prepayment Review

When prepayment review is automated, decisions are made at the system level, using available electronic information, without the intervention of contractor personnel. See Section 5.1 for further discussion of automated prepayment review.

B. Routine Prepayment/Postpayment Review

Routine prepayment review is limited to rule-based determinations performed by specially trained MR staff. An intervention can occur at any point in the review process.

For example, a claim may be suspended for routine review because an MR determination cannot be automated.

Routine review requires hands-on review of the claim, and/or claims history file and/or internal MR guidelines but does not require the application of clinical judgment by a licensed medical professional.

C. Complex Prepayment/Postpayment Review

Complex medical review involves the application of clinical judgment by a licensed medical professional in order to evaluate medical records. Medical records include any medical documentation, other than what is included on the face of the claim that supports the service that is billed. For items of durable medical equipment that require a Certificate of Medical Necessity (CMN), the CMN is considered part of the face of the claim. Complex medical review determinations require a licensed medical professional to make a clinical judgment about whether a service is covered, and is reasonable and necessary.

Complex review for the purpose of making coverage determinations must be performed by nurses (RN/LPN) or physicians, unless this task is delegated to other licensed health care professionals. Contractors must 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 claim). Contractors should establish QI processes that verify the accuracy of MR decisions made by licensed health care professionals.

Contractors must maintain a credentials file for each reviewer who performs one or more complex reviews (including consultants, contract staff, subcontractors, and temporary MR staff). The credentials file must contain at least a copy of the reviewer's professional license.

During complex review, nurse and physician reviewers may call upon other health care professionals (e.g., dieticians, and physician specialists) for advice. Any determination must be documented and include the rationale for the decision. While MR staff must follow national coverage determinations and local coverage determinations, they are expected to use their expertise to make clinical judgments when making medical review determinations. They must take into consideration the clinical condition of the beneficiary as indicated by the beneficiary's diagnosis and medical history when making these determinations. For example, if a medical record indicates that a beneficiary is a few days post-op for a total hip replacement and femur plating, even though the medical record does not specifically state that the beneficiary requires the special skills of ambulance transportation, MR nurses and physicians must use their clinical knowledge to conclude that ambulance transportation is appropriate under such circumstances.

Complex medical review performed by medical review staff for purposes other than MR (for example, for benefit integrity investigations or for appeals) should be charged for expenditure reporting purposes to the area requiring medical review services.

D. Examples

The following examples are provided to assist contractors in understanding the definitions of automated, routine, and complex review.

EXAMPLE 1: A contractor sets up the system so that for a particular HCPCS/ICD9 combination, the computer will request documentation, suspend for manual review, and auto-deny in 45 days if no documentation is received. For claims where no documentation is received within 45 days, the computer auto-denies the claim without manual intervention. Even though the contractor intended to perform manual review, because they ACTUALLY performed automated review, this review should be counted a AUTOMATED.

EXAMPLE 2:A contractor sets up the system so that for a particular HCPCS/ICD9 combination, the computer will suspend for routine review. During routine manual review, the reviewer determines that complex review is needed and initiates a request for additional documentation. For claims where no documentation is received within 45 days, the computer denies the claim. Because the contractor ACTUALLY performed routine manual review, this claim should be counted as ROUTINE review.

EXAMPLE 3:A contractor sets up the system so that for a particular HCPCS/ICD9 combination, the computer will suspend for routine manual review. During routine manual review, the reviewer determines that complex review is needed and initiates a request for additional documentation. For claims where documentation is received, MR nurses (RN/LPN) or physicians will review the documentation and make a decision regarding the services billed. Because the HIGHEST LEVEL of review the contractor performed was complex manual review, this claim should be counted as COMPLEX review.

3.4.6 -Spreading Workload Evenly

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

The type and amount of workload a contractor must perform each year is specified in their MR strategy or Statement of Work (SOW).

3.4.7 - New Provider/ New Benefit Monitoring

(Rev. 71, 04-09-04)

Contractors must monitor through data analysis the billing patterns of new providers and for new statutory benefits to ensure correct coverage and coding from the beginning. Contractors have the option of performing prepay or postpay review of new providers as needed. Where contractors choose to perform pre or postpay review of a new provider,

the contractors should perform only limited review (i.e., 20-40 claims) in order to ensure accurate billing. The sample size should not impose an administrative burden or significantly impact on the provider's cash flow. New benefit edits should be continued until they no longer prove effective or until the contractor determines that resources would best be spent on other types of review.

NOTE: While program savings are realized through denials for inappropriate provider billing, the optimal result occurs when providers no longer bill for non-covered or incorrectly coded services.

3.4.8 - Review That Involves Utilization Parameters
(Rev. 71, 04-09-04)

A. General

During any type of MR-directed review (prepay or postpay; automated, routine or complex), contractors shall not deny services that exceed utilization parameters unless:

1. Clear policy (see PIM Chapter 3, section 3.4.1.1) serves as the basis for the denial;

2. The denial is based on apparent typographical errors (e.g., 10,000 blood cultures for the same beneficiary on the same day);

3. The contractor sent an ADR letter and reviewed the ADR response, but the ADR response failed to support the coverage or coding of the claim; or

4. No timely response is received in response to an ADR letter.

B. Automated vs. Complex Review of Non-Lab Claims Involving Utilization Parameters

Contractors should always seek to implement prepayment edits that will prevent payment of services to providers billing egregious amounts and/or to providers with a pattern of billing for services that are not covered. When contractors identify egregious overutilization of a non-lab service within the context of their MR Strategy and prioritization of review targets, they must respond timely.

- When overutilization of a non-lab service is identified and clear policy serves as the basis for denial, contractors may establish edits to automatically deny the services.

- When overutilization of a non-lab service is identified and there is not clear policy to serve as the basis for denial, contractors must establish complex review edits and make individual claim determinations. Contractors must develop the claims for additional documentation in these situations.

If the overutilization problem is determined to be widespread, the contractor should follow the requirements in progressive corrective action.

C. Automated vs. Complex Review of Lab Claims Involving Utilization Parameters

Contractors should always seek to implement prepayment edits that will prevent payment of services to providers billing egregious amounts and/or to providers with a pattern of billing for services that are not covered. When contractors identify egregious overutilization of a lab service within the context of their MR strategy and prioritization of review targets, they must respond timely.

- When overutilization of a lab service is identified and clear policy serves as the basis for denial, contractors may establish edits to automatically deny the services.

- When overutilization of a lab service is identified and there is not clear policy to serve as the basis for denial, contractors must quickly establish manual review edits that do not involve utilization parameters and make individual claim determinations. For example, if the problem is limited to a few laboratory providers, the contractor could develop a provider-specific prepayment edit to suspend all of the lab services in question from the problem providers. If the problem is widespread in nature, the contractor could develop a service-specific edit to suspend all of the lab services in question or all of the services in question for a particular diagnosis code or revenue code. Based on data analysis findings within each contractor's jurisdiction, the contractor should attempt to focus the edit to the greatest extent possible by provider, by diagnosis, by procedure code or in any way OTHER THAN by use of a utilization parameter.

3.5 - Prepayment Review of Claims For MR Purposes

(Rev. 131, Issued: 11-10-05; Effective: 02-10-06; Implementation: 02-10-06)

The instructions listed in this section (section 3.5) apply only to reviews conducted for MR purposes unless otherwise noted.

Contractors may not initiate non-random prepayment review of a provider or supplier based on the initial identification by that provider or supplier of an improper billing practice unless there is a likelihood of a sustained or high level of payment error. For more information regarding identifying providers or suppliers with a sustained or high level of payment errors please refer to chapter 3, section 11, of this manual.

Claims

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 only a few limited exceptions. Accordingly, contractors shall not require providers to submit paper claims when they are targeted for prepayment complex medical review. Contractors must, however, allow providers that qualify for an ASCA mandatory

electronic billing exception to submit paper claims when they are targeted for prepayment review (see chapter 24, section 90, of the Medicare Claims Processing Manual for exceptions).

Supporting Documentation

Contractors may not require or request, from any provider regardless of size, the submission of supporting documentation with the initial claim(s) through contractor developed forms, local policies, or any other communications with providers. Supporting documentation may only be requested through the Additional Documentation Request (ADR) process or alternate contractor process that permits matching.

Contractors shall associate supporting documentation with claims as a part of the on-going medical review process. Unsolicited supporting documentation submitted outside of the ADR process may be considered at the contractors' discretion, but contractors cannot require paper claims as a way to match documentation. If a contractor chooses to allow supporting paper documentation to be submitted with the claim for medical review purposes the contractor shall inform providers in their jurisdiction of that fact.

Only if identified as a prioritized problem in their medical review strategy, and when consistent with section 11.1.1, of the PIM, contractors may choose to suspend to medical review lab services with one of the laboratory negotiated rulemaking ICD-9 "Codes that Do Not Support Medical Necessity (where documentation could result in payment)". In these cases, contractors shall continue to use the documentation submitted with the claim in order to make their determination whether the lab service was reasonable and necessary for that particular ICD-9 code. Contractors shall continue to follow the instructions found at section 3.4.1.2.B, of the PIM when requesting additional documentation in order to perform medical review of laboratory claims.

3.5.1 - Automated Prepayment Review

(Rev. 220, Issued: 08-24-07, Effective: 09-03-07, Implementation: 09-03-07)

When prepayment review is automated, decisions are made at the system level, using available electronic information, without the intervention of contractor personnel. When appropriately implemented, automated review increases efficiency and consistency of decisions. Contractors must implement automated prepayment review whenever appropriate.

Automated review must:

Have clear policy that serves as the basis for denial; or

Be based on a medically unbelievable service(s); or

Occur when no timely response is received in response to an ADR letter.

When a clear policy (see PIM, chapter 3, section 3.4.1.1) exists or in the case of a medically unbelievable service(s), contractors may automatically deny the services without stopping the claim for routine or complex review, even if documentation is attached. Reviewers must still make a §1879 of the Act limitation on liability determination, which may require routine review. If additional documentation has been requested for a claim and the information has not been received within 45 days, the denial can be counted as an automated review if there was no human intervention. If human intervention occurs, the denials are counted as routine review.

NOTE: The term "clear policy" means a statute, regulation, NCD, coverage provision in an interpretive manual, or LCD specifies the circumstances under which a service will always be considered non-covered or incorrectly coded. Clear policy that will be used as the basis for frequency denials must contain utilization guidelines that the contractor considers acceptable for coverage.

3.5.1.1 - Prepayment Edits

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

Prepayment edits are designed by contractor staff and put in place to prevent payment for non-covered and/or incorrectly coded services and to select targeted claims for review prior to payment. Medical review (MR) edit development is the creation of logic (the edit) that is used during claims processing prior to payment that validates and/or compares data elements on the claim.

Contractors may not install edits that result in the automatic denial of services based solely on the diagnosis of a progressively debilitating disease where treatment may be reasonable and necessary. The appearance of a progressively debilitating disease on a claim or history does not permit automated prepay denials that presume a stage of that disease that negates the effectiveness of treatment. Additionally, when a beneficiary with a progressively debilitating disease experiences an illness or injury unrelated to their progressively debilitating disease, the provider should submit a claim with a primary diagnosis that most accurately reflects the need for the provided service. For example, following a hip replacement in a patient with Alzheimer's Disease, a physical therapy provider should submit a claim using ICD-9 Code V54.81 (aftercare following joint replacement) as the primary diagnosis, not ICD-9 Code 331.0 (Alzheimer's Disease). Automated denials may only be used when the service, in that circumstance, is never reasonable and necessary. For example, an electromyography (EMG) for Alzheimer's may be auto denied because it will never be reasonable and necessary for that ICD code; but EMG may not be auto denied when the claim shows "focal muscular weakness" -- even though that claim also shows Alzheimer's. Physical therapy may not be auto denied solely because multiple sclerosis appears on the claim, but may be if there is no other justification for the service listed. There are stages of the disease at which, for example, physical therapy for gait training will not be effective, but MR must look into the claims history or examine records to make that determination**.**

A. Ability to Target

Contractors must focus edits to suspend only claims with a high probability of being denied on MR. Focused edits reduce provider burdens and increases the efficiency of MR activities. Edits should be specific enough to identify only the services that the contractor determines to be questionable based on data analysis. Prepayment edits must be able to key on a beneficiary's health insurance claim number (HICN), a provider's identification (e.g., provider identification number (PIN), UPIN) and specialty, service dates, and medical code(s) (i.e., HCPCS and/or ICD-9 diagnoses codes). Intermediary edits must also key on Type of Bill (TOB), revenue codes, occurrence codes, condition codes, and value codes.

Medicare fiscal intermediary and carrier systems must be able to select claims for prepayment review using different types of comparisons. At a minimum, those comparisons must include:

- Procedure-to-Procedure – This relationship permits contractor systems to screen multiple services at the claim level and in history.

- Procedure to Provider – For a given provider, this permits selective screening of services that need review.

- Frequency to Time – This allows contractors to screen for a certain number of services provided within a given time period.

- Diagnosis to Procedure – This allows contractors to screen for services submitted with a specific diagnosis. For example, the need for a vitamin Bl2 injection is related to pernicious anemia, absence 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 (carrier) or TOB (FI) – This permits contractors to screen services provided by a certain specialty or TOB.

- Procedure to Place of Service – This allows selective screening of claims where the service was provided in a certain setting such as a comprehensive outpatient rehabilitation facility.

Additional intermediary edits include, but are not limited to, the following:

- Diagnoses alone or in combination with related factors, e.g., all ICD-9-CM codes XXX.X-XXX.X with revenue code (REV) XXX and units greater than X;

- Revenue and/or HCPCS codes, e.g., a REV with a selected HCPCS (REV XXX with HCPCS XXXXX);

- Charges related to utilization, e.g., an established dollar limit for specific REV or HCPCS (REV XXX with HCPCS XXXXX with charges over $500);

- Length of stay or number of visits, e.g., a selected service or a group of services occurring during a designated time period (bill type XXX with covered days/visits exceeding XX); and

- Specific providers alone or in combination with other parameters (provider XX-XXXX with charges for REV XXX).

B. Evaluation of Prepayment Edits

Development or retention of edits should be based on data analysis, identification, and prioritization of identified problems. The contractor must evaluate all service specific and provider specific prepayment edits as follows:

- Automated edits must be evaluated annually.

- All routine or complex review edits must be evaluated quarterly.

These evaluations are to determine their effectiveness and contribution to workload. Contractors shall consider an edit to be effective when an edit 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. 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, if a measurable impact is expected, or if a quarter is too brief a time to observe a change. Contractors should analyze prepayment edits in conjunction with data analysis to confirm or re-establish priorities. Contractors should replace, if appropriate, existing effective edits to address problems that are potentially more costly.

FACTORS CONTRACTORS MUST CONSIDER IN LOOKING AT EDIT EFFECTIVENESS FOR **ESTABLISHED AUTOMATED** EDITS:

- Time and staff needed for review, including appeals reviews. Contractors must implement mechanisms (e.g., manual logs, automated tracking systems) to allow the appeals unit to communicate to the MR unit information such as which denial categories are causing the greatest impact on appeals, the outcome of the appeal) Contractors must maintain and make available to the RO (for (PSCs, the Primary GTL, Associate GTL, and SME) and central office (CO) staff documentation demonstrating that they consider appeals in their edit evaluation process; and

- Specificity of edits in relation to identified problem(s).

- Contractors should note that even an automated edit that results in no denials may be effective so long as the presence of the edit is not preventing the installation of other automated edits.

FACTORS CONTRACTORS MUST CONSIDER IN LOOKING AT EDIT EFFECTIVENESS FOR **ALL OTHER** EDITS:

- Time and staff needed for review, including appeals reviews. Contractors must implement mechanisms (e.g., manual logs, automated tracking systems) to allow the appeals unit to communicate to the MR unit information such as which denial categories are causing the greatest impact on appeals, the outcome of the appeal. Contractors must maintain and make available to RO and CO staff documentation demonstrating that they consider appeals in their edit evaluation process.

- Specificity of edits in relation to identified problem(s);

- Demonstrated change in provider behavior, e.g., the contractor can show the 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 presence of more costly problems identified in data analysis that needs higher priority than existing edits considering the number of claims/days/charges reviewed in comparison to claims/days/charges denied.

Contractors must test each edit before implementation and determine the impact on workload and whether the edit accomplishes the objective of efficiently selecting claims for review.

C. Adding Local Medical Review Policy (LMRP)/Local Coverage Determination (LCD) and National Coverage Determination (NCD) ID Numbers to Edits

The FIs must ensure that any edit that may result in a denial based on an LMRP/LCD or NCD includes the LMRP/LCD or NCD ID number(s) associated with the denial.

The FIs must ensure that any edit that may result in a denial based on a lab negotiated NCD includes the NCD ID number(s) associated with the denial.

The VMS carriers and PSCs must ensure the analysis and design is completed for any edit that may result in a denial based on an LMRP/LCD or NCD includes the LMRP/LCD ID number(s) or NCD ID number(s) associated with the denial.

The MCS carriers must ensure that the analysis and design is completed for any edit that may result in a denial based on an LMRP/LCD or NCD includes the LMRP/LCD ID number(s) or NCD ID number(s) associated with the denial.

The VMS carriers and PSCs must ensure the testing and documentation is completed for any edit that may result in a denial based on an LMRP/LCD or NCD and includes the LMPRP/LCD ID number(s) or NCD ID number(s) associated with the denial. All Medicare Summary Notices (MSNs) must contain the new MSN message for denials based on an LMRP/LCD or NCD.

The MCS carriers must ensure that the testing and documentation is completed for any edit that may result in a denial based on an LMRP/LCD or NCD includes the LMRP/LCD ID number(s) or NCD ID number(s) associated with the denial. All MSNS must contain the new MSN message for denials based on an LMRP/LCD.

D. Payment for Emergency Medical Treatment and Labor Act (EMTALA) - Mandated Screening and Stabilization Services

Under section 1862 of the Social Security Act, as amended by section 944 of the Medicare Modernization Act, in the case of an item or service provided by a hospital or critical access hospital pursuant to section 1867of the Social Security Act (EMTALA) on or after January 1, 2004, FIs must make determinations of whether the item or service is reasonable and necessary on the basis of information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not only on the patient's principal diagnosis). The frequency with which an item or service is provided to the patient before or after the time of the service shall not be a consideration.

The National Uniform Billing Committee designated Form Locator 76 of the UB-92 claim form (837i 2300 HI segment, HI02-2. HI02-1 (the qualifier for HI02-2) must = ZZ. This HI02 is used only once per claim.) to be used for the ICD-9-CM code that represents the patient's reason for the visit in 1999. Recently CMS added edit criteria to require this on an outpatient claim Types of Bill (TOBs) 13X, 14X, 23X, 71X, 73X, 83X, and 85X. Only one diagnosis code may be shown on a claim as the reason for the visit, and that is recorded in Form Locator 76. At the provider's discretion, additional signs and symptoms codes not inherent in the principal diagnosis may be reported in Form Locators 68 through 75 (837i 2300 HI segment, HI01-2. HI01-1 (the qualifier for HI01-2) must = BF. Additional codes may be added in HI02 through HI12). The FIs shall instruct providers that they may use these fields when billing for items or services, including diagnostic tests, performed under EMTALA, and/or when billed with revenue codes 045X, 0516, or 0526 to assure appropriate payment. The system must scan these fields as well for payable diagnosis codes. For LCDs with frequency edits, you must turn off those frequency edits for these services.

The FIs may target MR for potentially aberrant ED billing, but decisions must be based on the information available to the treating physician or practitioner, including the

patient's presenting conditions. FIs will continue to perform their data analysis on EDs to ensure that there are no aberrant patterns of outliers.

The FIs shall reopen claims for ED services provided on or after January 1, 2004, that were previously denied prior to the issuance of this instruction if the provider so requests.

3.5.2– Categories of MR Edits

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

Because it is important to have the flexibility to modify MR edits based on workload demands and changes in provider behavior, contractors are encouraged to ensure that most MR edits are located in the table driven portion of the system and are not hard coded.

For reporting purposes, there are three kinds of prepayment edits:

A. Service-Specific Edits

These are edits that select claims for specific services for review. They may compare two or more data elements present on the same claim (e.g., diagnosis to procedure code), or they could compare one or more data elements on a claim with data from the beneficiary's history file (e.g., procedure code compared to history file to determine frequency in past 12 months).

B. Provider-Specific System Edits

These are edits that select claims from specific providers flagged for review. These providers are singled out due to unusual practice patterns, knowledge of service area abuses, and/or utilization complaints received from beneficiaries or others. These edits can suspend all claims from a particular provider or focus on selected services, place of service, etc. (e.g., all claims for holter monitoring from a given provider).

C. Random Edits

Contractors may no longer operate any random edits.

3.5.3 – CMS Mandated Edits

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

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

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

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

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

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

3.5.4 – Non-random Prepayment Complex Medical Review
(Rev.)

3.6 – Postpayment Review of Claims for MR Purposes
(Rev. 220, Issued: 08-24-07, Effective: 09-03-07, Implementation: 09-03-07)

The instructions listed in this section (section 3.6) apply only to reviews conducted for MR purposes unless otherwise noted.

Postpayment claims review occurs when a contractor makes a coverage or coding determination after a claim has been paid. When a medically unbelievable service(s) exists, contractors may automatically deny the service without the review of the claim. This section describes the requirements that contractors must follow when conducting postpayment claims review for MR purposes. Contractors who are reviewing claims on a postpayment basis for potential fraud case development purposes are not required to follow these requirements.

A. Major Steps

There are nine major steps in the postpayment review process:

Step 1: Selecting the Cases for Review (see PIM Chapter 3, Section 3.6.1)

Step 2: Deciding the Location of the Review (See PIM Chapter 3, Section 3.6.2)

Step 3: Re-Adjudicating the Claims (See PIM Chapter 3, Section 3.6.3)

Step 4: Estimating the Over/Underpayment (See PIM Chapter 3, Section 3.6.4)

Step 5: Notification of Review Results (See PIM Chapter 3, Section 3.6.5)

Step 6: Considering/Responding to a Provider's Rebuttal (See PIM Chapter 3, Section 3.6.6)

Step 7: Recovering the Overpayment (See PIM Chapter 3, Section 3.6.7)

Step 8: Evaluating Postpayment Review and Next Steps (See PIM Chapter 3, Section 3.6.8)

Step 9: Maintaining Files (See PIM Chapter 3, Section 3.6.9)

If at any point in these steps a contractor detects potential fraud, the contractor should not take any further steps in the process but should follow the instructions in section 3.6.8.

B. Adherence to Reopening Rules

When conducting a postpayment review, contractors shall adhere in all cases to reopening rules. (See 42CFR405.750; 20 CFR404.988(b) and 404.989.) A high error rate and/or potential overutilization identified through data analysis are reasons to perform postpay review and represents good cause to reopen claims for that purpose in accordance with 42CFR405.750(b)(2).

3.6.1 - Postpayment Review Case Selection

(Rev. 96, Issued: 01-14-05, Effective: 02-14-05, Implementation: 02-14-05)

Postpayment reviews are usually conducted on providers or suppliers, whether individuals or groups, who have demonstrated aberrant billing and/or practice patterns. However, some postpay reviews (e.g., widespread Error Validation reviews) may involve multiple providers or suppliers.

Contractors must use all available relevant information when selecting postpayment review cases. (See PIM, chapter 3, section 3.2 for Verifying Potential Errors and Setting Priorities.)

There are three types of postpayment reviews:

- Error Validation reviews (see PIM, chapter 3, section 3.2 for more information about Error Validation reviews);

- Statistical Sampling for Overpayment Estimation reviews (see PIM, chapter 3, sections 3.10.1 through 3.10.5 and 3.10.9 through 3.10.11); and

- Consent Settlement reviews (see PIM, chapter 3, section 3.8.3.3).

NOTE: In the process of selecting providers or suppliers for postpay review, MR staff should review their provider tracking system (PTS) and consult with the PSC or Medicare contractor or BI unit to ensure duplicate efforts are not being undertaken. (See PIM, chapter 3, section 3.1.2.)

A. Identifying Providers or Suppliers for Error Validation Reviews

The PIM, chapter 3, section 3.2 describes the requirements regarding which providers or suppliers should be selected for error validation (probe) review.

B. Identifying Providers or Suppliers for Statistical Sampling for Overpayment Estimation Reviews

The first step in conducting a statistical sampling review is the identification of all services under review from the provider or supplier or group of providers or suppliers for the specified time period (this is termed the "universe") followed by selection of a sample of these claims. Contractors work with their statistical staff and follow all statistical sampling guidelines in PIM, chapter 3, sections 3.10.1 through 3.10.5 and 3.10.9 through 3.10.11.

Case selection is based on profiling providers or suppliers who have generated one or more assigned claims during the period under review. Generally contractors should not perform postpay review of unassigned claims. Intermediaries use provider or supplier numbers and carriers use UPINs for physicians and individual PINs for non-physicians. DMERCs should use the NSC issued supplier numbers. As with physician UPINs and PINs, it may be appropriate to analyze suppliers by their six-digit base number and their 10-digit (six-digit base plus four-digit) location ID number. It may be necessary to conduct sub-studies of locality practices for physicians using their PINs because physicians with one UPIN may have different practices with multiple PINs. Their patterns of practice may vary across different locations (e.g., hospital-based, office-based, SNF-based), especially when physicians designate different specialties for their different PINs.

C. Identify Overpayment for Consent Settlement

At a minimum, select fifteen (15) claims as a sample from a three (3) to six (6) month period to identify the overpayment. Project this sample of claims to the universe where the problem is occurring.

3.6.2 - Location of Postpayment Reviews

(Rev. 179, Issued: 12-15-06; Effective: 11-29-06; Implementation: 01-16-07)

This section applies to all three types of postpayment reviews (error validation reviews, statistical sampling for overpayment estimation reviews, and consent settlement reviews).

Contractors must decide whether to conduct the postpay review at the provider or supplier site or at the contractor site. Considerations in determining whether to conduct a provider or supplier site review are:

- The extent of aberrant patterns identified in their focused review program; (See PIM chapter 3, section 3.2);

- The past failure of a provider or supplier to submit appropriate and timely medical records; and

- Contractor resources.

A. Contractor Site Reviews

The contractor notifies the provider(s) or supplier(s) that they have 30 calendar days from the date of the letter to provide the medical record or other requested documentation. (See PIM Exhibit 7.2 for a sample letter.) Contractors have the discretion to grant an extension of the timeframes upon request.

If the information requested is **NOT** received within the allowed timeframe (or allowed extended time frame), the contractor shall review the claims with the information on hand. Contractors shall make a medical review determination, and mail the notification letter to the provider or supplier within 60 calendar days from the end of the allowed timeframe or allowed extended timeframe. If the contractor needs more than 60 calendar days, they must request an extension from the RO (for PSCs, the Primary GTL, Associate GTL, and SME).

B. Provider or Supplier Site Reviews

Contractors determine what, if any, advance notification of a scheduled review is given to a provider or supplier. The contractor may give advance notice when a provider or supplier has satellite offices from which medical records will have to be retrieved. When giving advance notice, the contractor shall include an explanation of why the review is being conducted.

The list of claims requiring medical records may be included with the advance notice or at the time of the visit at the discretion of the contractor.

Contractors may conduct team reviews when potential problems exist in multiple areas. The team may consist of MR, audit, BI, State surveyors, provider enrollment or Medicaid staff depending on the issues identified. As a minimum, before conducting provider or supplier site reviews, consult and share information with other internal and external staff as appropriate to determine if there are issues that the reviewers should be aware of or if a team review is needed.

Annually, contractors shall instruct providers or suppliers (via bulletin article, Web article, etc.) that any Medicare contractor staff person who visits the provider or supplier site shall show a photo identification indicating their affiliation with the Medicare contractor. Contractors shall provide to all reviewers who participate in provider or supplier site reviews a photo identification card indicating the reviewer's affiliation with the Medicare contractor. To perform provider or supplier site reviews, all reviewers shall present photo identification cards indicating their affiliation with the Medicare contractor to the provider or supplier staff and other reviewers on site.

During provider or supplier site reviews, reviewers shall photocopy pertinent medical records when services are denied, when a physician or other medical consultation is needed, or when it appears that records have been altered. Contractors shall retain these records for appeals or BI purposes.

Reviewers shall hold entrance and exit interviews with appropriate provider or supplier staff. A provider or supplier representative can also be present while claims are reviewed. Reviewers shall answer any questions the provider or supplier staff may have.

During entrance interviews, reviewers explain the following:

- Scope and purpose of the review;
- Why postpayment review is being conducted;
- The list of claims that require medical records;
- How recumbent of overpayment is made if claims are denied;
- Answer any questions related to the review; and
- Notify the provider or supplier of their rebuttal rights. (See PIM, chapter 3, section 3.6.6.)

During exit conferences, the contractor shall discuss the findings of the review. The provider or supplier must be allowed an opportunity to discuss or comment on the claims decisions.

3.6.3 - Re-adjudication of Claims

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

This section applies to all three types of postpayment reviews (error validation reviews, statistical sampling for overpayment estimation reviews, and consent settlement reviews).

For each claim in the sample, contractors re-adjudicate claims by making a coverage, limitation of liability and/or coding determination in accordance with PIM, chapter 3, section 3.4.1. Contractors must document all items/services incorrectly paid, denied or under coded (e.g., billed using a HCPCS or other code that is lower than what is supported by the medical record). They report services newly denied as a result of re-adjudication as positive values and they report services that were denied but are reinstated as a result of re-adjudication as negative values. Contractors document the amount of the over/underpayment and how it was determined. Intermediaries must do this in conjunction with Audit/Reimbursement staff. (See PIM, chapter 3, section 3.8.4.) Contractors must assure that their documentation is clear and concise and includes the basis for revisions in each case (this is important for provider appeals). They include copies of the NCD, coverage provision in interpretive manual or LCD and any applicable

references needed to support individual case determinations. Compliance with these requirements facilitates adherence to the provider or supplier notification requirements in PIM, chapter 3, section 3.6.5.

3.6.4 - Calculation of the Correct Payment Amount and Subsequent Over/Underpayment

(Rev. 96, Issued: 01-14-05, Effective: 02-14-05, Implementation: 02-14-05)

This section applies to two types of postpayment reviews (statistical sampling for overpayment estimation reviews, and consent settlement reviews).

The results of the re-adjudication within the sampling units are used to determine the total overpayment amount for each provider or supplier under review. MR shall refer to instructions in PIM, chapter 3, §3.10 and to Exhibits 9, 10, 11 and 12 for projection methodologies based on provider types for claims where PPS was not in effect. For claims paid under PPS rules, contractors should develop projection methodologies in conjunction with their statistician that are consistent with the requirements found in PIM, chapter 3, section 3.10. Contractors must net out the dollar amount of charges underbilled.

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

- Initially paid claims which are denied on re-adjudication, and for which the provisions of §1879 of the Act apply and the provider or supplier is liable for the overpayment because: (1) the provider or supplier knew or could reasonably have been expected to know that items or services were excluded from coverage, and (2) the provider or supplier was not without fault for the overpayment under §1870 of the Act.

- Initially paid claims which are denied on re-adjudication, and for which the provisions of §1879 do not apply, but the provider or supplier is liable because it is determined to be not without fault for the overpayment under §1870 of the Act.

- Initially denied claims which are found to be payable on readjudication (in whole or in part). Such claims should be included to reduce the amount of the overpayment sample. For appeal purposes, overpayment estimations will be separately identified for denials in which §1879 of the Act is applied, and denials in which §1879 of the Act does not apply. Where both types of denials occur in the sample, contractors calculate and document separate under/overpayments for the two types of denials. For recovery purposes, however, both denial results are combined.

3.6.5 – Notification of Provider(s) or Supplier(s) and Beneficiaries of the Postpayment Review Results

(Rev. 149, Issued: 06-30-06, Effective: 07-31-06, Implementation: 07-31-06)

This section applies to all three types of postpayment reviews (error validation reviews, statistical sampling for overpayment estimation reviews, and consent settlement reviews).

A. Provider or Supplier Notification

Contractor MR staff must prepare a letter to notify each provider or supplier of the results of the postpayment review. These letters may (but are not required to) contain a demand for repayment of any overpayments they may have made. Some contractors may wish to have another department issue the actual demand letter. Contractors must notify the provider(s) that the postpayment review has been completed even in those instances where no corrective actions or overpayments are involved.

Contractors must send the Notification of Postpayment Review Results to each provider or supplier within 60 days of the exit conference (for provider or supplier site reviews) or receipt of medical records (for contractor site reviews). If the contractors need more than 60 days, they are to contact their RO (for PSCs, the Primary GTL, Associate GTL, and SME) for an extension. Each letter must include:

- Identification of the provider(s) or supplier(s)--name, address, and provider or supplier number;

- The reason for conducting the review;

- A narrative description of the overpayment situation: state the specific issues involved which created the overpayment and any pertinent issues as well as any recommended corrective actions the provider should consider taking;

- 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 including the actual amounts determined to be noncovered, the specific reason for noncoverage, the amounts denied, the amounts which will not be recovered from the provider or supplier, under/overpayment amounts and the §§1879 and 1870 determinations made for each specific claim;

- For statistical sampling for overpayment estimation reviews, any information required by PIM, chapter 3, section 3.10.4.4;

- Total underpayment amounts;

- Total overpayment amounts for which the provider or supplier is responsible;

- Total overpayment amounts for which the provider or supplier is not responsible because the provider or supplier was found to be without fault;

- Intermediaries must include an explanation that subsequent adjustments may be made at cost settlement to reflect final settled costs;

- An explanation of the provider's or supplier's right to submit a rebuttal statement prior to recoupment of any overpayment (see PIM Chapter 3, Section 3.6.6);

- 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, and the provider's or supplier's right to request an extended repayment schedule;

- The provider or supplier appeal rights; and

- A discussion of any additional corrective actions or follow-up activity the contractor is planning (i.e., prepayment review, re-review in 6 months).

Contractors may send the final notification letter by certified mail and return receipt requested.

When the contractor is aware that the provider or supplier is no longer occupying a physical address, the notification letter shall only reference the claim control numbers and not list the individual beneficiary data, e.g., names and health insurance claim numbers.

The following are situations where the contractor can assume the provider or supplier no longer occupies the location. This list is not exhaustive and the contractor shall use discretion in other situations.

1. The contractor has on file mail that has been returned by the post office indicating the provider or supplier no longer occupies the address or the address is unknown;

2. An onsite visit has confirmed the address is vacant or is occupied by another occupant; or

3. A beneficiary complaint(s) is on record stating the provider or supplier is no longer at the address. A follow-up telephone call is made and confirmed that the provider or supplier is no longer at the address.

In the above situations, the contractor shall only mail the notification letter with the claim control number stating the overpayment amount and advising the provider or supplier to contact the contractor for a listing of the specific claims associated with the overpayment. This process will prevent the potential compromise of Medicare beneficiary names and/or HIC numbers 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.

B. Beneficiary Notification

Contractors must also notify each beneficiary when re-adjudication of the claim results in a change to the initial determination. This can be done via an MSN or individual letter. In

the case where a sample of claims is extrapolated to the universe, only those beneficiaries in the sample need to be notified.

3.6.6 - Provider(s) or Supplier(s) Rebuttal(s) of Findings
(Rev. 96, Issued: 01-14-05, Effective: 02-14-05, Implementation: 02-14-05)

This section applies to all three types of postpayment reviews (error validation reviews, statistical sampling for overpayment estimation reviews, and consent settlement reviews).

A. Provider(s) or Supplier(s) Timeframes for Submitting Rebuttal Statements

Within 15 calendar days of notification of the results, each provider or supplier may submit a rebuttal statement in accordance with 42 CFR 405.374. The rebuttal statement and any accompanying evidence must be submitted within 15 calendar days from the date of the notification letter described in section 3.6.5 unless MR or Audit/Reimbursement (A/R) staff find cause otherwise to extend or shorten the time afforded for submission of the statement.

B. Contractor Review of Rebuttal Statement(s)

Audit/Reimbursement staff should consider all of the evidence concerning the provider's or supplier's financial obligation timely submitted to reach a determination regarding whether recoupment should be delayed. However, recovery of any overpayment will not be delayed beyond the date indicated in the notification 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).)

Prior to recoupment of overpayments, providers or suppliers have a right to submit a rebuttal statement in accordance with 42 CFR 405.370-375. The rebuttal statement and any accompanying evidence must be submitted within 15 days from the date of the notification letter unless Audit/Reimbursement staff find cause otherwise to extend or shorten the time afforded for submission of the statement. The provider's or supplier's rebuttal statement should address why the recovery should not be put into effect on the date specified in the notification letter. Audit/Reimbursement staff should consider all of the evidence timely submitted to reach a determination regarding whether the recoupment should be delayed. However, recovery of any overpayment will not be delayed beyond the date indicated in the CMR notification letter in order to review and respond to the rebuttal statement. (See 42 CFR 405.375(a).)

Substantive evidence that MR claims determinations were incorrect shall not be considered during the rebuttal process unless such evidence relates to the timing of the recoupment of the overpayment.

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 or supplier 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.

3.6.7 - Referral of Overpayments
(Rev. 71, 04-09-04)

This section applies to all three types of postpayment reviews (error validation reviews, statistical sampling reviews, and consent settlement reviews).

Contractor MR staff shall refer all overpayments to overpayment staff for recoupment. PSCs shall refer all overpayments to the AC for recoupment.

3.6.8 – Evaluation of the Effectiveness of Postpayment Review and Next Steps
(Rev. 135, Issued: 01-06-06, Effective: 02-06-06, Implementation: 02-06-06)

This section applies to all three types of postpayment reviews (error validation reviews, statistical sampling for overpayment estimation reviews, and consent settlement reviews).

Contractors must determine if any other corrective actions are necessary such as:

- In cases where the MR unit uncovers potential fraud in the course of its postpayment review activities, the MR unit shall refer these cases to the Medicare contractor BI unit or the PSC. If it is believed that the overpayment has been caused by fraud, do not request a refund until the fraud issue is resolved (see PIM, chapter 3, section 3.8).

- Initiate provider or supplier specific edit to focus prepayment review on the problem provider or supplier or group of providers or suppliers (see PIM, chapter 3, section 3.5.1) if appropriate;

- Work with the RO (for PSCs, the Primary GTL, Associate GTL, and SME) to suspend payment to the provider or group of providers (see PIM, chapter 3, section 3.9);

- Refer provider certification issues to the State survey agency through the RO (for PSCs, the Primary GTL, Associate GTL, and SME) staff.

- Refer quality issues involving inpatient hospital services, if any, to the QIO;

- Coordinate with the QIO and carrier/intermediary on interrelated billing problems;

Contractors perform a follow-up analysis of the provider(s) or supplier(s) periodically 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 3 month time period. Contractors must continue monitoring the provider or supplier or group of providers or suppliers until there is a referral to the Medicare contractor BI unit or the PSC, there is evidence that the utilization problem is corrected, or data analysis indicates resources would be better utilized elsewhere.

3.6.9 - Postpayment Files

(Rev. 135, Issued: 01-06-06, Effective: 02-06-06, Implementation: 02-06-06)

Contractors must establish an audit trail that identifies:

- Claims and beneficiaries selected;
- The period of review;
- The reason for the review (aberrancy validation, high provider error rate, wide-spread service-specific problem.); and
- Findings to show why the original claim determination was changed. The documentation must be clear and concise, and include the basis for revision.

Contractors must complete a Summary Report for each postpayment review case. Include in the report:

- The reason(s) the provider or group of providers was selected for review;
- A chronological record of all review events and actions;
- The information used to perform the review (e.g., relevant LMRP)
- A record of all decisions made and all actions taken to deal with the provider's MR problem, including who made the decisions and the reasons for taking the actions;
- Documentation of statistical methods used if overpayment is projected;
- Whenever possible, postpayment savings in terms of actual overpayment, settlement based, or statistically extrapolated;
- A record of all contacts with providers or beneficiaries; and
- Documentation of §§1879, 1870, or 1842(1) determinations. (See PIM Exhibit 14.)

Retain the summary report and all postpay files for 36 months following the conclusion of a postpay case unless the RO (for PSCs, the Primary GTL, Associate GTL, and SME) requires a longer period or unless the case is referred to the PSC or Medicare contractor BI unit (and in this case, retain the files for the longer of 36 months or the completion of the investigation). A sample summary report is found in Exhibit 13. Contractors have the option of using an alternate format for the postpay summary report with RO (for PSCs, the Primary GTL, Associate GTL, and SME) approval.

3.7 - Appeal of Denials
(Rev. 71, 04-09-04)

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 405.841(a), (b), and (c).) 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 Carriers Manual §12000, 42 CFR 405.841, and 20 CFR 404.989.) 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.

3.8 – Overpayment Procedures

(Rev. 282, Issued: 01-08-09 , Effective: 01-26-09, Implementation: 01-26-09)

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 3, §3.10.)

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.

3.8.1 – Overpayment Assessment Procedures

(Rev. 71, 04-09-04)

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

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	

3.8.1.1 – Definition of Overpayment Assessment Terms
(Rev. 71, 04-09-04)

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.

3.8.2 – Assessing Overpayment When Review Was Based on Statistical Sampling for Overpayment Estimation
(Rev. 71, 04-09-04)

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.

3.8.3 – Assessing Overpayment or Potential Overpayment When Review Was Based on Limited Sample or Limited Sub-sample
(Rev. 71, 04-09-04)

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 3, §3.10 and recoup the projected overpayment; or

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

3.8.3.1 – Contractor Activities to Support Assessing Overpayment
(Rev. 71, 04-09-04)

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 chapter 3 §3.6.7 and Exhibit 14.1);

- The §1870 determination for the provider for each overpaid assigned claim in the sample (see 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.

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

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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 3, §3.10, 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.

3.8.3.3 - Consent Settlement Instructions

(Rev. 96, Issued: 01-14-05, Effective: 02-14-05, Implementation: 02-14-05)

3.8.3.3.1 - Background on Consent Settlement

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.8.3.3.2 - Opportunity to Submit Additional Information Before Consent Settlement Offer

(Rev. 96, Issued: 01-14-05, Effective: 02-14-05, Implementation: 02-14-05)

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.

3.8.3.3.3. - Consent Settlement Offer

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.8.3.3.4 - Option 1 - Election to Proceed to Statistical Sampling for Overpayment Estimation

(Rev. 184, Issued: 01-26-07; Effective/Implementation Dates: 02-26-07)

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 3, §3.10

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

3.8.3.3.5 - Option 2 - Acceptance of Consent Settlement Offer
(Rev. 96, Issued: 01-14-05, Effective: 02-14-05, Implementation: 02-14-05)

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.

3.8.3.3.6 - Consent Settlement Budget and Performance Requirements for ACs
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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

3.8.4 - Coordination With Audit and Reimbursement Staff
(Rev. 71, 04-09-04)

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 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.

3.9 – Suspension of Payment

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.1 – When Suspension of Payment May Be Used

(Rev. 71, 04-09-04)

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.

3.9.1.1 – Fraud or Willful Misrepresentation Exists - Fraud Suspensions

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

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

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.1.3 – Payments to be Made May Not be Correct - General Suspensions

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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".

3.9.1.4 –Provider Fails to Furnish Records and Other Requested Information - General Suspensions

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.2 – Procedures for Implementing Suspension of Payment
(Rev. 71, 04-09-04)

3.9.2.1 – CMS Approval
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.2.2 – The Notice of Intent to Suspend
(Rev. 71, 04-09-04)

3.9.2.2.1 – Prior Notice Versus Concurrent Notice
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.2.2.2 – Content of Notice

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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% 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*.

3.9.2.2.3 – Shortening the Notice Period for Cause

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.2.2.4 – Mailing the Notice to the Provider

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.2.2.5 – Opportunity for Rebuttal

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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*.

3.9.2.3 – Claims Review During the Suspension Period
(Rev. 71, 04-09-04)

3.9.2.3.1 – Claims Review
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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% pre-pay medical review of suspended claims. *If 100% prepayment review*

is not conducted, a 100% 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 3, §3.10, 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).)

3.9.2.3.2 – Case Development – Benefit Integrity

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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).

3.9.2.4 – Duration of Suspension of Payment

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.2.5 – Removing the Suspension

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.2.6 – Disposition of the Suspension

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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 3, §3.8.) 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.

3.9.2.7 – Contractor Suspects Additional Improper Claims

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.3 – Suspension Process for Multi-Region Issues
(Rev. 71, 04-09-04)

3.9.3.1 –DME MACs and DME PSCs*, and ZPICs*
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.9.3.2 – *Reserved for Future Use*
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

3.10 - Use of Statistical Sampling for Overpayment Estimation
(Rev. 71, 04-09-04)

3.10.1 – Introduction
(Rev. 71, 04-09-04)

3.10.1.1 – General Purpose
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.1.2 - The Purpose of Use of Statistical Sampling
(Rev. 114, Issued: 06-10-05, Effective: 12-08-04, Implementation: 05-31-05)

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.

3.10.1.3 - Steps for Conducting Statistical Sampling

(Rev. 114, Issued: 06-10-05, Effective: 12-08-04, Implementation: 05-31-05)

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.

3.10.1.4 - Determining When Statistical Sampling May Be Used

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.1.5 - Consultation With a Statistical Expert

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.1.6 - Use of Other Sampling Methodologies

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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).

3.10.2 - Probability Sampling

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.3 - Selection of Period to be Reviewed and Composition of Universe
(Rev. 71, 04-09-04)

3.10.3.1 - Selection of Period for Review
(Rev. 114, Issued: 06-10-05, Effective: 12-08-04, Implementation: 05-31-05)

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 Carriers and Intermediary Manuals: MCM, Part 3, chapter XII, section 12100, and MIM, Part 3, chapter VIII, section 3799, for Reopening Standards).

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.**

3.10.3.2 - Defining the Universe, the Sampling Unit, and the Sampling Frame

(Rev. 114, Issued: 06-10-05, Effective: 12-08-04, Implementation: 05-31-05)

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.

3.10.3.2.1 - Composition of the Universe

(Rev. 114, Issued: 06-10-05, Effective: 12-08-04, Implementation: 05-31-05)

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.

3.10.3.2.2 - The Sampling Unit
(Rev. 114, Issued: 06-10-05, Effective: 12-08-04, Implementation: 05-31-05)

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.

3.10.3.2.3 - The Sampling Frame
(Rev. 71, 04-09-04)

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.

3.10.4 - Sample Selection
(Rev. 71, 04-09-04)

3.10.4.1 - Sample Design
(Rev. 71, 04-09-04)

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.

3.10.4.1.1 - Simple Random Sampling
(Rev. 71, 04-09-04)

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.)

3.10.4.1.2 - Systematic Sampling
(Rev. 71, 04-09-04)

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.

3.10.4.1.3 - Stratified Sampling
(Rev. 114, Issued: 06-10-05, Effective: 12-08-04, Implementation: 05-31-05)

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 3.10.11.1.

3.10.4.1.4 - Cluster Sampling

(Rev. 114, Issued: 06-10-05, Effective: 12-08-04, Implementation: 05-31-05)

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 3.10.11.2.

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.

3.10.4.1.5 - Design Combinations

(Rev. 71, 04-09-04)

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."

3.10.4.2 - Random Number Selection

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.4.3 - Determining Sample Size

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.4.4 - Documentation of Sampling Methodology

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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

3.10.4.4.1 - Documentation of Universe and Frame

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.4.4.2 - Arrangement and Control Totals

(Rev. 71, 04-09-04)

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.

3.10.4.4.3 - Worksheets

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.4.4.4 - Overpayment/Underpayment Worksheets
(Rev. 71, 04-09-04)

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.

3.10.4.5 - Informational Copies to Primary GTL, Associate GTL, SME or CMS RO
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.5 - Calculating the Estimated Overpayment
(Rev. 71, 04-09-04)

3.10.5.1 - The Point Estimate
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.)

3.10.5.2 - Calculation of the Estimated Overpayment Amount
(Rev. 71, 04-09-04)

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.

3.10.6 - Actions to be Performed Following Selection of Provider or Supplier and Sample
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.6.1 – Notification of Provider or Supplier of the Review and Selection of the Review Site
(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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).

3.10.6.1.1 - Written Notification of Review

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.6.1.2 - Determining Review Site

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

3.10.6.2 - Meetings to Start and End the Review
(Rev. 71, 04-09-04)

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.

3.10.6.3 - Conducting the Review
(Rev. 71, 04-09-04)

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.

3.10.7 - Overpayment Recovery

(Rev. 71, 04-09-04)

3.10.7.1 - Recovery From Provider or Supplier

(Rev. 282, Issued: 01-08-09, Effective: 01-26-09, Implementation: 01-26-09)

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.

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

(Rev. 135, Issued: 01-06-06, Effective: 02-06-06, Implementation: 02-06-06)

Send an informational copy of the demand letter to the Primary GTL, Associate GTL, SME or 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 RO.

3.10.8 - Corrective Actions

(Rev. 71, 04-09-04)

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.

3.10.9 - Changes Resulting From Appeals

(Rev. 71, 04-09-04)

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.

3.10.9.1 - Sampling Methodology Overturned

(Rev. 135, Issued: 01-06-06, Effective: 02-06-06, Implementation: 02-06-06)

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 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.

3.10.9.2 - Revised Initial Determination
(Rev. 71, 04-09-04)

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.

3.10.10 - Resources
(Rev. 71, 04-09-04)

American Institute of Certified Public Accountants, Statistical Sampling Subcommittee, Audit Sampling, 1999.

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Hansen, M. H., Hurwitz, W. W., and Madow, W. G., Sample Survey Methods and Theory, New York: John Wiley and Sons, 1953 (Paperback 1993).

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Levy, P. and Lemeshow, S., Sampling of Populations Methods and Applications, 3rd ed., John Wiley & Sons, 1999.

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3.10.11 - Additional Discussion of Stratified Sampling and Cluster Sampling
(Rev. 71, 04-09-04)

3.10.11.1 – Stratified Sampling
(Rev. 71, 04-09-04)

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.

3.10.11.2 - Cluster Sampling
(Rev. 71, 04-09-04)

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.

3.11 – Progressive Corrective Action (PCA)
(Rev. 71, 04-09-04)

3.11.1 – General Information

(Rev. 71, 04-09-04)

The principles of Progressive Corrective Action (PCA) provide further guidance, underlying principles and approaches to be used in deciding how to deploy resources and tools for medical review. These concepts are already part of existing manual instructions (e.g., how to conduct medical review) but are amplified here for easy understanding of expectations and basic requirements. Listed below are some key steps that are important for efficient and effective use of medical review resources and tools.

For Medicare to consider coverage and payment for any item or service, the information submitted by the supplier or provider (e.g., claims and CMNs) must be corroborated by the documentation in the patient's medical records that Medicare coverage criteria have been met. The patient's medical records include: physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and/or test reports. This documentation must be maintained by the physician and/or provider and available to the contractor upon request.

This supporting information may be requested by CMS and its agents on a routine basis in instances where diagnoses on the claims or CMN do not clearly indicate medical necessity. For example, documentation supporting the medical necessity of a power wheelchair would not be requested in the vast majority of cases where patients have definite medical conditions such as neurological spinal cord injury, cerebral palsy, MS or stroke with residual meiplegia (not all inclusive). On the other hand, it is more likely that documentation would be requested for patients whose diagnoses are limited to non-neurological conditions such as COPD, congestive heart failure, coronary artery disease, arthritis or obesity (not all inclusive).

The contractor medical review staff employs a number of procedures to identify claims that do not definitively indicate medical necessity. These techniques include data analysis, beneficiary complaints, alerts from other organizations, and others.

Once a contractor identifies a claim using one or more of the above procedures, the contractor requests supporting documentation in the form of medical records as referenced above.

3.11.1.1 – Review of Data

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

Data analysis is an essential first step in determining whether patterns of claims submission and payment indicate potential problems. Such data analysis may include simple identification of aberrancies in billing patterns within a homogeneous group, or much more sophisticated detection of patterns within claims or groups of claims that might suggest improper billing or payment.

Data analysis itself may be undertaken as part of general surveillance and review of submitted claims, or may be conducted in response to information about specific

problems stemming from complaints, provider or beneficiary input, fraud alerts, reports from CMS, other contractors, or independent government and nongovernmental agencies.

3.11.1.2 - "Probe" Reviews

(Rev. 123, Issued: 09-23-05, Effective: 02-01-05, Implementation: 10-24-05)

Before deploying significant medical review resources to examine claims identified as potential problems from data analysis, take the interim step of selecting a small "probe" sample of 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. Such a sample should be large enough to provide confidence in the result, but small enough to limit administrative burden

For post-pay review of an individual provider in the case of a possible provider specific problem, contractors should include in the probe sample a random or stratified sample of generally 20 -40 claims from that provider with dates of service from the period under review. For post-pay review in the case of a possible systemic problem, the contractor should generally include a random or stratified sample of 100 claims with dates of service from the period under review from across all providers or suppliers that bill the particular item or service in question.

For pre-pay review of an individual provider in the case of a possible provider specific problem, contractors should generally use the first 20 -40 claims submitted by the individual provider. For pre-pay review in the case of a possible systemic problem, the contractor should include a random or stratified sample of generally 100 claims submitted from across all providers or suppliers that bill the particular item or service in question.

We recognize that in the pre-payment setting, obtaining a certain number of claims may be impossible if the provider stops billing Medicare.

For provider specific problems, notify providers (in writing or by telephone) that a probe sample is being done and of the result of the probe review. Contractors may use a letter similar to the letters in Program Integrity Manual (PIM) Exhibit 7 when notifying providers of the probe review and requesting medical records. Contractors may advise providers of the probe sample at the same time that medical records are requested.

Generally, a provider should be subject to no more than one probe review at any time; however, multiple probes may be conducted for very large billers as long as they will not constitute undue administrative burden.

For service specific probes (widespread probes) contractors must attempt to narrow the focus of the review so as to not place undue burden on providers. Contractors must strive to target only aberrant providers, to the extent possible, during the course of widespread probe reviews.

3.11.1.3 – Target Medical Review Activities

(Rev. 71, 04-09-04)

Subject providers only to the amount of medical review necessary to address the nature and extent of the identified problem.

After validating that claims are being billed in error, target medical review activities at providers or services that place the Medicare trust funds at the greatest risk while ensuring the level of review remains within the scope of the budget for medical review; that is, does not vary widely from the level of review set out in the budget and performance requirements (BPRs). This will ensure resources are available to follow through with the PCA process for targeted providers or services. Ensure that actions imposed upon Medicare providers for failure to meet Medicare rules, regulations and other requirements are appropriate given the level of non-compliance (e.g., a small level of non-compliance would not warrant 100% prepayment medical review).

3.11.1.4 - Requesting Additional Documentation

(Rev. 91, Issued: 12-10-04, Effective: 01-01-05, Implementation: 01-03-05)

When requesting additional documentation for medical review purposes notify providers that the requested documentation is to be submitted to the contractor within 30 days of the request. If no response is received within 45 days after the date of the request (or extension), the contractor must deny the service as not reasonable and necessary (except for ambulance claims where the denial may be based on §1861(s)(7) or §1862(a)(1)(A) of the Act. Do not return the claim to the provider (RTP). If the claim is denied, deny payment or collect the overpayment. Fiscal intermediaries must reverse the claims denied on post pay review from the claims processing system so they do not appear on the Provider Statistical and Reimbursement Report.

3.11.1.5 – Provider Error Rate

(Rev. 71, 04-09-04)

The provider error rate* is an important consideration in deciding how to address the problem.

Other factors, though, deserve consideration as well--such as the total dollar value of the problem and past history of the provider. Assess the nature of the problem as minor, moderate or significant concerns and use available tools appropriate to characterize the problem. Section 3.11.3 provides some vignettes for guidance on how to characterize and respond to varying levels of problems.

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

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

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 underbilled

3.11.1.6 – Provider Notification and Feedback

(Rev. 220, Issued: 08-24-07, Effective: 09-03-07, Implementation: 09-03-07)

Provider notification and feedback is an essential part of solving problems.

Provider notification and feedback means direct communication between the contractor and the provider through written communication and may follow up by telephone as a result of or directly related to a specific claim or group of claims reviewed on probe or complex medical review. The overall goal of providing notification and feedback is to ensure proper billing practices so that claims will be submitted and paid correctly. Remove providers from medical review as soon as possible when they demonstrate compliance with Medicare billing requirements, based on follow-up data analysis conducted by the MR department.

Contractors shall send written notification to all providers when they are placed on medical review and removed from medical review. We recognize that some providers may remain on medical review for long periods of time, despite interventions and use of the PCA concepts. In the case of "extended medical review", meaning the provider that remains on medical review beyond 6 months or until they are referred to BI or have evidence that the problem or utilization (behavior) is corrected, provide written notification at least every 6 months. Notification letters must be clear and concise and must include at least the following information: the reasons for medical review; previous review findings (if applicable); planned medical review (level of review and duration), potential for continuation of or increase in medical review levels (if identified problems continue, additional problems are identified, etc.); description of the specific actions the provider must take to resolve the problems identified in the medical review process.

When appropriate, an offer to provide individualized education may be included in the notification letter, along with contact information for POE, the department which will be responsible for further educating on the topic. 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 should be charged to Medical Review, in the appropriate CAFM activity code for the type of review performed.

Comparative Billing Reports

Contractors can develop and issue comparative billing reports in 3 situations: (1) Included in provider-specific notification and feedback letter, (2) provider-specific reports for individuals who have requested a report, and (3) service-specific reports.

1) Provider-specific reports.

To address potential over-utilization, contractors may give provider-specific comparative billing reports to those providers that demonstrate the highest utilization for the services they bill, to be included in the feedback and notification letters issued as a result of probe or targeted medical review. These reports must provide comparative data on how the provider varies from other providers in the same specialty payment area or locality. Graphic presentations may help to communicate the provider's billing pattern more clearly. Contractors may NOT charge a fee for providing these reports.

2) Provider-specific or specialty-specific comparative billing reports for requestors.

In order to provide good customer service, contractors may give provider-specific reports to providers or provider associations who request such a report. Contractors may charge a fee for providing these discretionary reports. However, any money collected must be reported as a credit in the applicable CAFM II Activity and accompanied with a rationale for charging the fee. Revenues collected from these discretionary activities must be used only to cover the cost of these activities, and may not be used to supplement other contractor activities. If contractors choose to make such reports available, contractors must describe on their website the mechanism by which a provider or provider association can request such a report and the fee for it.

3) Service-specific comparative billing reports.

When widespread problems are verified, contractors should refer that information to POE for possible Web site posting. Contractors may NOT charge a fee for posting these reports.

The contractor shall ensure that POE staff have ready access to copies of all MR provider notification and feedback letters so that POE staff will have this information available should a provider contact POE requesting education. If the problem identified by MR is of medium or high priority, a priority referral may also be made to POE, to alert POE staff to the degree of severity and educational need.

3.11.1.7 – Overpayments
(Rev. 71, 04-09-04)

All overpayments identified must be collected or offset, as appropriate, as determined by CMS directives and your overpayment collection procedures.

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

At any time, if the medical review detects possible fraud, refer the issue to the appropriate Program safeguard contractor. See Pub. IOM 100-08, chapter 4, §2.1-Examples of Medicare fraud.

The PCA requirements do not apply when a fraud development is initiated.

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

Track contacts with individual providers through a provider tracking system (PTS).

The PTS will identify all individual providers and track all contacts made as a result of actions taken by MR to notify the provider of and to correct identified problems. Record the name of the person contacted in the PTS. Use the PTS to coordinate contacts with providers (e.g., medical review contacts directly related to probe or complex medical reviews). If a provider is contacted as a result of more than one problem, ensure that multiple contacts are necessary, timely and appropriate, not redundant. Coordinate this information with the PSC Benefit Integrity unit to assure contacts are not in conflict with benefit integrity related activities. Also, maintain communication regarding these contacts with POE for any cases referred to that unit.

The PTS should contain the date a provider is put on a provider specific edit for medical review. Reassess all providers on medical review quarterly to determine if their behavior has changed. Note the results of the quarterly assessment in the PTS. If the behavior has resolved sufficiently and the edit was turned off, note the date the edit was turned off in the PTS. When a provider appeals a medical review determination to the administrative law judge (ALJ), share appropriate information in the PTS with the ALJ to demonstrate corrective actions that you have taken. This instruction does not alter the existing appeal process used by providers.

3.11.1.10 – Track Appeals
(Rev. 71, 04-09-04)

Track and consider the results of appeals in your medical review activities.

It is not an efficient use of medical review resources to deny claims that are routinely appealed and reversed. When such outcomes are identified, take steps to (1) understand why hearing or appeals officers viewed the case differently than you did; and (2) discuss appropriate changes in policy, procedure, outreach or review strategies with your regional office.

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

Contractors shall communicate with specific providers about the aspects of PCA performed by MR. Include PCA as a regular part of your ongoing medical review training and new provider orientation training.

NOTE: Provider includes physicians, suppliers, etc. A definition of provider can be found in the PIM Exhibit 1.

3.11.3 – Vignettes

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

The following are examples of vignettes that may result from medical review accompanied by suggested administrative actions. This information should be used only as a guide. It is not meant to be a comprehensive list of possible vignettes or an inclusive list of appropriate administrative actions. Also, contractor MR departments must include communication and follow-up with POE throughout the PCA process to ensure coordinated efforts toward problem resolution. The contractor shall ensure that POE staff have ready access to copies of all MR provider notification and feedback letters so that they may be prepared for provider requests for education and monitor for trends warranting widespread education (See Pub. 100-04, §20.3.4.2, for further information).

1. Twenty claims are reviewed. One claim is denied because a physician signature is lacking on the plan of care. The denial reflects 7% of the dollar amount of claims reviewed. Judicious use of medical review resources indicates no further review is necessary at this time. Data analysis will determine where medical review activities should be targeted in the future.

2. Forty claims are reviewed. Twenty claims are for services determined to be not reasonable and necessary. These denials reflect 50% 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 contractor 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 are reviewed. Thirty-five claims are denied. These denials reflect 70% of the dollar amount of claims reviewed. Payment suspension is initiated due to the high denial percentage and the Medicate dollars at risk. The contractor 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.

4. Forty claims are reviewed. Thirty-three claims are denied. These denials reflect 25% of the dollar amount of the claims reviewed. The contractor provides notification to the provider about specific errors made. The contractor initiates a moderate amount (e.g., 30%) of prepayment medical review to ensure proper billing.

5. Thirty-five claims are reviewed. Thirty claims are denied representing 75% of the dollar amount of the claims reviewed. Many of the denials are because services were provided to beneficiaries who did not meet the Medicare eligibility requirements. The contractor 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 a statistical sample for overpayment estimation is performed and an overpayment is projected to the universe. Overpayment collection is initiated.

6. Twenty-five claims are reviewed. Five claims representing 5% of the dollar amount of the claims are denied. This supplier is known to the DMERC as one who has a significant decrease in billing volume when targeted medical review is initiated. The DMERC 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 are reviewed. Ten claims are denied for lack of complete physician orders representing 65% of the dollar amount of the claims. The RHHI issued a letter to inform the home health agency 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% prepayment medical review. Results of the review indicated an improvement in the error rate to 30% (based on dollars denied divided by dollars reviewed). On appeal, nearly all of the denials were overturned. The RHHI consults with the ALJ to understand why the cases are being overturned and consults with the regional office on appropriate next steps.

3.12 - MR High Risk

(Rev.)

3.13 – Prior Determination Process

(Rev.)

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R282PI	01/08/2009	Zone Program Integrity Contractor (ZPIC) Updates	01/26/2009	6170
R278PI	12/19/2008	Zone Program Integrity Contractor (ZPIC) Updates - Rescinded and replaced by Transmittal 282	01/26/2009	6170
R264PI	08/07/2008	Transition of Responsibility for Medical Review From Quality Improvement Organizations (QIOs)	08/15/2008	5849
R248PI	03/28/2008	Signature Requirements Clarification	04/28/2008	5971
R245PI	02/29/2008	Processing Part B Therapy Claims While the Therapy Cap Exceptions Process is in Effect	03/31/2008	5945
R220PI	08/24/2007	Various Medical Review Clarifications	09/03/2007	5550
R185PI	01/26/2007	Updating Financial Reporting Requirements for Workload and Cost Associated With the Return of Demand Bills	02/26/2007	4378
R184PI	01/26/2007	Revisions for MACs and PSCs	02/26/2007	5399
R181PI	12/29/2006	Outpatient Therapy Cap Exceptions Process for Calendar Year (CY) 2007	01/29/2007	5478
R179PI	12/15/2006	Revised Medical Review Timeliness and Reopening Requirements for Medical Review	01/16/2007	5252
R174PI	11/17/2006	Transition of Medical Review Educational Activities	10/06/2006	5275
R171PI	11/09/2006	Outpatient Therapy Cap Clarifications	12/09/2006	5271
R170PI	11/03/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 174	10/06/2006	5275
R167PI	10/27/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFS) for Claims Processing	10/01/2006	4296
R163PI	09/29/2006	Transition of Medical Review Educational Activities – Replaced by Transmittal 170	10/06/2006	5275
R159PI	09/22/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFS) for Claims Processing - Replaced by Transmittal 167	10/02/2006	4296
R149PI	06/30/2006	Notification to Providers, Suppliers, and Beneficiaries of Postpayment Review Results	07/31/2006	5115

Rev #	Issue Date	Subject	Impl Date	CR#
R142PI	03/02/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFS) for Claims Processing – Replaced by Transmittal 159	10/02/2006	4296
R140PI	02/15/2006	Therapy Caps Exception Process	03/13/2006	4364
R139PI	02/13/2006	Therapy Caps Exception Process - Replaced by Transmittal 140	03/13/2006	4364
R138PI	02/10/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFS) for Claims Processing - Replaced by Transmittal 142	10/03/2006	4296
R135PI	01/06/2006	Changes to the GTL Titles	02/06/2006	4228
R131PI	10/10/2005	Medical Review Matching of Electronic Claims and Additional Documentation in the Medical Review Process	02/10/2006	4052
R125PI	09/30/2005	Medical Review Additional Documentation Requests	12/30/2005	4022
R123PI	09/23/2005	MMA Section 935	10/24/2005	3703
R122PI	09/16/2005	Medical Review Collection Number Requirements	10/17/2005	4091
R120PI	08/25/2005	Correction to Change Request (CR) 3222: Local Medical Review Policy/ Local Coverage Determination Medicare Summary Notice (MSN) Message Revision	N/A	3880
R118PI	08/12/2005	Various Benefit Integrity (BI) Clarifications	09/12/2005	3896
R114PI	06/10/2005	Change in Statistical Sampling Instructions	05/31/2005	3734
R108PI	04/29/2005	Change in Statistical Sampling Instructions	05/31/2005	3734
R100PI	01/21/2005	Review of Documentation During Medical Review	02/22/2005	3644
R098PI	01/21/2005	Psychotherapy Notes	02/22/2005	3457
R096PI	01/14/2005	Consent Settlements	02/14/2005	3626
R094PI	01/14/2005	Informing Beneficiaries About Which Local Medical Review Policy (LMRP) and/or Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) is Associated with Their Claim Denial	07/05/2005	3602
R091PI	12/10/2004	Revision of Program Integrity Manual (PIM), Section 3.11.1.4	01/03/2005	3560
R090PI	12/10/2004	Prepayment Review of Claims for MR	01/10/2005	3569

Rev #	Issue Date	Subject	Impl Date	CR#
		Purposes		
R087PI	11/05/2004	Informing Beneficiaries About Which Local Medical Review Policy (LMRP) and/or Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) is Associated with Their Claim Denial	04/04/2005	3363
R086PI	11/05/2005	Payment for Emergency Medical Treatment and Labor Act (EMTALA) - Mandated Screening and Stabilization Services	11/22/2004	3437
R85PI	10/22/2004	Informing Beneficiaries About Which Local Medical Review Policy (LMRP) and/or Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) is Associated with Their Claim Denial - Replaced by Transmittal 87	04/04/2005	3363
R084PI	10/22/2004	Payment for Emergency Medical Treatment and Labor Act (EMTALA) - Mandated Screening and Stabilization Services - Replaced by Transmittal 86	11/22/2004	3437
R079PI	07/09/2004	Local Medical Review Policy/ Local Coverage Determination Medicare Summary Notice (MSN) Message Revision; Denial Notices	08/09/2004	3222
R076PI	05/28/2004	Clarification of Complex Medical Review	06/28/2004	3211
R075PI	05/14/2004	Informing Beneficiaries About Which Local Medical Review Policy (LMRP) and/or Local Coverage Determination (LCD) and/or National Coverage Determination (NCD) is Associated with Their Claim Denial	10/04/2004	3089
R072PI	04/16/2004	Automated Prepayment Review	05/01/2004	3088
R071PI	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
R070PI	04/09/2004	New Requirements for Self-Administered Drug (SAD) Exclusion List Articles in the Medicare Coverage Database (MCD)	05/10/2004	3136
R066PI	02/20/2004	Progressive Corrective Action Program Memorandum and Updated Instructions on How Contractors Must Identify, Verify, and Correct Billing Errors	04/02/2004	3124
R064PI	01/30/2004	Role Conditions of Participation (COPs) Requirements When Making a Payment	03/02/2004	3042

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		Decision		
R059PI	11/28/2003	Documentation Specifications for Areas Selected for Prepayment or Postpayment MR	01/05/2004	2937
R054PI	10/31/2003	Denial Notices	04/05/2004	2936
R053PI	10/31/2003	Prepayment Edits	04/05/2004	2916
R049PI	09/26/2003	Changing the Use of Remittance Advice Code N109 From Mandatory to Contractor's Discretion	10/10/2003	2873
R047PI	07/25/2003	CMS Mandated Edits	08/08/2003	2517
R046PI	07/25/2003	Prepayment Edits	08/01/2003	2681
R039PI	03/14/2003	MR Review and Documentation	04/01/2003	2417
R038PI	02/03/2003	When Contractors May Publish Coverage/Coding Articles In Their Bulletins And Web Sites	02/14/2003	2120
R035PI	11/29/2002	Types of Prepayment and Postpayment Review	01/01/2003	2418
R033PI	11/01/2002	FY 2003 Budget Performance Requirements	11/01/2002	2407
R032PI	10/25/2002	Consent Settlements, CMPs Delegated to CMS and Referrals to OIG	10/25/2002	2333
R031PI	10/25/2002	Revised Prepayment Edits	09/01/2002	1793
R017PIM	12/12/2001	Reorganizes chapter 3, sections 4, 5, and 6 and Removes reference to outdated MCM and MIM overpayment collection instructions and lists the more current CFR citations instead.	04/01/2002	1891
R016PIM	11/28/2001	Adds Various Program Memoranda for BI Requests for Information, Organizational Requirements, Unsolicited Voluntary Refund Checks, Anti-Kickback Statute Implications	11/28/2001	1732
R013PIM	09/26/2001	Administrative Relief from Medical Review and Benefit Integrity in Disaster Situations	09/26/2001	1879
R003PIM	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292
R001PIM	06/2000	Initial Release of Manual	NA	931