Medicare Program Integrity Manual

Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

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(Rev. 71, 04-09-04)

*3.*1 – Introduction

(Rev. 71, 04-09-04)

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.

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 feedback and reevaluation after education. At any time, evidence of fraud should result in referral to the *BI* for development.

*3.*1.1 – Provider Tracking System (PTS)

(Rev. 71, 04-09-04)

Carriers 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. *Carriers* should use the PTS to coordinate contacts with providers (e.g., MR education contacts). *Carriers* 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. *Carriers* should also coordinate this information with the *PSC or Medicare contractor 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 *carrier* should reassess all providers on MR quarterly to determine whether the behavior has changed. The *carrier* 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 *carrier*.

*3.*1.2 – Evaluating Effectiveness of Corrective Actions

(Rev. 71, 04-09-04)

Carriers 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. *Carriers* must use the PTS for anyone in their organization who provides education and other contacts with providers. *Carriers* must use the PTS to coordinate contacts with providers (e.g. MR education contacts). *Carriers* must 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. *Carriers* 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. 71, 04-09-04)

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 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, 8, and 9.

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 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 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, *QIO*s, 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 review. In all cases, they must clearly document the issues cited and the applicable law or their published national coverage policies or local medical review policy.

Contractors *shall* select a minimum of 30 claims for review, and generally limit the review to claims processed within the most recent year.

B – Setting Priorities

Contractors must 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 focus*es* 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 must 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 must 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. 71, 04-09-04)

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 review of 100 potential problems claims from a representative sample of providers--prepay or postpay and deny or collect money as appropriate. Take service-specific corrective actions:

- Contact medical and specialty societies to assist in education; and
- Develop new/revised LMRPs if needed; and/or
- Issue bulletin article clarifying rules; and/or
- Initiate service-specific prepay edits.

If the error is limited to a small number of providers, contractors should validate the concern by review of 20-40 potential problem claims for each provider in question—prepay and postpay and deny or collect money as appropriate.

*3.*2.2 - *Administrative Relief from Medical Review in the Presence of a Disaster*

(Rev. 71, 04-09-04)

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 more 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 duplicate, lost record, 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

Providers Directly Impacted By Disaster

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 suspended for providers who have been directly affected for at least 30 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 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 "anti-bunching" rules, 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 review teams, CCMO staff, and local regional office staff, upon request.

*3.*3 – Provider Education

(Rev. 71, 04-09-04)

A – Widespread Provider Education

Issuing a provider bulletin as an educational tool may be helpful if a problem is general or widespread.

B – Focused Provider Education

In addition to the MIP-PET activities identified in Chapter 1, §*1.4.1*, contractors must initiate focused provider education when a specific error is verified. Focused provider education means direct 1-to-1 contact between the contractors and the provider through a telephone contact, letter, or meeting. When individual providers are contacted, 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. Contractors are encouraged to have contact with providers to make them aware that they have noticed unusual patterns and to gather information. Contact may be in the form of telephone calls, written correspondence or an informal in-person meeting. Contractors must deny non-covered and incorrectly coded services even while provider education is occurring. Reviews of applicable LMRPs with providers may be useful to emphasize the contractors' point.

3.3.1 - Articles

(Rev. 71, 04-09-04)

Contractors have an obligation to assist providers in complying with Medicare's coverage, coding and medical review related billing and claim rules.

For the purposes of this manual, the term "article" will be used to describe any bulletin article, Web site article, educational handout or any other non-LMRP document intended for public release that contains coverage/coding statements or medical review related billing or 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.

Contractors may publish articles communicating certain information to providers.

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 LMRP 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 LMRP 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.

Beginning in 2003, contractors will be required to enter into the Medicare coverage database those articles that address local coverage, coding or medical review related billing and claims considerations. Instructions for this requirement are in PM AB-02-098. Articles may include any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy. Contractors are encouraged to send articles to specialty societies for inclusions in their publications and Web sites. All newly created articles must be posted on the contractor's Web site where duplicate copies may be obtained by physician/suppliers.

*3.*4 - Overview of Prepayment and Postpayment Review for MR Purposes

(Rev. 71, 04-09-04)

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.

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 MCM §12001 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 pay a claim (in full or in part), deny payment or 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; and
- If postpayment, the list of claims that require medical records.

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.

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. 71, 04-09-04)

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, Section *3*.4.1.2.

A -- Review of Documentation Submitted with the Claim

If a claim targeted for prepayment or postpayment review (including automated, routine, or complex) contains a modifier indicating that additional documentation is attached or was submitted simultaneously with an electronic claim, the contractor must review the documentation before denying the claim. 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 LMRP 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.

B – Signature Requirements

Medicare requires a legible identifier for services provided/ordered. The method used (e.g., hand written, electronic, or signature stamp) to sign an order or other medical record documentation for medical review purposes in determining coverage is not a relevant factor. Rather, an indication of a signature in some form needs to be present. Do not deny a claim on the sole basis of type of signature submitted.

Providers using alternative signature methods (e.g., a signature stamp) should recognize that there is a potential for misuse or abuse with a signature stamp or other alternate signature methods. For example, a rubber stamped signature is must less secure than other modes of signature identification. The individual whose name is on the alternate signature method 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 (CMN). CMNs are a term of art specifically describing particular Durable Medical Equipment forms. As stated on CMN forms, "Signature and date stamps are not acceptable" for use on CMNs. No other forms or documents are subject to this exclusion.

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 LMRP.

- **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 LMRP (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 LMRP for that service. Contractors must educate providers about this requirement beginning no later than January 1, 2002. This outreach should occur via website 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 LMRP 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 LMRP 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.*4.1.2 - Additional Documentation Requests (ADR) During Prepayment or Postpayment MR

(Rev. 71, 04-09-04)

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 by issuing an Additional Documentation Request (ADR). Contractors must ensure that all records requested are from the period under review.

Contractors must specify in the ADR the specific pieces of documentation needed (and ONLY those pieces needed) to make a coverage or coding determination.

A -- Development of Non-Lab Claims for Additional Documentation

If, during pre- or postpay review, a contractor chooses to send an Additional Documentation Request (ADR) regarding a non-lab targeted service, they must solicit the documentation from the **billing provider** 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 ADR. Contractors must send ADRs in accordance with the following requirements:

BILLING PROVIDER ADRs

- Contractors who choose to request additional documentation must solicit such information from the billing provider and must notify them that they have 30 days to respond. Contractors have the discretion to grant an extension of the timeframe upon request. The contractor must pend the claim for 45 days. Contractors may cc a third party.
- Contractors have the discretion to issue no more than 2 "reminder" notices via letter or phone call prior to the 45th day;
- If information is automatically requested only from the billing provider and 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 depending upon the reason for the requested information). This would count as automated review.
- If information is requested **only** from the **billing provider** and the information received fails to support the coverage or coding of the claim, in full or in part, the contractor must deny the claim, in full or in part, using the appropriate denial code (see section 4.2). This would count as a complex review.

THIRD PARTY ADRs

A contractor may NOT solicit documentation from a **third party** unless the contractor first or simultaneously solicits the same information from the **billing provider**. Beneficiaries are not third parties.

When a contractor solicits documentation from a third party:

- The contractor must notify the third party that they have 30 days to respond and copy the billing provider. Contractors have the discretion to grant extensions of the timeframe upon request.
- For prepay review, the contractor must pend the claim for 45 days. This 45 day time period may run concurrent with the 45 day time period for the billing provider ADR letter;
- Contractors have the discretion to issue no more than 2 "reminder" notices via email, letter or phone call prior to the 45th day;
- If information is requested from **both** the billing provider and a third party and no response is received from either within 45 days after the date of the request (or extension), the contractor must deny the claim, in full or in part, as reasonable and necessary. This would count as automated review.
- If information requested from **both** the billing provider and a third party and a response is received from one or both, but the information fails to support the coverage or coding of the claim, the contractor must deny the claim, in full or in part, using appropriate denial code (see Section *3*.4.2).

B - Development of Lab Claims for Additional Documentation

Effective November 25, 2002, contractors shall develop lab claims in accordance with the following requirement:

- If, during pre- or postpay review, a contractor chooses to send an ADR regarding a targeted lab service, they must solicit the documentation from the billing provider, and under certain circumstances, must also solicit documentation from the ordering provider.

Contractors must send ADRs in accordance with the following requirements:

Billing Provider ADRs

- Contractors who choose to request additional documentation must solicit such information from the **billing provider** and must 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 must 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;
- Diagnostic or other medical information supplied to the billing provider by the ordering provider, including any ICD-9 codes or narratives supplied.

- Contractors have the discretion to issue no more than 2 "reminder" notices via letter, e-mail, or phone call prior to the 45th day;
- If no response is received from the billing provider within 45 days after the date of the request (or extension), the contractor must deny the service as not reasonable and necessary. This would count as automated review;
- If a response is received that demonstrates that the service is not covered or correctly coded, the contractor must deny;
- If the information requested from the **billing provider** is received, does not demonstrate noncoverage or incorrect coding of the claim, but fails to support the coverage or coding of the claim in full or in part, the contractor must:
  - 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:

1) Solicits information from the **billing provider,**

2) Finds the ADR response from the billing provider 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 must provide to the ordering provider information sufficient to identify the claim being reviewed.

- The contractor must solicit from the ordering provider those parts of the medical record that are relevant to the specific claim(s) being reviewed. The contractor must notify the ordering provider that they have 30 days to respond and copy the

billing provider. Contractors have the discretion to grant extensions of the time frame upon request.

- For prepay review, the contractor must pend the claim for 45 days.
- Contractors have the discretion to issue no more than 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 must deny the claim, in full or in part, as not reasonable and necessary. This 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, the contractor must deny the claim, in full or in part, using appropriate denial code (see Section *3.*4.2). This would count as a complex review.

*3.*4.1.3 – Completing Complex Reviews

(Rev. 71, 04-09-04)

A -- Medical Review Timeliness Requirement

For ADR responses that are received within the timeframe (or extended time frame) contractors must complete claims review and notify the provider and beneficiary, if indicated, within 60 days of receiving documentation.

B -- How to Count the 60 Days

- For prepay reviews (e.g., prepay probe, regular prepay review) the contractor should begin counting with the receipt of each medical record. Each new medical record received should start a new 60 day clock.
- For postpay reviews (e.g., quality improvement reviews, OIG CFO, postpay probe, statistical sampling, etc.), contractors have the option of:
    - Beginning the counting with the receipt of each medical record. Each new medical record received would start a new 60 day clock, or
    - Waiting until all requested medical records are received and then start the 60 day clock.

See *PIM Chapter 3 section 3.4.2.C* for description of the notification requirements.

*3.*4.1.4 - Handling Late Documentation

(Rev. 71, 04-09-04)

Contractors Who Choose to Reopen -- If a contractor receives the requested information after a denial has been issued but within a reasonable number of days (generally 15 days after the denial date), the contractor may **reopen** the claim. Contractors who choose to reopen must notify the provider of their intent, make a medical review determination, and notify the provider of the determination within 60 days of receipt of late documentation. The workload, costs, and savings associated with this activity should be allocated to the appropriate **MR** activity code in CAFM and PIMR (i.e., 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.

3.4.2 – Denials

(Rev. 71, 04-09-04)

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 Ruling 95-1 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, or LMRP/LCD;
- 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.

Contractors must give the specific reason for denial. Repeating one of the above bullets is not a specific reason.

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, §4.21.2.6*.

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

Effective January 1, 2004 intermediaries must notify beneficiaries when a LMRP/LCD was the basis for the claim denial.

Effective April 1, 2004, contractors must notify beneficiaries when a NCD was the basis for the claim denial.

In the future, contractors will be required to notify beneficiaries when an LMRP or non-lab NCD was the basis for the claim denial.

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.

Effective January 1, 2003, for claims where the contractor makes a denial following complex review, contractors must 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 down coding, 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 Part A providers cannot appeal benefit category and statutory exclusion denials, and 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 CMS 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. 71, 04-09-04)

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 LMRPs 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., the appeals unit, phone inquiry unit, etc.), *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. 71, 04-09-04)

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 *3.*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 any attachment submitted by the provider (other than medical records) and/or claims history file and/or internal MR guidelines.

C -- Complex Prepayment/Postpayment Review

Complex medical review involves evaluating medical records or any other documentation by a licensed medical professional. Complex medical review determinations require the reviewer to make a judgment about whether a service is covered and is reasonable and necessary.

MR-directed and BI-directed complex review (i.e., review that involves any evaluation of medical records) for the purpose of making coverage determinations must be conducted 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, etc). 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.

Nurse and physician complex reviewers may call upon other health care professionals (e.g., dieticians, and physician specialists) for advice. Any determination made by complex MR staff must be documented and include the rationale for the decision. While complex MR staff must follow NCD and LMRPs, 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, complex 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 BI 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. 71, 04-09-04)

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

Contractors should attempt to avoid "bunching" workload.

*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. 71, 04-09-04)

The instructions listed in this section (Section *3.*5) apply only to reviews conducted for MR purposes unless otherwise noted.

Contractors may not prohibit providers from submitting electronic claims, even those providers who have been selected for prepayment review. Contractors may encourage providers who are on 100 percent prepayment MR for a particular service to submit paper claims.

*3.*5.1 - Automated Prepayment Review
(Rev. 71, 04-09-04)

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:

1. Have **clear policy** that serves as the basis for denial;
2. Be based on an apparent typographical error (e.g., hysterectomy for a male); or
3. 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 an apparent typographical error, 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 LMRP specifies the circumstances under which a service will always be considered non-covered or incorrectly coded.

3.5.1.1 - Prepayment Edits

(Rev. 71, 04-09-04)

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 V43.64 (Hip joint replacement by artificial or mechanical device or prosthesis) 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 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 medical review. Focused edits reduce provider burdens and increases the efficiency of medical review 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.

Carrier systems must be able to select claims for prepayment review using different types of comparisons. By January 2001 (unless otherwise specified), FI systems must be able to perform these comparisons as well. 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. Intermediaries on the FISS system are waived from this requirement until the FI Standard System is updated to include this capability.

- 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. Intermediaries on the FISS system are waived from this requirement until the FI Standard System is updated to include this capability.

- 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 (Intermediary) – This permits contractors to screen services provided by a certain specialty or type of bill.

- 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, etc. Contractors must maintain and make available to RO *(for PSCs, the GTL, Co-GTL, and SME)* and 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, etc. 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 LMRP and NCD ID Numbers to Edits

By January 1, 2004, FISS FIs must ensure that any edit that may result in a denial based on an LMRP/LCD includes the LMRP/LCD ID number(s) associated with the denial.

By april 1, 2004, FISS FIs must ensure that any edit that may result in a denial based on a NCD includes the NCD ID number(s) associated with the denial.

By July 1, 2004, VMS carriers *and PSCs* must ensure that any edit that may result in a denial based on an LMRP or NCD includes the LMRP ID number(s) or NCD ID number(s) associated with the denial.

In the future, MCS carriers will be required to ensure that any edit that may result in a denial based on an LMRP or NCD includes the LMRP ID number(s) or NCD ID number(s) associated with the denial.

*3.*5.2– Categories of MR Edits

(Rev. 71, 04-09-04)

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

Once contractors have implemented the Comprehensive Error Rate Testing (CERT) program, they may no longer operate any random edits.

*3.*5.*3 – CMS* Mandated Edits

(Rev. 71, 04-09-04)

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.

Effective January 1, 2003, 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.*6 – Postpayment Review of Claims for MR Purposes
(Rev. 71, 04-09-04)

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. This section describes the requirements that contractors must follow when conducting postpayment claims review for MR purposes. Contractors who are reviewing claim 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 Postpay 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 must adhere in all cases to reopening rules. (See *Medicare Carrier and Intermediary Manuals: MCM, Part 3, Chapter XII, Section 12100 and MIM, Part 3, Chapter VII, Section 3799, for Reopening Standards*).

*3.*6.1 - Postpayment Review Case Selection
(Rev. 71, 04-09-04)

Postpayment reviews are usually targeted to providers, whether individuals or groups, who have demonstrated aberrant billing and/or practice patterns. However, some postpay reviews (e.g., widespread probes) may involve multiple providers.

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, also known as "probe" reviews (see PIM Chapter 3, Section *3.*2 for more information about probe 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 for postpay review, MR staff should review the provider tracking system (PTS) and consult with the BI unit to ensure duplicate efforts are not being undertaken. (See PIM Chapter 3, Section *3.*1.2

A -- Identifying Providers for Error Validation Reviews

PIM Chapter 3, Section *3.*2 describes the requirements regarding which providers should be selected for error validation (probe) review.

B -- Identifying Providers 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 group of providers 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, §3.10.1 through 3.10.5 and 3.10.9 through 3.10.11*.

Case selection is based on profiling providers 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 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.

*3.*6.2 - Location of Postpayment Reviews
(Rev. 71, 04-09-04)

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 site or at the contractor site. Considerations in determining whether to conduct a provider-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 to submit appropriate and timely medical records; and
- Contractor resources.

A -- Contractor Site Reviews

The contractor notifies the provider(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 45 days, the contractor shall review the claims with the information on hand. Contractors must complete the review and notify the provider in writing of their findings within 60 calendar days from the start of the review, or receipt of medical records, whichever is later. If the contractor needs more than 60 calendar days, they must request an extension from the RO *(for PSCs, the GTL, Co-GTL, and SME)*.

B -- Provider Site Reviews

Contractors determine what, if any, advance notification of a scheduled review is given to a provider. The contractor may give advance notice when a provider has satellite offices from which medical records will have to be retrieved. When giving advance notice, the contractor must 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 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 must instruct providers (via bulletin article, Web article, etc.) that any Medicare contractor staff person who visits the provider site must show a photo identification indicating their affiliation with the Medicare contractor. Contractors must provide to all reviewers who participate in provider site reviews a photo identification card indicating the reviewer's affiliation with the Medicare contractor. Upon arrival to the provider site, the reviewer must show this photo identification card to the provider staff.

During provider 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 staff. A provider representative can also be present while claims are reviewed. Reviewers must answer any questions the provider 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 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 must be allowed an opportunity to discuss or comment on the claims decisions.

*3.*6.3 - Re-adjudication of Claims

(Rev. 71, 04-09-04)

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 LMRP and any applicable references needed to support individual case determinations. Compliance with these requirements facilitates adherence to the provider notification requirements in PIM Chapter 3, Section *3.*6.5.

*3.*6.4 - Calculation of the Correct Payment Amount and Subsequent Over/Underpayment

(Rev. 71, 04-09-04)

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 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, §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 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 is liable for the overpayment because: (1) the provider knew or could reasonably have been expected to know that items or services were excluded from coverage, and (2) the provider 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 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) and Beneficiaries of the Postpayment Review Results

(Rev. 71, 04-09-04)

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 Notification

Contractor MR staff must prepare a letter to notify each provider 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 within 60 days of the exit conference (for provider-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 GTL, Co-GTL, and SME)* for an extension. Each letter must include:

- Identification of the provider(s)--name, address, and provider 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, 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, §3.10.4.4*;
- Total underpayment amounts;
- Total overpayment amounts for which the provider is responsible;
- Total overpayment amounts for which the provider is not responsible because the provider 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 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 right to request an extended repayment schedule;
- The provider 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, etc.).

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

Sample letters are in PIM Exhibit 7.*3* with attachment Exhibit 7.*3.1* and the Part B sample letter is Exhibit 7.*4* with attachment Exhibit 7.*4.1*. Contractors may adapt the language used under each heading to the particular situation they are addressing.

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) Rebuttal(s) of Findings
(Rev. 71, 04-09-04)

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) Timeframes for Submitting Rebuttal Statements

Within 15 calendar days of notification of the results, each provider 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)

MR and A/R staff should consider all of the evidence concerning the provider's financial obligation timely submitted to reach a determination regarding whether *the determinations were incorrect and 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 and 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 CMR notification letter unless MR or Audit/Reimbursement staff find cause otherwise to extend or shorten the time afforded for submission of the statement. The provider's rebuttal statement should address why the recovery should not be put into effect on the date specified in the notification letter. MR and AR 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 generally should not be considered during the rebuttal process unless such evidence relates to the timing of the recoupment of the overpayment. Substantive evidence on claims determinations is properly heard during a reconsideration under Part A or a review determination or *Hearing Officer (*HO*)* hearing under Part B. However, in order to avoid unnecessary appeals, if it is clear from the evidence submitted that MR revised determination was in whole, or in part, incorrect, they may consider such evidence. If such evidence warrants changes to any claims determinations made during the reopening, they work with Audit/Reimbursement staff to recalculate the amount of the overpayment, and issue a modified revised determination.

Should MR issue a modified revised determination, they send notice of the results of the modification to any beneficiary whose claims have been affected. In addition, they notify the provider that the applicable time period for filing a request for reconsideration of Part A services or a review determination of Part B services begins on the date of the modified revised determination. **However, recovery of any overpayment, even if the principal of the debt is modified after reviewing the rebuttal statement, will not be delayed beyond the date indicated on the revised determination.** Furthermore, since the provider has previously had an opportunity to submit a rebuttal statement, MR *staff* is not required to offer a provider an opportunity to submit a rebuttal statement in response to the modified revised determination. The provider may challenge the claims determinations and sampling methodology in the administrative appeals process.

C -- Cost Report Issues

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

*3.*6.7 - *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. 71, 04-09-04)

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 specific edit to focus prepayment review on the problem provider or group of providers (see PIM Chapter 3, Section *3.*5.1) if appropriate;

- Work with the RO *(for PSCs, the GTL, Co-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 GTL, Co-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) 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 after the 3 month time period. Contractors must continue monitoring the provider or group of providers 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. (See Progressive Corrective Action PM -- transmittal AB-00-72)

*3.*6.9 - Postpayment Files

(Rev. 71, 04-09-04)

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 GTL, Co-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 GTL, Co-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. 71, 04-09-04)

PSCs shall refer all identified overpayments to the AC 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. *PSCs and Medicare contractor BI units* 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. *Medicare contractor BI units* refer such requests to the RO *(for PSCs, such requests are referred to the GTL, Co-GTL, and SME)*. If delaying recoupment minimizes eventual recovery, delay may not be appropriate. *Medicare contractor BI units* must forward any correspondence received from law enforcement requesting the overpayment not be recovered to the RO *(PSCs forward this to the GTL, Co-GTL, and SME)*. The RO *(for PSCs, the GTL, Co-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*)

*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 PIM Chapter 3 §*3.*6.7 and Exhibit 14.1);
- The §1870 determination for the provider for each overpaid assigned claim in the sample (see PIM Chapter 3 §*3.*6.7 and Exhibit 14.2); and

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

B – Step 2

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

C – Step 3

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

D – Step 4

Calculate the final overpayment.

E – Step 5

Refer to the overpayment recoupment staff.

*3.*8.3.2 – Conduct of Expanded Review Based on *Statistical Sampling for Overpayment Estimation* and Recoupment of Projected Overpayment by Contractors

(Rev. 71, 04-09-04)

ACs shall perform the actual recoupment identified by the PSCs.

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.*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 PIM Chapter 3, §3.6.1 and applicable Exhibits.*

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

In most instances, the Audit/Reimbursement staff will:

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

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

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

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

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

*3.*9 – Suspension of Payment
(Rev. 71, 04-09-04)

The process by which the PSC notifies and coordinates with the AC of a CMS-approved suspension of payment shall be documented in the JOA. PSCs shall advise and coordinate with the AC when payment suspension has been approved by CMS. The PSCs 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. 71, 04-09-04)*

Suspension of payment may be used when the contractor *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. An example carriers 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 or PSC* 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 *and PSC* 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 shall* recommend

suspension of payment to the RO *and PSCs shall recommend suspension of payment to the GTL, Co-GTL, and SME.*

B – Provider Identified in *CMS* Fraud Alert

Contractors *shall* recommend suspension to the RO *and PSCs shall recommend suspension to the GTL, Co-GTL, SME* 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 *and PSCs shall* follow the suspension of payment actions for each agency request indicated below.

- *CMS* -- Initiate suspension as requested.
- OIG/FBI – *Contractors shall* forward the written request to the *CMS* RO *and PSCs shall forward the request to the GTL, Co-GTL, and SME* for its review and determination. The RO or *for PSCs, the GTL, Co-GTL, and SME will decide.*
- AUSA/DOJ – *Contractors shall* forward the written request to the *CMS* RO *and* for *PSCs, the GTL, Co-GTL, and SME* for review and determination.
- Other – Other situations the contractor *or PSC* may consider recommending suspension of payment to the RO *or for PSCs, the GTL, Co-GTL, and SME* 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; 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. 71, 04-09-04)

Suspension of payment may be used when the contractor *or CMS* possesses reliable information that an overpayment exists but has not yet determined the amount of the overpayment. *In this situation, the contractor shall recommend suspension to the RO and the PSC shall recommend suspension to the GTL, Co-GTL, and SME.* 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. 71, 04-09-04)

Suspension of payment may be used when the contractor *or CMS* possesses reliable information that the payments to be made may not be correct. *In this situation, the contractor shall recommend suspension to the RO and the PSC shall recommend suspension to the GTL, Co-GTL, and SME.* 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. 71, 04-09-04)

Suspension of payment may be used when the contractor *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 shall recommend suspension to the RO and the PSC shall recommend suspension to the GTL, Co-GTL, and SME.* 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. 71, 04-09-04)

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* RO *or for PSCs, the GTL, Co-GTL, and SME*. The designated approving authority in the RO *or for PSCs, the GTL, Co-GTL, and SME* will seek the advice of the Regional Chief Counsel's Office (RCCO) and coordinate suspension action with its law enforcement partners as it deems appropriate.

The contractor *or PSC 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 RO *or for PSCs, the GTL, Co-GTL, and SME*. *The contractor shall* not take suspension action without the explicit approval of the resident RO *or for PSCs, the GTL, Co-GTL, and SME*. In most cases, the RO *or if a PSC, the GTL, Co-GTL, and SME* 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*, a PSC, or CMS* has been working with law enforcement on the case, immediately notify them of the recommendation to the RO *or for PSCs, the GTL, Co-GTL, and SME*. Notice may consist of a telephone call or a fax if there is a need to expedite suspension. If law enforcement wants more time to study or discuss the suspension, *contractors shall* discuss their request with the RO *or for PSCs, the GTL, Co-GTL, and SME*. If law enforcement requests that suspension action should, or should not, be taken, contractors *shall* contact the RO *or for PSCs, the GTL, Co-GTL, and SME*. *Contractors and PSCs 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. 71, 04-09-04)

Contractors *and PSCs 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 *and PSCs shall* recommend to the RO *or for PSCs, the GTL, Co-GTL, and SME, not to give prior notice if* in the contractor's *or PSC'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 jurisdiction before the overpayment can be recovered; *or*

3. The contractor *or PSC* 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 RO *or for PSCs, the GTL, Co-GTL, and SME* waives the advance notice requirement, contractors *and PSCs* 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 and PSCs shall recommend that the RO or for PSCs, the GTL, Co-GTL, and SME waive prior notice requirements for failure to furnish information requested by the contractor or PSC that is needed to determine the amounts due the provider.

If the RO or for PSCs, the GTL, Co-GTL, and SME waives the prior notice requirement, contractors and PSCs 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 and PSCs shall recommend to the RO or for PSCs, the GTL, Co-GTL, and SME that prior notice not be given. The RO or for PSCs, the GTL, Co-GTL, and SME will decide whether to waive the notice. The RO or for PSCs, the GTL, Co-GTL, and SME will also direct the content of the notice.

If the RO *or for PSCs, the GTL, Co-GTL, and SME* waives the advance notice requirement, *the contractor or PSC 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. 71, 04-09-04)

Contractors *and PSCs shall* prepare a "draft notice" and send it, along with the recommendation, to the RO *or for PSCs, the GTL, Co-GTL, and SME* 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 *and PSCs shall also state* why the suspension action is being taken.

For fraud suspensions, the contractor *or PSC 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 RO or for PSCs, the GTL, Co-GTL, and SME will direct the content of the notice. The notice does not need to specify that the provider is suspected of fraud or willful misrepresentation. It can identify the claims involved and state, for example, that the claims paid or to be paid should not have been.*

*3.*9.2.2.3 – Shortening the Notice Period for Cause (Rev.)

At any time, the contractor *or PSC* may recommend to the RO *or for PSCs, the GTL, Co-GTL, and SME* that the advance notice be shortened **during** the notice period. Such a recommendation would be appropriate if the contractor *or PSC* 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 or PSC shall* notify the provider in writing of the change and the reason.

*3.*9.2.2.4 – Mailing the Notice to the Provider (Rev.)

After consultation with and approval from the RO *or for PSCs, the GTL, Co-GTL, and SME*, contractors *and PSCs 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.)

The suspension notice gives the provider an opportunity to submit to the contractor *or PSC* 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 RO *or for PSCs, the GTL, Co-GTL, and SME* will consult with OGC and will advise the contractor *or PSC* before the contractor *or PSC* responds to any rebuttal statements.

Contractors *and PSCs shall* ensure the following:

- *CMS Review –* Contractors *and PSCs shall immediately* forward provider responses to the *CMS* RO or *for PSCs, the GTL, Co-GTL, and SME.*
- 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 *and PSCs shall also* carefully review the provider's rebuttal statement and consider all facts and issues raised by the provider. If the contractor *or PSC* is convinced that the suspension action should be non-initiated or terminated, *they shall* consult immediately with the RO *or for PSCs, the GTL, Co-GTL, and SME*.
- Response – Respond to the provider's rebuttal within 15 days from the date the statement is received, following consultation with the RO *or for PSCs, the GTL, Co-GTL, and SME*.

*3.*9.2.3 – Claims Review During the Suspension Period
(Rev. 71, 04-09-04)

*3.*9.2.3.1 – Claims Review
(Rev. 71, 04-09-04)

A – Claims Review of Suspended Claims:

Once suspension has been imposed, contractors *and PSCs shall* follow normal claims processing and MR procedures. Contractors *shall* make every attempt within the MR budget to determine if suspended claims are payable. *Contractors and PSCs 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 shall* send a remittance advice to the provider showing that payment was approved but not sent. *Contractors and PSCs are not required to perform 100% pre-pay medical review of suspended claims. Contractors and PSCs shall consult with their RO or for PSCs, with their GTL, Co-GTL, and SME when resources would be better utilized by determining what percentage of claims in a universe of suspended claims are payable through use of statistical sampling procedures.*

Contractors and PSCs 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 *and PSCs 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 *and PSCs 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. 71, 04-09-04)

Even though suspension action was recommended and/or implemented, *PSCs and Medicare* contractor *BI units 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 Medicare* contractor *BI units 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 Medicare* contractor *BI units 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 Medicare* contractor *BI unit shall* enter the suspension into the FID, no later than the effective date of suspension. *See PIM Chapter 4, §4.11 for FID entry and update requirements. In the Suspension Narrative field, the contractor or PSC 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. 71, 04-09-04)

A – *Time Limits*

The RO *or for PSCs, the GTL, Co-GTL, and SME* will initially approve suspension for a period up to 180 days. The RO *or for PSCs, the GTL, Co-GTL, and SME* may extend the period of suspension for up to an additional 180 days upon the written request of the *contractor or PSC*, 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 RO *or for PSCs, the GTL, Co-GTL, and SME* may grant an additional extension to the Department of Justice if it submits a written request. 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 RO *or for PSCs, the GTL, Co-GTL, and SME* 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 or PSC shall notify the provider of the requested extension.

The contractor or PSC shall obtain the RO *or if a PSC, GTL, Co-GTL, and SME 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. 71, 04-09-04)

Contractors *shall* recommend to the RO *and PSCs shall recommend to the GTL, Co-GTL, and SME* that suspension of payments be terminated at such time as the time limit expires.

The contractor or PSC may recommend on a case by case basis to the RO or for the PSC, the GTL, Co-GTL, and SME that it be terminated earlier if any of the following apply:

A – If the basis for the suspension action was that an overpayment existed but the amount of the suspected overpayment is not yet determined, *and*:

- No overpayment was identified;
- The amount of suspected overpayment has been determined and it is no longer accruing; or
- The amount of the suspended monies exceeds the estimated amount of the suspected overpayment.

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 or PSC 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 previously requested records, and the contractor *or PSC* 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. 71, 04-09-04)

Payments for appropriate Medicare claims that are withheld during a suspension should not exceed the suspected amount of overpayment. Contractors *and PSCs shall* maintain an accurate, up-to-date record of the amount withheld and the claims that comprise the suspended amount. Contractors *and PSCs 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 used to recoup any overpayment. (See PIM Chapter 3, §*3*.8.) Contractors *and PSCs 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 overpayment. Contractors *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 shall* initiate recoupment action.

3.9.2.7 – Contractor Suspects Additional Improper Claims
(Rev. 71, 04-09-04)

A – Present Time

If the contractor *or PSC* 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 *or PSC* believes there are past periods of time that may contain possible overpayments, contractors *and PSCs 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.

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

*3.*9.3 – Suspension Process for Multi-Region Issues
(Rev. 71, 04-09-04)

*3.*9.3.1 – DMERCs *and DMERC PSCs*
(Rev. 71, 04-09-04)

The DMERCs *and DMERC PSCs 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 DMERC *or DMERC PSC* suspends payments.

A – The initiating DMERC or *DMERC PSC shall* get the approval of its lead RO *or for PSCs, the GTL, Co-GTL and SME*. *CMS*'s ROs have agreed to support the decision of another RO.

B – The initiating DMERC *or DMERC PSC shall* share the suspension of payment information with all of the other DMERCs *and DMERC PSCs*. Reliable information that payments should be suspended in one region is sufficient reason for suspension decisions to apply to the other regions.

C – The lead RO *or for PSCs, the GTL, Co-GTL, and SME shall* issue one suspension letter on *CMS* letterhead advising that payments will be held by all DMERCs *and*

DMERC PSCs. This letter *shall* advise the supplier to contact the initiating DMERC *or DMERC PSC* should the supplier have any questions.

D – Should the suspension action require an extension of time, the lead RO *or for PSCs, the GTL, Co-GTL, and SME* will send an extension letter to the supplier.

*3.*9.3.2 – Other Multi-Regional Contractors
(Rev. 71, 04-09-04)

In some situations, more than one *CMS* RO may be involved. For example, both the Seattle (resident RO) and Kansas City (RHHI RO) have jurisdiction in Idaho. Where there are multiple ROs, it is incumbent on the ROs (not the contractors *or PSCs*) to reach consensus on suspension action and to provide a single point of contact at the resident RO for the contractor *or PSCs*. In other words, it is usually the RO that services the geographic State or area where the beneficiary and providers are located that would be responsible for coordinating *CMS*'s decision and contacts with interested law enforcement agencies. *The PSC shall contact their GTL, Co-GTL, and SME for the correct RO contact on payment suspensions.*

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

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. 71, 04-09-04)

The purpose of this section is to provide the guidance necessary to use statistical sampling to calculate and project overpayments identified following administrative review of claims. 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 administrative reviews performed by the PSC or Medicare contractor BI unit. Reviews using statistical sampling that are conducted by the PSC or Medicare contractor BI unit to assist with the identification, case development and/or investigation of suspected fraud or other unlawful activities may use procedures that differ from those prescribed herein.

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

3.10.1.2 - Use of Statistical Sampling

(Rev. 71, 04-09-04)

Statistical sampling is used to calculate and project the amount of overpayments made on claims. HCFA Ruling 86-1 (HCFAR 86-1) explains CMS's authority to use statistical sampling to estimate overpayments made to Medicare providers and suppliers. The PSC or Medicare contractor BI unit shall use statistical sampling to project overpayments to providers and suppliers when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible. The ruling recognizes that statistical sampling conserves the resources of the Medicare program when reviews are performed on a large universe of claims. The ruling states that in most cases it would not be administratively feasible, given the volume of records involved and the cost of retrieving and reviewing all the beneficiary records, for an examination of all individual claims for the period in question.

3.10.1.3 - Steps for Conducting Statistical Sampling

(Rev. 71, 04-09-04)

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 claims or line(s) on the claim and determining if there was an overpayment, or, for administrative reviews, 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 - When Statistical Sampling May Be Used

(Rev. 71, 04-09-04)

The PSC or Medicare contractor BI unit shall use statistical sampling to project overpayments to providers and suppliers when erroneous billing or reimbursement, or overutilization is suspected, and when a case-by-case review is not administratively feasible or practical.

Use of statistical sampling to determine overpayments may be used in conjunction with other corrective actions. Reviews that involve the use of statistical sampling may be utilized when there is a "major level of concern" regarding the provider or supplier's billing, reimbursement, and/or utilization (see Progressive Corrective Action (PCA) instructions).

Factors also to be considered for determining when to undertake statistical sampling 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. 71, 04-09-04)

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 Medicare contractor BI 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 Medicare contractor BI 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 Medicare contractor BI 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 Medicare contractor BI 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. 71, 04-09-04)

Nothing in these instructions precludes the Centers for Medicare and Medicaid Services (CMS) or the PSC or Medicare contractor BI unit from relying on statistically valid audit sampling methodologies employed by other audit organizations, including but not limited to the OIG, the GAO, and other authoritative sources. Where it is foreseen that the results of a review may be referred to law enforcement or another agency for litigation and/or other enforcement actions, the PSC or Medicare contractor BI 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, 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. 71, 04-09-04)

Regardless of the method of sample selection used, the PSC or Medicare contractor BI 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 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, etc.) 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. 71, 04-09-04)

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

- *How long the pattern of erroneous billing or overutilization 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 Carrier 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. 71, 04-09-04)

The universe and sampling frame will usually be 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, 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. 71, 04-09-04)

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 clams, 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 be 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 occured.*

3.10.3.2.2 - The Sampling Unit

(Rev. 71, 04-09-04)

Sampling units are the elements that are selected according to 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. 71, 04-09-04)

Stratified sampling involves classifying the sampling units in the frame into non-overlapping groups, or strata. One useful stratification results in a sampling unit from one stratum more likely being 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 where 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 obtained 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. 71, 04-09-04)

Cluster sampling involves drawing a random sample of clusters and reviewing everything or a sample of units in the sampled clusters. Unlike strata, clusters are groups of units that do not necessarily have strong similarities, but can be efficiently accessed for review purposes. 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 are methods of grouping units. The former is frequently recommended when there is sufficient 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. 71, 04-09-04)

The PSC or Medicare contractor BI unit shall identify the source of the random numbers used to select the individual sampling units. The PSC or Medicare contractor BI 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 Medicare contractor BI unit shall document any starting point if using a random number table or drawing a systematic sample. In addition, the PSC or Medicare contractor BI unit shall document the known seed value if a computer algorithm is used. The PSC or Medicare contractor BI unit 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 services or the same ease in operation. For any particular problem, the PSCs or Medicare contractor BI 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. 71, 04-09-04)

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 Medicare contractor BI 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. 71, 04-09-04)

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

3.10.4.4.1 - Documentation of Universe and Frame

(Rev. 71, 04-09-04)

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, etc.), 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 Medicare contractor BI unit 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. 71, 04-09-04)

The PSC or Medicare contractor BI unit 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., UB92 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 Works**heets***

(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 GTL, Co-GTL, SME or CMS RO

(Rev. 71, 04-09-04)

The PSC or Medicare contractor BI unit shall send informational copies of the statistician-approved sampling methodology to their GTL, Co-GTL, SME or CMS RO. The GTL, Co-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 Medicare contractor BI unit shall not repeatedly send the methodology to the GTL, Co-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. 71, 04-09-04)

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 Medicare contractor BI 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. 71, 04-09-04)

NOTE: *The instructions in this section dealing with notification and determination of location of the review do not supercede instructions for PSCs or Medicare contractor BI 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. 71, 04-09-04)

The PSC or Medicare contractor BI 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 Medicare contractor BI 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 Medicare contractor BI unit shall obtain the advance approval of the GTL, Co-

GTL, SME or 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 Medicare contractor BI unit).

3.10.6.1.1 - Written Notification of Review

(Rev. 71, 04-09-04)

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/PSC 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 Medicare contractor BI 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. 71, 04-09-04)

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 Medicare contractor BI unit Site Reviews

PSC or Medicare contractor BI unit site reviews are performed at a location of the PSC or Medicare contractor BI 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. 71, 04-09-04)

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, only ACs 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/issues identified during the review, and any recommended corrective actions.

3.10.7.2 - Informational Copy to GTL, Co-GTL, SME or CMS RO

(Rev. 71, 04-09-04)

Send an informational copy of the demand letter to the GTL, Co-GTL, SME or CMS RO. They will maintain copies of demand letters and will forward to CO upon request. If the demand letter is used routinely and repeatedly, you shall not repeatedly send it to the GTL, Co-GTL, SME or CMS 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. 71, 04-09-04)

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 GTL, Co-GTL, SME or CMS RO to confirm that this course of action is consistent with the decision of the hearing officer (HO), administrative law judge (ALJ) or Departmental Appeals Board (DAB), or with the court order.

B. You may elect to recover the actual overpayments related to the sampled claims and then initiate a new review of the provider or supplier. If the actual overpayments related to the sampling units in the original review have been recovered, then these individual sampling units shall be eliminated from the sampling frame used for any new review. Consult with your GTL, Co-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 GTL, Co-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)

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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. 71, 04-09-04)

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 nongovernment agencies.

3.11.1.2 - "Probe" Reviews
(Rev. 71, 04-09-04)

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. A general rule of thumb for the decision about how many claims should be included in the probe sample is that it should not exceed more than 20-40 claims for any individual provider (in the case of a hypothesized provider specific problem), or 100 claims distributed among a wider universe of providers (in the case of a hypothesized systemic problem). 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 letter in Program Integrity Manual (PIM) Exhibit 7.5 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. 71, 04-09-04)

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.

However, if the documentation needed to make a medical review determination is not received within 45 days from the date of the documentation request, make a medical review determination based on the available medical documentation. 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 postpay 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 Feedback and Education
(Rev. 71, 04-09-04)

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

When a widespread problem is identified affecting a large number of providers, solicit medical and specialty societies to help with educational efforts. See Exhibit 1 for additional interventions. When a problem is limited to a small group, provide feedback to providers on (1) the nature of the problems identified; (2) what steps they should take to address the problem; and (3) what steps you will take to address the problem . Focused provider education means direct l:l contact between you and the provider through a telephone contact, letter, or meeting. You 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 problem more clearly. The overall goal of providing feedback and education 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.

You must 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 your educational interventions and use of the PCA concepts. In the case of extended medical review activities, 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; and the name and telephone number of a contact person who is familiar with the contents of the notification letter. If a provider requests a meeting with you, you must make reasonable efforts to comply.

*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. 71, 04-09-04)

At any time, if the medical review detects possible fraud, refer the issue to the Benefit Integrity Unit.

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

3.11.1.9 – Track Interventions
(Rev. 71, 04-09-04)

Track interventions (reviews and educational 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 to correct identified problems such as eligibility and medical necessity issues. Record the name of the person contacted in the PTS. Use the PTS to coordinate contacts with providers (e.g., medical review education contacts). 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 your Benefit Integrity 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 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. 71, 04-09-04)

You must educate providers about the PCA concepts. Include PCA as a regular part of your ongoing medical review training and new provider orientation training. In addition, request assistance from state medical societies to help with provider education.

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

3.11.3 – Vignettes
(Rev. 71, 04-09-04)

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.

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.

3. Forty claims are reviewed. Thirty-five claim 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.

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 feedback to the provider about specific errors made and educates the provider on the correct way to bill. 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. 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 informed the home health agency about the denials and the reason for the denials. In response, 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.

Medicare Program Integrity Manual
Chapter 4 - *Benefit Integrity*

Table of Contents
(Rev. 71, 04-09-04)

4.1 - Introduction

(Rev. 71, 04-09-04)

The Program Integrity Manual (PIM) reflects the principles, values, and priorities of the Medicare Integrity Program (MIP). The primary principle of Program Integrity (PI) is to pay claims correctly. In order to meet this goal, *Program Safeguard Contractors (PSCs), Affiliated Contractors (ACs), and Medicare contractors* must ensure that they pay the right amount for covered and correctly coded services rendered to eligible beneficiaries by legitimate providers. *The Centers for Medicare & Medicaid Services (CMS)* follows four parallel strategies in meeting this goal: 1) preventing fraud through effective enrollment and through education of providers and beneficiaries, 2) early detection through, for example, medical review and data analysis, 3) close coordination with partners, including *PSCs, ACs, Medicare* contractors, and law enforcement agencies, and 4) fair and firm enforcement policies.

Fiscal Intermediaries (FIs) and Carriers that have transitioned their Benefit Integrity (BI) work to a PSC (referred to as Affiliated Contractors or ACs) and Fiscal Intermediaries and Carriers that have not transitioned their BI work to a PSC (from this point forward, referred to as Medicare contractors) shall follow the entire PIM for BI functions as they relate to their respective roles and areas of responsibility relating to BI.

ACs and DMERCs shall use the PSC support service activity codes in the Budget Performance Requirements (BPR) to report costs associated with support services provided to the PSC.

PSCs shall follow the PIM to the extent outlined in their respective task orders. The PSC shall only perform the functions outlined in the PIM as they pertain to their own operation. The PSC, in partnership with CMS, shall be proactive and innovative in finding ways to enhance the performance of PIM guidelines.

4.1.1 - Definitions

(Rev. 71, 04-09-04)

To facilitate understanding, the terms used in the PIM are defined in PIM Exhibit 1.

4.2 - The Medicare Fraud Program

(Rev. 71, 04-09-04)

The primary goal of the *PSC and the Medicare contractor BI* unit is to identify cases of suspected fraud, develop them thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and

that any mistaken payments are recouped. Suspension and denial of payments and the recoupment of overpayments are an example of the actions that may be taken. All cases of potential fraud are referred to the Office of Inspector General (OIG), Office of Investigations Field Office (OIFO) for consideration and initiation of criminal *or civil prosecution*, civil monetary penalty, or administrative sanction actions. *AC and Medicare* contractor personnel conducting each segment of claims adjudication, Medical Review (MR), and professional relations functions *shall* be aware of their responsibility for identifying fraud and be familiar with internal procedures for forwarding potential fraud cases to the *PSC and the Medicare contractor BI* unit. *Any area within the AC (e.g., medical review, enrollment, second level screening staff) that refers potential fraud and abuse to the PSC shall maintain a log of all these referrals, and all areas within the Medicare contractor shall maintain a log of all potential fraud and abuse referrals to the Medicare contractor BI unit. At a minimum, the log shall include the following information: provider/physician/supplier name, beneficiary name, HIC number, nature of the referral, date the referral is forwarded to the PSC or Medicare contractor BI unit, name of the individual who made the referral.*

Preventing and detecting potential fraud involves a cooperative effort among beneficiaries, *PSCs, ACs,* Medicare contractors, providers, *Quality Improvement Organizations (QIOs)*, state Medicaid Fraud Control Units (MFCUs), and federal agencies such as *CMS*, the Department of Health and Human Services (DHHS), OIG, the Federal Bureau of Investigation (FBI), and the Department of Justice (DOJ).

Each investigation is unique and *shall* be tailored to the specific circumstances. These guidelines are not to be interpreted as requiring the *PSCs and Medicare* contractor *BI units* to follow a specific course of action or establishing any specific requirements on the part of the government or its agents with respect to any investigation. Similarly, these guidelines *shall* not be interpreted as creating any rights in favor of any person, including the subject of an investigation.

When the *PSC or Medicare contractor BI* unit has determined that a situation is not fraud, it *shall* refer these situations to the appropriate unit at the *PSC, AC, or Medicare contractor.*

4.2.1 - Examples of Medicare Fraud

(Rev. 71, 04-09-04)

The most frequent kind of fraud arises from a false statement or misrepresentation made, or caused to be made, that is material to entitlement or payment under the Medicare program. The violator may be a provider, a beneficiary, or an employee of a provider or some other person or business entity, including a billing service or an intermediary employee.

Providers have an obligation, under law, to conform to the requirements of the Medicare program. Fraud committed against the program may be prosecuted under various

provisions of the United States Code and could result in the imposition of restitution, fines, and, in some instances, imprisonment. In addition, there is also a range of administrative sanctions (such as exclusion from participation in the program) and civil monetary penalties that may be imposed when facts and circumstances warrant such action.

Fraud may take such forms as:

- Incorrect reporting of diagnoses or procedures to maximize payments.
- Billing for services not furnished and/or supplies not provided. This includes billing Medicare for appointments that the patient failed to keep.
- Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both Medicare and the beneficiary for the same service, or billing both Medicare and another insurer in an attempt to get paid twice.
- Altering claim forms, electronic claim records, medical documentation, etc., to obtain a higher payment amount.
- Soliciting, offering, or receiving a kickback, bribe, or rebate, e.g., paying for a referral of patients in exchange for the ordering of diagnostic tests and other services or medical equipment.
- Unbundling or "exploding" charges.
- Completing Certificates of Medical Necessity (CMNs) for patients not personally and professionally known by the provider.
- Participating in schemes that involve collusion between a provider and a beneficiary, or between a supplier and a provider, and result in higher costs or charges to the Medicare program.
- Participating in schemes that involve collusion between a provider and an *AC or Medicare* contractor employee where the claim is assigned, e.g., the provider deliberately over bills for services, and the *AC or Medicare* contractor employee then generates adjustments with little or no awareness on the part of the beneficiary.
- Billing based on "gang visits," e.g., a physician visits a nursing home and bills for 20 nursing home visits without furnishing any specific service to individual patients.

- Misrepresentations of dates and descriptions of services furnished or the identity of the beneficiary or the individual who furnished the services.
- Billing non-covered or non-chargeable services as covered items.
- Repeatedly violating the participation agreement, assignment agreement, and the limitation amount.
- Using another person's Medicare card to obtain medical care.
- Giving false information about provider ownership in a clinical laboratory.
- Using the adjustment payment process to generate fraudulent payments.

Examples of cost report fraud include:

- Incorrectly apportioning costs on cost reports.
- Including costs of non-covered services, supplies, or equipment in allowable costs.
- Arrangements by providers with employees, independent contractors, suppliers, and others that appear to be designed primarily to overcharge the program through various devices (commissions, fee splitting) to siphon off or conceal illegal profits.
- Billing Medicare for costs not incurred or which were attributable to non-program activities, other enterprises, or personal expenses.
- Repeatedly including unallowable cost items on a provider's cost report except for purposes of establishing a basis for appeal.
- Manipulation of statistics to obtain additional payment, such as increasing the square footage in the outpatient areas to maximize payment.
- Claiming bad debts without first genuinely attempting to collect payment.
- Certain hospital-based physician arrangements, and amounts also improperly paid to physicians.
- Amounts paid to owners or administrators that have been determined to be excessive in prior cost report settlements.
- Days that have been improperly reported and would result in an overpayment if not adjusted.

- Depreciation for assets that have been fully depreciated or sold.
- Depreciation methods not approved by Medicare.
- Interest expense for loans that have been repaid for an offset of interest income against the interest expense.
- Program data where provider program amounts cannot be supported.
- Improper allocation of costs to related organizations that have been determined to be improper.
- Accounting manipulations.

4.2.2 - *Program Safeguard Contractor and* Medicare *Contractor* Benefit Integrity Unit

(Rev. 71, 04-09-04)

The PSC and Medicare contractor BI unit is responsible for preventing, detecting, and deterring Medicare fraud. The *PSC and Medicare contractor* BI unit:

- Prevents fraud by identifying program vulnerabilities.
- Proactively identifies incidents of fraud that exist within its service area and takes appropriate action on each case.
- *Investigates* (determines the factual basis of) allegations of fraud made by beneficiaries, providers, CMS, OIG, and other sources.
- Explores all available sources of fraud leads in its jurisdiction, including the MFCU and its corporate anti-fraud unit.
- Initiates appropriate administrative actions to deny or to suspend payments that should not be made to providers where there is reliable evidence of fraud.
- Refers cases to the Office of the Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions *(see PIM Chapter 4, §4.18ff, §4.19ff, and §4.20ff).*
- Provides outreach to providers and beneficiaries.
- Initiates and maintains networking and outreach activities to ensure effective interaction and exchange of information with internal components as well as outside groups.

PSCs and Medicare contractor BI units are required to use a variety of techniques, both proactive and reactive, to address any potentially fraudulent billing practices.

Proactive (self-initiated) leads may be generated and/or identified by any internal *PSC, AC, or Medicare* contractor component, not just the *PSC and Medicare contractor* BI unit*s* (e.g., claims processing, data analysis, audit and reimbursement, appeals, medical review, enrollment, etc.). However, the *PSCs and Medicare contractor BI units* shall pursue leads through data analysis, the Internet, the Fraud Investigation Database (FID), news media, etc.

PSCs and Medicare contractor BI units shall take prompt action after scrutinizing billing practices, patterns, or trends that may indicate fraudulent billing, i.e., reviewing data for inexplicable aberrancies (other than the expected) and relating the aberrancies to specific providers, identifying "hit and run" providers, etc. *PSCs and Medicare contractor BI units shall* meet periodically with staff from *their respective* internal components *and PSCs shall also meet with AC staff* to discuss any problems identified that may be a sign of potential fraud.

Fraud leads from any external source (e.g., law enforcement, CMS referrals, beneficiary complaints, etc.) are considered to be reactive and not proactive. However, taking ideas from external sources, such as non-restricted fraud alerts and using them to look for unidentified aberrancies within *PSC or Medicare* contractor data is proactive.

4.2.2.1 - Organizational Requirements

(Rev. 71, 04-09-04)

Organizationally, each *Medicare* contractor *that has not transitioned to a PSC* shall have a component responsible for the detection, development, and initiating corrective action of fraud cases. Staff supervised by a full-time unit manager shall conduct required fraud activities. This group is referred to as the Benefit Integrity unit. It may consist of employees who work full-time on Medicare fraud issues or employees who work part-time on Medicare and part-time on BI or fraud for the *Medicare* contractor's private line of business. If an employee works on both Medicare and private-side cases, the *Medicare* contractor *shall* not mix Medicare and private-side data. Staff from the BI unit *shall* identify themselves to providers *with their name and the name of the PSC or Medicare contractor* when making contact with providers suspected of committing fraud. If workload supports a full-time unit, it *shall* be a separate and distinct unit within the *Medicare* contractor organization and may not be combined with the MR and corporate-side PI units, i.e., it shall handle only Medicare cases. Multi-state *Medicare* contractors shall maintain at least one contact at each site. Separate time records shall be maintained on any part-time staff assigned to the BI unit. Large *Medicare* contractors shall, however, establish separate distinct BI units. Regardless of the number of personnel in the BI unit, all necessary action *shall* be taken to ensure the integrity of Medicare payments. This means that an effective Medicare payment safeguard program *shall* be in place.

Full PSCs are not required to separate their MR and BI units. However, all BI information shall be kept confidential and secure and shared with MR only on a need-to-know basis.

The *PSC and Medicare contractor BI unit* managers shall have sufficient authority to guide *BI* activities. The managers shall be able to establish, control, evaluate, and revise fraud-detection procedures to ensure their compliance with Medicare requirements.

The *PSC and Medicare contractor BI unit* manager shall prioritize work coming into the *PSC or Medicare contractor BI unit* to ensure that *investigations and* cases with the greatest program impact are given the highest priority. Allegations or cases having the greatest program impact would include cases involving:

- Patient abuse.
- Multi-state fraud.
- High dollar amounts of potential overpayment.
- Likelihood for an increase in the amount of fraud or enlargement of a pattern.
- Fraud complaints made by Medicare supplemental insurers. *PSCs, ACs, and Medicare* contractors shall give high priority to fraud complaints made by Medicare supplemental insurers. If a referral by a Medigap insurer includes investigatory findings indicating fraud stemming from site reviews, beneficiary interviews and/or medical record reviews, *PSCs and Medicare* contractor *BI units* shall 1) conduct an immediate data run to determine possible Medicare losses, and 2) refer the case to the OIG.

4.2.2.2 - Liability of *Program Safeguard Contractor* and *Medicare Contractor Benefit Integrity* Unit Employees

(Rev. 71, 04-09-04)

Under the terms of their contracts and proposed rule 42 CFR § 421.316(a), PSCs, their employees and professional consultants are protected from criminal or civil liability as a result of the activities they perform under their contracts as long as they use due care. If a PSC, or any of its employees or consultants are named as defendants in a lawsuit, CMS will determine, on a case-by-case basis, whether to request that the U.S. Attorney's office offer legal representation. If the U.S. Attorney's office does not provide legal representation, the PSC will be reimbursed for the reasonable cost of legal expenses it incurs in connection with defense of the lawsuit as long as funds are available and the expenses are otherwise allowable under the terms of the contract.

When a provider is under investigation, the *provider might* sue the *Medicare* contractor *BI unit*. Such suits are not common, and even more rarely are they successful. It should be noted that courts, over the past several years, have begun sanctioning attorneys for filing frivolous complaints. *Courts have generally agreed that as agents* of the federal government, *Medicare* contractor *BI units* have what is referred to as official immunity.

The doctrine of official immunity provides that government officials enjoy an absolute privilege from civil liability should the activity in question fall within the scope of their authority and if the action undertaken requires the exercise of discretion. Moreover, *Medicare* contractors are assured an offer of a defense by the U.S. Attorney's office as long as the *Medicare* contractors were performing activities required by *CMS* and were within the scope of the job description. *Medicare* contractors are protected even if the *Medicare* contractors make honest mistakes or errors of judgment.

Medicare contractors are not protected if the *Medicare* contractors go beyond their authority or scope of activities or commit torts or criminal acts (e.g., *libel or trespass*). *Medicare* contractors are subject to risk if the *Medicare* contractors act with malice or vindictiveness.

Investigating fraud and prosecuting offenders falls well within the government's interests and whatever resources are needed will be used to protect *Medicare* contractors and those activities. Sections 1816(i) and 1842(e) of the Social Security Act (the Act) are the authorities that *CMS* has construed to provide a basis for *Medicare* contractors' entitlement to indemnification for litigation costs and adverse judgments that are incurred as a consequence of performing the claims payment portion of their official duties. This includes fraud and abuse activities.

When *Medicare contractor BI units* are served with a complaint, they *shall* immediately contact the corporate general counsel. *If a PSC is served with a complaint, it shall immediately contact its chief legal counsel and GTL. PSCs and Medicare* contractor *BI units shall* forward the complaint to the Department of Health and Human Services Office of the Regional Chief Counsel (*CMS* Regional Attorney) who, in turn, will notify the U.S. Attorney. The HHS office forwards complaint*s against Medicare contractor BI units* to the U.S. Attorney within 20 calendar days of receipt. *The HHS office and/or the GTL will notify the PSC whether legal representation will be sought from the U.S. Attorney prior to the deadline for filing an answer to the complaint.*

4.2.2.3 – Anti-Fraud Training

(Rev. 71, 04-09-04)

All levels of *PSCs and Medicare* contractor employees shall know the goals and techniques of fraud detection and control in general and as they relate to their own areas of responsibility (i.e., general orientation for new employees and highly technical sessions for BI unit, claims processing, medical review, audit, and appeals staff). All *PSCs and Medicare contractor* BI unit staff shall be adequately qualified for the work of

detecting and investigating situations of potential fraud. CMS separates the requirements into two different levels in recognition that new and experienced staff have different needs. *Medicare contractor* BI units shall consult the Regional Office (RO) if they want to confirm that specific training sessions will meet CMS's requirements.

A - Level I - One-Time Completion

This does not apply to PSCs.

Within the first year of employment, *Medicare contractor* BI *unit* employees shall complete 36 hours of Level I training, as per the three categories below. This training will be directly pertinent to fraud detection and investigation and easily applied to the health care and Medicare environment. This means that Level I training shall be completed one-time only.

- Fraud detection - 16 hours
- Data analysis - 16 hours
- Interviewing techniques - 4 hours

B - Level II - Annual Completion

This does not apply to PSCs.

Medicare contractor BI unit employees shall annually complete a total of 6 hours of advanced training, to maintain skills and learn the most advanced techniques in 2 areas that can be easily applied to the health care and Medicare environment:

- Advanced fraud detection - 4 hours
- Advanced data analysis - 2 hours

C - CMS National Benefit Integrity Training

Each *PSC and Medicare* contractor *BI unit* shall send the appropriate representative(s) to CMS's national benefit integrity training each year it is provided.

4.2.2.3.1 - Training for Law Enforcement Organizations

(Rev. 71, 04-09-04)

FBI agents and DOJ attorneys need to understand Medicare. *PSCs and Medicare* contractors *BI units shall* conduct special training programs for them *upon request. PSCs and Medicare* contractors should *also* consider inviting DOJ attorneys, *OIG agents,* and

FBI agents to existing programs intended to orient employees to *PSC or Medicare contractor* operations, or to get briefings on specific cases or Medicare issues.

4.2.2.4 - Procedural Requirements

(Rev. 71, 04-09-04)

Medicare contractors *shall* provide written procedures for *Medicare contractor* BI unit personnel and for personnel in other *Medicare* contractor components (claims processing, MR, beneficiary services, intermediary audit, etc.) to help identify potential fraud situations. Include provisions to ensure that personnel *shall*:

- Refer potential fraud cases promptly to the BI unit.
- Forward complaints alleging fraud *through the second level screening staff* to the BI unit.
- Maintain confidentiality of referrals to the BI unit so that the civil rights of those involved are protected.
- Forward to the BI unit documentation of the details of telephone or personal contacts involving fraud issues discussed with providers or provider staff, and retain such information in individual provider files.

In addition, PSCs and Medicare contractor BI units shall ensure the performance of the functions below and have written procedures for these functions:

- Keep educational/warning correspondence with providers and other fraud documentation concerning specific issues in individual provider files *(refer to §4.2.2.4.2 for retention of this documentation),* so that *PSCs and Medicare* contractors are able to retrieve such documentation easily.
- Maintain communication and information flowing between the *PSC or Medicare contractor* BI *unit, and the PSC, AC, or Medicare contractor* MR *staff*, and as appropriate, intermediary audit staffs.
- Take appropriate administrative action on cases not accepted by OIG *or other investigative agencies.* At a minimum, provide *information* for recovery of identified overpayments and other corrective actions discussed in *PIM Chapter 3, §8ff and §9ff.*
- Properly prepare and document cases referred to OIG/OI; *two copies of* a summary page shall be included with each fraud referral made to the OIG. The referral format listed in PIM Exhibits 16.1 and 16.2 shall be followed, unless written guidance is provided by the applicable OIG/OI office and approved by the

GTL, Co-GTL, and SME (if a PSC) or the applicable CMS RO *(if a Medicare contractor BI unit). PSCs and Medicare* contractor *BI units* shall maintain files on the written guidance provided by the OIG/OI.

- *Meet (in-person or telephone call) quarterly, or more frequently if necessary, with OIG agents to discuss pending or potential cases.*

- *Meet (in-person or telephone) regularly with DOJ to enhance coordination with them on current or pending cases.*

- Furnish all available information *upon request* to OIG/OI with respect to *excluded* providers requesting reinstatement.

- Ensure that all cases *that have been identified* where a provider consistently fails to comply with the provisions of the assignment agreement are reported *by the PSC to the GTL, Co-GTL, and SME; and reported by the Medicare contractor BI unit to the* RO.

- Maintain documentation on the number of *investigations* alleging fraud, *the number of* cases referred to OIG/OI (and the disposition of those cases), processing time of *investigations,* and types of violations referred to OIG (e.g., item or service not received, unbundling, waiver of co-payment).

- *Conduct investigations* (including procedures for reviewing questionable billing codes), make beneficiary contacts (*see PIM Chapter 4, §4.7.1 for details concerning investigations),* and refer cases to and from the MR unit *within your organization.*

- *Ensure that before making an unannounced visit where fraud is suspected, clear it first with the GTL, Co-GTL, and SME (if a PSC) or RO (if a Medicare contractor BI unit), and the OI* F*ield Office, and ensure that any other appropriate investigative agency is also apprised of the plan. PSC and Medicare* contractor *BI unit* staff shall never engage in covert operations (e.g., undercover or surveillance activities).

- *Provide notification by email, letter, or telephone call (if a telephone call, follow up with a letter or email) to the GTL, Co-GTL, and SME (if a PSC) or to the* RO *(if a Medicare contractor BI unit), when* the *PSC or Medicare* contractor *BI unit* is asked to accompany the OI or any other law enforcement agency when they are going onsite to a provider for the purpose of gathering evidence in a fraud case (e.g., executing a search warrant). However, law enforcement must make clear the role of *PSC or Medicare* contractor *BI unit* personnel in the proposed onsite visit. The potential harm to the case and the safety of *PSC or Medicare* contractor *BI unit* personnel shall be thoroughly evaluated. *PSC or Medicare* contractor *BI unit* personnel shall properly identify themselves as *PSC or Medicare* contractor *BI unit* employees, and under no circumstances shall they represent themselves as

law enforcement personnel or special agents. Lastly, under no circumstances shall *PSC or Medicare* contractor *BI unit* personnel accompany law enforcement in situations where their personal safety is in question.

ACs ensure the performance of the functions below and have written procedures for these functions:

- Ensure no payments are made for *items or* services ordered, referred, or furnished by an individual or entity following the effective date of exclusion (see PIM *Chapter 4, §4.19ff* for exceptions).

- Ensure all instances where an excluded individual or entity that submits claims for which payment may not be made after the effective date of the exclusion are reported *to the OIG (see PIM Chapter4, §4.19ff).*

- Ensure no payments are made for an excluded individual or entity who is employed by a Medicare provider or supplier.

4.2.2.4.1 - Maintain Controlled Filing System and Documentation

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* maintain files on providers who have been the subject of complaints, prepayment flagging, *PSC or Medicare contractor BI unit* investigations, OIG/OI *and/or DOJ* investigations, U.S. Attorney prosecution, and any other civil, criminal, or administrative action for violations of the Medicare or Medicaid programs. The files *shall* contain documented warnings and educational contacts, the results of previous investigations, and copies of complaints *resulting in investigations*.

PSCs and Medicare contractors BI units *shall* set up a system for assigning and controlling numbers at the initiation of *investigations,* and *shall* ensure that:

- All incoming correspondence or other documentation associated with a*n investigation* contains the same file number and is placed in a folder containing the original *investigation* material.

- *Investigation* files are adequately documented to provide an accurate and complete picture of the investigative effort.

- All contacts are clearly and appropriately documented.

- Each *investigation* file lists the name, organization, address, and telephone numbers of all persons with whom the *PSC or Medicare* contractor *BI unit* can discuss the *investigation* (including those working within the *PSC or Medicare contractor BI unit*).

It is important to establish and maintain histories and documentation on all fraud and abuse *investigations and* cases. *PSCs and Medicare* contractor *BI units shall* conduct periodic reviews of the kinds of fraud detected over the past several months to identify any patterns of potential fraud and abuse situations for particular providers. The *PSCs and Medicare* contractor *BI units shall* ensure that all evidentiary documents are kept free of annotations, underlining, bracketing, or other emphasizing pencil, pen, or similar marks.

PSCs and Medicare contractor *BI units shall* establish an internal monitoring and *investigation and* case review system to ensure the adequacy and timeliness of fraud and abuse activities.

4.2.2.4.2- File/Document Retention

(Rev. 71, 04-09-04)

Files/documents shall be retained for 10 years. However, files/documents shall be retained indefinitely and shall not be destroyed if they relate to a current investigation or litigation/negotiation; ongoing Workers' Compensation set aside arrangements, or documents which prompt suspicions of fraud and abuse of overutilization of services. This will satisfy evidentiary needs and discovery obligations critical to the agency's litigation interests.

4.2.2.5 - Medicare Fraud Information Specialist

(Rev. 71, 04-09-04)

This section only applies to Medicare contractors who have not transitioned their BI work to a PSC.

The Medicare Fraud Information Specialist (MFIS) position is to be 100 percent dedicated to the MFIS activities described below, unless the CO and the applicable RO approve otherwise. The primary responsibility of MFISs is to share information concerning fraud with ROs, *PSCs and Medicare* contractor *BI units* in their jurisdiction, other MFISs, law enforcement agencies, state agencies, and other interested organizations (e.g., Ombudsmen, Administration on Aging (AoA), Harkin Grantees and other grantee recipients), for both Part A and Part B of the Medicare program. The MFISs are not fraud investigators. Without RO and CO concurrence, the MFISs are not to perform functions such as *investigations*, clearinghouse functions, OIG hotline referrals, FID entries, data analysis, incentive reward program (IRP) entries, or onsite audits.

The MFISs are Medicare contractor employees. As such, they report directly to the *Medicare* contractor's BI unit manager or BI unit director equivalent. The jurisdiction of the MFISs will correspond to their RO's jurisdiction; it is not to cross over RO boundaries, other than when needed on an exception basis. The ROs, in coordination with

the CO, will promptly determine the *Medicare* contractor that will employ each MFIS whenever an MFIS terminates their employment with the *Medicare* contractor or a *Medicare* contractor leaves the Medicare program.

The DMERC MFIS position *shall* report to Region X, and *shall be* responsible for informing other ROs of schemes, investigations and/or cases affecting those regions.

All *Medicare* contractors, regardless of where the MFIS is located, *shall* communicate with their assigned MFIS and utilize his/her services. The major duties and responsibilities listed below *shall* be performed by the MFIS equally for all *Medicare* contractors within his/her jurisdiction.

For budget purposes, MFISs *shall be* required to submit a work plan and the level of activity for all training and outreach functions to their RO 30 days before the beginning of the fiscal year. MFISs *shall* submit monthly reports to the RO. These reports should quantify activities wherever possible. At a minimum, the reports *shall* include the following information:

- Networking activities, such as meetings attended and conference calls, complete with a) the identity of each meeting and the speakers, b) the date of each meeting, c) the location of each meeting, d) the number of meetings attended, e) the number of attendees at each meeting, and f) the results of each meeting.

- Outreach/training activities (e.g., CMS health care partner interaction), complete with a) the identify of the outreach/training, b) the date of each outreach/training, c) the location of each outreach/training, d) the number of outreach/training sessions conducted, and e) the number of attendees at each session.

- Planned events (e.g., calendar of upcoming months).

- Alerts (CMS, OIG, MFIS), including those authored by the MFIS and those not authored by the MFIS but distributed by them.

- Special projects (e.g., significant activities not included in the above).

4.2.2.5.1 – Medicare Fraud Information Specialist Position Description

(Rev. 71, 04-09-04)

This section applies to Medicare contractors that have not transitioned their BI work to a PSC. PSCs shall perform the functions specified in this section, but they are not required to create an MFIS position.

Major Duties and Responsibilities of the Medicare Fraud Information Specialist

- Obtains and shares information on health care issues/fraud investigations among fellow MFISs, Carriers (including Durable Medical Equipment Regional Carriers (DMERCs)), Fiscal Intermediaries (including Rural Home Health Intermediaries (RHHIs)), *PSCs, CMS,* and law enforcement.

- Serves as a reference point for law enforcement and other organizations and agencies to contact when they need help or information on Medicare fraud issues and *do not* know whom to contact.

- Assists *PSCs, Medicare* contractors*, CMS* ROs, law enforcement, and *CMS* health care partners by coordinating and attending fraud-related meetings/conferences and informs all appropriate parties about these meetings/conferences. These meetings/conferences include, but are not limited to, health care task force meetings, MFIS meetings (in-person/annual meetings), and MFIS conference calls. The MFIS is to relay all pertinent information from these meetings/conferences to the *PSC and Medicare contractor BI unit* managers within the MFIS's jurisdiction and applicable *CMS* ROs as appropriate.

- Distributes all fraud alerts to the appropriate parties within their jurisdiction. Shares *PSC and Medicare* contractor *BI unit* findings on fraud alerts with *PSCs, Medicare* contractors in their jurisdiction, fellow MFISs, and *CMS*.

- Works with the CMS RO to develop and organize external programs and perform training as appropriate for law enforcement, ombudsmen, grantees (e.g., Harkin Grantees) and other *CMS* health care partners (e.g., AoA, state MFCU).

- Conducts regular calls/visits with the *PSC and Medicare contractor BI unit* managers within the MFIS's jurisdiction, to address their needs.

- Serves as a resource to *CMS* as necessary. For example, serves as a resource to *CMS* on the FID, including FID training. While the MFIS should not enter *investigations and* cases into the FID or monitor FID quality, if the MFIS detects any inaccuracies or discrepancies they should notify the *PSC or Medicare* contractor *BI unit*. Upon request, the MFIS will furnish FID reports to the BI *unit* managers within their jurisdiction.

- Helps develop fraud-related outreach materials (e.g., pamphlets, brochures, videos, etc.) in cooperation with beneficiary services and/or provider relations departments of the *ACs and Medicare* contractors, for use in their training. Submits written outreach materials to the *CMS* RO for clearance. Ensures these materials are incorporated into the existing outreach efforts *of the ACs and Medicare* contractors. Conducts high level, fraud-specific presentations/training.

- Assists in preparation and development of fraud-related articles for *AC and Medicare* contractor newsletters/bulletins for all *PSCs and Medicare* contractors within the MFIS's jurisdiction.

- Serves as a resource for the development of annual internal and new hire fraud training. (The *PSC and Medicare contractor* BI unit staff is responsible for performing the actual fraud training.)

- Attends 32 hours of training sessions on training and, presentation skills (16 hours) and fraud-related training (16 hours) the first year of employment, and every 3 years thereafter. *PSCs shall provide training as necessary.*

- Travels to support MFIS activities

Knowledge and Skills Required by MFIS Position

- Effective written and oral communication skills

- Effective presentation skills

- Extensive knowledge of the Medicare program, both Part A and Part B

- Working knowledge and/or experience in one or more of the following fields:

    - Health care delivery system

    - Health insurance business

    - Law enforcement

- Demonstrated organizational, analytical, and coordination skills to effectively coordinate and schedule meetings, conferences, and training

- Ability to work independently

4.2.2.5.2 - Medicare Fraud Information Specialist Budget Performance Requirements

(Rev. 71, 04-09-04)

This section applies only to Medicare contractors that have not transitioned their BI work to a PSC.

MFISs are to report all costs associated with MFIS activity in Activity Code 23001. This activity code applies only to *Medicare* contractors at which the RO has indicated an MFIS will be located. The BPR states to report the number of fraud conferences/meetings coordinated by the MFIS in workload column 1; the number of fraud conferences/ meetings attended by the MFIS in workload column 2; and the number of presentations performed for law enforcement, ombudsmen, Harkin Grantees and other grantees, and

other CMS health care partners in workload column 3. To clarify workload columns 1 and 2, "conferences and meetings" include conference calls coordinated and attended by the MFIS in lieu of coordinating and attending in-person conferences and meetings.

4.2.2.6 – Benefit Integrity Security Requirements

(Rev. 71, 04-09-04)

PSCs and Medicare contractors shall ensure a high level of security for this sensitive function. *PSCs and Medicare contractor* BI unit staff, as well as all other *PSC and Medicare* contractor employees, shall be adequately informed and trained so that information obtained by, and stored in, the *PSC and Medicare contractor* BI unit is kept confidential.

Physical and operational security within the *PSC and Medicare contractor* BI unit is essential. Operational security weaknesses in the day-to-day activities of *PSCs and Medicare contractor* BI units may be less obvious and more difficult to identify and correct than physical security. The interaction of *PSCs and Medicare contractor* BI units with other *PSC or Medicare* contractor operations, such as the mailroom, could pose potential security problems. Guidelines that shall be followed are discussed below.

Most of the following information can be found in the Business Partners Security Manual, which is located at http://www.cms.hhs.gov/manuals/117_systems_security. It is being reemphasized in this PIM section.

A - *Program Safeguard Contractor and Medicare Contractor* Benefit Integrity Unit Operations

PSC and Medicare contractor BI unit activities shall be conducted in areas not accessible to the general public and other non-BI *Medicare* contractor staff. Other requirements *shall* include:

- *Complying with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provisions.*

- Limiting access to *PSC and Medicare contractor* BI unit sites to only those who need to be there on official business. (Tours of the *Medicare* contractor shall not include the BI unit.)

- Ensuring that discussions of highly privileged and confidential information cannot be overheard by surrounding units. Ideally, the unit does not have an unmonitored entrance or exit to the outside, and has a private office for the manager, for the discussion of sensitive information.

- Ensuring that visitors to the *PSC or Medicare contractor* BI unit who are there for official purposes unrelated to *PSC or Medicare contractor* BI unit functions (e.g., cleaning crews, mail delivery personnel, technical equipment repair staff) are not left unobserved.

- Securing the *PSC or Medicare contractor* BI unit site when it is not occupied by *PSC or Medicare contractor* BI unit personnel.

- Barring budget constraints and a specific written waiver (exception) from the CMS RO, the *Medicare* contractor BI unit shall be completely segregated from all other *Medicare* contractor operations. This segregation shall include closed walls or partitions that prevent unauthorized access or overhearing of sensitive investigative information. *Full PSCs are not required to separate their MR and BI units. However, all BI information shall be kept confidential and secure and shared with MR only on a need-to-know basis.*

B - Handling and Physical Security of Sensitive Material

PSCs and Medicare contractor BI units shall consider all fraud and abuse allegations and associated *investigation and* case material to be sensitive material. The term "sensitive material" includes, but is not limited to, *PSC or Medicare contractor* BI unit *investigation and* case files and related work papers (correspondence, telephone reports, complaints and associated records, personnel files, reports/updates from law enforcement, etc.). Improper disclosure of sensitive material could compromise an investigation or prosecution of a case; it could also cause harm to innocent parties or potentially jeopardize the personal safety of law enforcement (e.g., covert/undercover investigations).

The following guidelines shall be followed:

- Employees shall discuss specific allegations of fraud only within the context of their professional duties and only with those who have a valid need to know. This may include staff from the *PSC, AC or Medicare contractor* MR or audit units, *data analysis,* senior management, or corporate counsel.

- Ensure the mailroom, general correspondence, and telephone inquiries procedures maintain confidentiality whenever correspondence, telephone calls, or other communications alleging fraud are received. All internal written operating procedures shall clearly state security procedures.

- Mailroom staff shall be directed not to open BI unit mail in the mailroom, unless the mailroom staff has been directed to do so *for safety and health precautions;* mail contents *shall* not be read and *shall* be held in confidence. Mail being sent to CO, another *PSC, Medicare contractor* BI unit, or MFIS, *shall* be marked "personal and confidential," and shall be addressed to a specific person.

- Where not prohibited by more specialized instructions, sensitive materials may be retained at employees' desks, in office work baskets, and at other points in the office during the course of the normal work day. Access to these sensitive materials is restricted, and such material shall never be left unattended.

- For mail processing sites located in separate *PSC or Medicare* contractor facilities, the *PSC or Medicare* contractor shall minimize the handling of BI unit mail by multiple parties before delivery to the *PSC or Medicare contractor* BI unit.

- When not being used or worked on, such materials shall be retained in locked official repositories such as desk drawers, filing cabinets, or safes. Such repositories shall be locked at the end of the work day and at other times when immediate access to their contents is not necessary.

- Where such materials are not returned to their official repositories by the end of the normal work day, they shall be placed in some other locked repository (e.g., an employee's desk), locked office, or locked conference room.

- *PSCs and Medicare* contractor *BI units* shall establish procedures for safeguarding keys, combinations, codes and other mechanisms, devices, or methods for achieving access to the work site and to lockable official repositories. The *PSCs and Medicare* contractor *BI units* shall limit access to keys, combinations, etc., and maintain a sign-off log to show the date and time when repositories other than personal desk drawers and file cabinets are opened and closed, the documents accessed, and the name of the person accessing the material.

- The *PSC and Medicare contractor BI* unit shall maintain a controlled filing system (see PIM *Chapter 4, §4.2.2.4.1*).

- Discarded sensitive information shall be shredded *on a daily basis* or stored in a locked container for subsequent shredding.

C - Designation of a Security Officer

The *PSC or Medicare contractor* BI unit manager shall designate an employee to serve as the security officer of the *PSC or Medicare contractor BI* unit. In addition to their BI duties, the security officer's responsibilities shall include:

- Continuous monitoring of component operations to determine whether the basic security standards *noted in B above* are being observed.

- Correcting violations of security standards immediately and personally, where practicable and within his/her authority. (This refers to locking doors mistakenly left open; switching off computer equipment left on after the employee using it

has departed for the day; locking file cabinets, desk drawers, storage (file) rooms, or safes left unlocked in error; and similar incidents where prompt action is called for.).

- Reporting violations of security standards to the appropriate supervisory authority, so that corrective and/or preventive action can be taken.

- Maintaining a log of *all reviews and indicating any* violations. The log shall identify the reported issue, the date reported, whom the issue was reported to, and any subsequent resolution. CMS staff may request to review this log periodically.

The *PSC or Medicare contractor* BI unit manager, compliance manager, or other designated manager shall:

- Review their general office security procedures and performance with the security officer at least once every 6 months.

- Document the results of the review.

- Take such action as is necessary to correct breaches of the security standards and to prevent recurrence. The action taken shall be documented and maintained by the *PSC or Medicare contractor* BI unit manager.

D - Staffing of the *Program Safeguard Contractor or Medicare Contractor* Benefit Integrity Unit and Security Training

The *PSC or Medicare contractor* BI unit manager shall ensure that *PSC or Medicare contractor* BI unit employees are well-suited to work in this area and that they receive appropriate CMS-required training.

All *PSC or Medicare contractor* BI unit employees should have easily verifiable character references and a record of stable employment.

The *PSC or Medicare contractor* BI unit manager shall ensure the following:

- Thorough background and character reference checks, *including at a minimum credit checks*, shall be performed for potential employees, to verify their suitability for employment with the *PSC or Medicare contractor* BI unit.

- In addition to a thorough background investigation, potential employees shall be asked whether their employment in the *PSC or Medicare contractor* BI unit might involve a conflict of interest.

- At the point a hiring decision is made for a *PSC or Medicare contractor* BI *unit* position, and prior to the person starting work, the proposed candidate shall be

required to fill out a conflict of interest declaration as well as a confidentiality statement.

- Existing employees shall be required annually to fill out a conflict of interest declaration as well as a confidentiality statement.

- Temporary employees, such as those from temporary agencies, students (non-paid or interns), and non-citizens shall not be employed in the *PSC or Medicare contractor* BI unit.

- The special security considerations under which the *PSC or Medicare contractor* BI unit operates shall be thoroughly explained and discussed.

- *The hiring of* fully competent and competitive staff, and *the implementation of* measures to foster their retention.

E - Access to Information

PSC, Medicare contractor, and CMS managers shall have routine access to sensitive information if the *PSCs, Medicare* contractors, and CMS managers are specifically authorized to work directly on a particular fraud case or are reviewing cases as part of *their oversight responsibilities and their performance evaluations*. This includes physician consultants who may be assisting the BI unit and whose work may benefit by having specific knowledge of the particular fraud case.

Employees not directly involved with a particular fraud case shall not have routine access to sensitive information. This *shall* include the following:

- Employees who are not part of the *PSC or* Medicare contractor *BI unit*.

- Corporate employees working outside the Medicare division.

- Clerical employees who are not integral parts of the *PSC or Medicare contractor* BI unit.

- MFISs. Typically, CMS would not expect MFISs to have routine access to fraud information. However, the MFISs may be directed by CMS to disseminate or convey certain privileged information. MFISs *shall* keep all sensitive information confidential.

Employees should keep in mind that any party that is the subject of a fraud investigation is likely to use any means available to obtain information that could prejudice the investigation or the prosecution of the case. As previously noted and within the above exceptions, *PSCs and Medicare contractor BI units* shall not release information to any

person outside of the *PSC or Medicare contractor* BI unit and law enforcement staff, including provider representatives and lawyers.

Although these parties may assert that certain information must be provided to them based on their "right to know," *PSCs and Medicare* contractor *BI units* have no legal obligation to comply with such requests. The *PSCs and Medicare* contractor *BI units* shall request the caller's name, organization, and telephone number. Indicate that verification of whether or not the requested information is authorized for release must occur before response may be given. Before furnishing any information, however, *PSCs and Medicare* contractor *BI units* shall definitely determine that a caller has a "need to know," and that furnishing the requested information will not prejudice the *investigation* or case or prove harmful in any other way. Each *investigation and* case file shall list the name, organization, address and telephone numbers of all persons with whom the *PSC or Medicare* contractor *BI unit* can discuss the *investigation or* case (including those working within the *PSC or Medicare contractor* BI unit).

While *PSC and Medicare* contractor *BI unit* management may have access to general case information, it shall only request on a need-to-know basis specific information about *investigations* that the *PSC or Medicare contractor* BI unit is actively *working*.

The OIG shall be notified if parties without a need to know are asking inappropriate questions. The *PSC and Medicare* contractor *BI unit* shall refer all media questions to the CMS press office.

F - Computer Security

Access to *BI information in* computers shall be granted only to *PSC or Medicare contractor BI* unit employees. The following guidelines shall be followed:

- Employees *shall* comply with all parameters/standards in CMS's Information System Security Policy, Standards and Guidelines Handbook and with the System Security Plan (SSP) Methodology.

- Access to computer files containing information on current or past fraud investigations shall be given only to employees who need such access to perform their official duties.

- Passwords permitting access to BI compatible files or databases shall be kept at the level of confidentiality specified by the *PSC or Medicare* contractor *BI unit* supervisory staff. Employees entering their passwords shall ensure that it is done at a time and in a manner that prevents unauthorized persons from learning them.

- Computer files with sensitive information shall not be filed or backed up on the hard drive of personal computers, *unless one of the* two following exceptions are met: 1) the hard drive is a removable one that can be secured at night (the presumption is that a computer with a fixed hard drive is not secure); and 2) the

computer can be protected (secured with a “boot” password, a password that is entered after the computer is turned on or powered on). This password prevents unauthorized users from accessing any information stored on the computer's local hard drive(s) (C drive, D drive).

- Another safe and efficient way to preserve data is to back it up. Backing up data is similar to copying it, except that back-up utilities compress the data so that less disk space is needed to store the files.

- Record sensitive information on specially marked floppy disks or CDs and control and file these in a secure container placed in a locked receptacle (desk drawer, file cabinet, etc.). Check computers used for sensitive correspondence to ensure that personnel are not filing or backing up files on the hard drive. The configuration of the software needs to be checked before and after the computer is used to record sensitive information.

- Limit the storage of sensitive information in provider files with open access. Conclusions, summaries, and other data that indicate who will be indicted shall be in note form and not entered into open systems.

- The storage of sensitive information on a Local Area Network (LAN) or Wide Area Network (WAN) is permissible if the two following parameters are satisfied:

  1) The LAN/WAN *shall* be located on a secure Server and the LAN/WAN drive *shall* be mapped so that only staff from the BI unit have access to the part of the LAN in which the sensitive information is stored.

  2) LAN/WAN Administrators have access to all information located on the computer drives they administer, including those designated for the BI unit. As such, LAN/WAN Administrators *shall* also complete an annual confidentiality statement.

Environmental security measures shall also be taken as follows:

- Electronically recorded information shall be stored in a manner that provides protection from excessive dust and moisture and temperature extremes.

- Computers shall be protected from electrical surges and static electricity by installing power surge protectors.

- Computers shall be turned off if not being used for extended periods of time.

- Computers shall be protected from obvious physical hazards, such as excessive dust, moisture, extremes of temperature, and spillage of liquids and other destructive materials.

- Class C (electrical) fire extinguishers shall be readily available for use in case of computer fire.

G - Telephone Security

The *PSC or Medicare contractor* BI unit shall implement phone security practices. As stated earlier in this section, the *PSC or Medicare contractor* BI unit *shall* discuss *investigations and* cases only with those individuals that have a need to know the information, and *shall not* divulge information to individuals not personally known to the *PSC or Medicare* contractor *BI unit* involved in the investigation of the related issue.

This applies to persons unknown to the *PSC or Medicare* contractor *BI unit* who say they are with the FBI, OIG, DOJ, etc. *The PSC or Medicare contractor BI unit shall* only use CMS, OIG, DOJ, and FBI phone numbers that can be verified. Management shall provide *PSC or Medicare contractor* BI unit staff with a list of the names and telephone numbers of the individuals of the authorized agencies that the *PSC or Medicare* contractor *BI unit* deal with and *shall* ensure that this list is properly maintained and periodically updated.

Employees *shall be* polite and brief in responding to phone calls, but *shall* not volunteer any information or confirm or deny that an investigation is in process. Personnel *shall be* cautious of callers who "demand" information and continue to question the *PSC or Medicare* contractor *BI unit* after it has stated that it is not at liberty to discuss the matter. Again, it is necessary to be polite, but firmly state that the information cannot be furnished at the present time and that the caller will have to be called back. *PSCs and Medicare* contractor *BI units shall* not respond to questions concerning any case being investigated by the OIG, FBI, or any other law enforcement agency. The *PSCs and Medicare* contractor *BI units shall* refer them to the OIG, FBI, etc., as appropriate.

PSCs and Medicare contractor BI units shall transmit sensitive information via facsimile (fax) lines only after it has been verified that the receiving fax machine is secure. Unless the fax machine is secure*, PSCs or Medicare* contractor *BI units* shall make arrangements with the addressee to have someone waiting at the receiving machine while the fax is being transmitted. Sensitive information via fax *shall not be transmitted* when it is necessary to use a delay feature, such as entering the information into the machine's memory.

4.2.3 - Durable Medical Equipment Regional Carrier Fraud Functions

(Rev. 71, 04-09-04)

This section applies to both DMERCs and any PSCs performing DMERC BI functions.

On October 1, 1993, separate Medicare carriers were established to pay and review claims for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). These items are described in further detail at 42 CFR 414.202. As Medicare carriers, DMERCs *shall be* subject to all *BI unit* requirements applicable to other carriers.

The fraud *investigation and case referral* function *shall* reside in the *PSC or* DMERC *BI unit*, which is Medicare-dedicated and physically and organizationally identifiable as a separate unit. The unit *shall be* led by a full-time *BI unit* manager. The decisions of the *BI unit* manager as they pertain to the referral of fraud cases to OIG are not subject to review by DMERC management.

PSCs and DMERCs shall process all complaints alleging DMEPOS fraud that are filed in their regions in accordance with requirements of *PIM Chapter 4, §4.6ff*. The BI *unit* manager has responsibility for all *BI unit* activity, including the coordination with outside organizations as specified in the *PIM Chapter 4, §4.4.2.1*.

A - General Requirements

Since the Medicare program has become particularly vulnerable to fraudulent activity in the DMEPOS area, each *PSC and* DMERC *shall*:

- Routinely communicate with and exchange information with its *PSC, AC or Medicare DMERC* MR unit and ensure that referrals for prepayment MR review or other actions are made.

- Consult *with DMERC* Medical Directors Workgroup in cases involving medical policy or coding issues.

- Fully utilize data available from the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC), to identify items susceptible to fraud.

- Keep other DMERCs, the SADMERC, *PSCs,* and *CMS* RO and CO staff informed of its ongoing activities and share information concerning aberrancies identified using data analysis, ongoing and emerging fraud schemes identified, and any other information that may be used to prevent similar activity from spreading to other jurisdictions.

B - Use of National Supplier Clearinghouse Alert Codes

DMERCs *shall* initiate appropriate and immediate action in cases where a supplier has had its file appended with a National Supplier Clearinghouse (NSC) alert code that indicates the company may have committed fraud or abuse. The following is a list of general definitions of current NSC alert codes:

A - Possible/suspect fraud and abuse

B - Overpayment - believe uncollectible

C - Violation of supplier standards

D - Violation of disclosure of ownership

E - Violation of participation agreement

F - Sanctioned by the OIG

G - Special review of existing supplier

H - New supplier under review

I - No claims processed by specific DMERC

J - No problem claims

K - Suspended because of fraudulent claims

L - Suspended by DMERC - discovered by DMERC Program Integrity staff investigation

M - Supplier is going through the appeals process

R - Revoked supplier number

4.3 – Medical Review for Benefit Integrity Purposes

(Rev. 71, 04-09-04)

The responsibilities of the *PSCs and Medicare contractor* BI units include looking for potential fraud. The MR unit's responsibilities include looking for potential errors. *PSCs and Medicare* contractor BI and MR staff *shall* work closely together, especially in the areas of:

- Data analysis
- Identification of potential errors or potential fraud (which *shall* be referred to the other component)

The *PSCs, Medicare contractor* BI units, and MR units *shall* have ongoing discussions and close working relationships regarding situations identified that may be signs of fraud. Intermediaries *shall* also include the cost report audit unit in the ongoing discussions.

A - Referrals from the Medical Review Unit to the Benefit Integrity Unit

If a provider appears to have knowingly and intentionally furnished services that are not covered, or filed claims for services not furnished as billed, or made any false statement on the claim or supporting documentation to receive payment, the *PSC, AC, or Medicare*

contractor MR unit personnel shall discuss *this* with the *PSC or Medicare contractor* BI unit. If the *PSC or Medicare contractor* BI unit agrees that there is potential fraud, the MR unit shall then *make a referral* to the *PSC or Medicare contractor* BI unit for *investigation.* Provider *documentation that* shows a pattern of repeated misconduct or conduct that is clearly abusive or potentially fraudulent despite provider education and direct contact with the provider to explain identified errors shall be referred to the *PSC or Medicare contractor* BI unit.

B - Referrals from the Benefit Integrity Unit to the Medical Review Unit and Other Units

PSCs and Medicare contractor *BI units* are also responsible for preventing and minimizing the opportunity for fraud. The *PSCs and Medicare* contractor *BI units* shall identify procedures that may make Medicare vulnerable to potential fraud and take appropriate action. For example, *PSCs and Medicare* contractor *BI units* may determine that there are problems in the provider enrollment process that make it possible for individuals excluded from the Medicare program to obtain a provider identification number. The *PSCs and Medicare contractor* BI *units* shall bring these vulnerabilities to the attention of the *AC or Medicare contractor* provider enrollment unit.

There may be situations where the *PSC and Medicare contractor* BI unit initiates the referral of potential fraud to the MR unit for a *prepayment or postpayment* medical determination. For example, the *Medicare contractor* BI unit may request the MR unit review *claims and corresponding records associated with an investigation* to determine if the services were performed at the level billed. The MR unit *shall* then return the *investigation with their determination* to the *Medicare contractor* BI unit.

Therefore, when the MR unit is requested by the *Medicare contractor* BI unit to perform medical review as part of *an investigation*, the MR costs shall be charged to the BI line (Activity Code 23007 in the BPR).

The PSC shall work with its own nurses to perform these types of reviews.

4.4 - Other Program Integrity Requirements

(Rev. 71, 04-09-04)

4.4.1 - Requests for Information from Outside Organizations

(Rev. 71, 04-09-04)

Federal and state law enforcement agencies may seek information to further their investigations or prosecutions of individuals or businesses alleged to have committed fraud. *PSCs and Medicare contractor BI units may share certain information with a broader community (including private insurers), such as the general nature of how*

fraudulent practices were detected, the actions being taken, and aggregated data showing trends and/or patterns.

In deciding to share information voluntarily or in response to outside requests, the *PSC or Medicare* contractor *BI unit* shall carefully review each request to ensure that disclosure would not violate the requirements of the Privacy Act of 1974 (5 U.S.C. 552a) *and/or the Privacy Rule (45 CFR, Parts 160 and 164) implemented under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).*

Both the Privacy Act and the Privacy Rule seek to strike a balance that allows the flow of health information needed to provide and promote high quality health care while protecting the privacy of people who seek this care. In addition, they provide individuals with the right to know with whom their personal information has been shared and this, therefore, necessitates the tracking of any disclosures of information by the PSC or Medicare contractor BI unit. PSC and Medicare contractor BI unit questions concerning what information may be disclosed under the Privacy Act or Privacy Rule shall be directed to CMS Regional Office Freedom of Information Act (FOIA)/Privacy coordinator. Ultimately, the authority to release information from a Privacy Act System of Records to a third party rests with the System Manager/Business Owner of the system of records.

The HIPAA Privacy Rule establishes national standards for the use and disclosure of individuals' health information (also called protected health information) by organizations subject to the Privacy Rule. It restricts the disclosure of any information, in any form, that can identify the recipient of medical services unless that disclosure is expressly permitted under the Privacy Rule.

The Privacy Act affords protection only to individuals. Therefore, there is a privacy issue only when the information pertains to specific persons, e.g., physicians or beneficiaries. In all cases, the *PSC or Medicare* contractor *BI unit* is free to share with law enforcement the nature of the scams or fraudulent schemes active in the area.

The Privacy Act *and the HIPAA Privacy Rule* protect information "records," which are maintained in "systems of records." A "record" is any item, collection, or grouping of information about an individual that is maintained by an agency. This includes, but is not limited to, information about educational background, financial transactions, medical history, criminal history, or employment history that contains a name or an identifying number, symbol, or other identifying particulars assigned to the individual. The identifying particulars can be a finger or voiceprint or a photograph. A "system of records" is any group of records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Federal Register *S*ystem of *R*ecords *notices* maintained by *CMS* may be found on the CMS website at http://cms.hhs.gov/privacy/tblsors.asp.

Information from some systems of records may be released only if the disclosure would be consistent with "routine uses" that CMS has issued and published. Routine uses specify who may be given the information and the basis or reason for access that must exist. Routine uses vary by the specified system of records, and a decision concerning the applicability of a routine use lies solely in the purview of the system's manager for each system of records. In instances where information is released as a routine use, the Privacy Act and Privacy Rule remain applicable.

A - Requests from Private, Non-Law Enforcement Agencies

Generally, *PSCs and Medicare* contractor *BI units may* furnish information on a scheme (*e.g., where it is operating, specialties involved). Neither the name of a beneficiary or suspect can be disclosed. If it is not possible to determine whether or not information is releasable to an outside entity, Medicare contractors shall contact the CMS RO for further direction. Similarly, PSCs shall contact their Government Task Leader (GTL), Co-GTL, and SME for any further guidance.*

B - Requests from Medicare Contractors *and Program Safeguard Contractors*

PSCs and Medicare contractor *BI units* may furnish requested specific information on ongoing fraud investigations *and on individually identifiable protected health information to any PSC, AC, or Medicare contractor BI unit. PSCs, ACs, and Medicare contractor BI units are "business associates" of CMS under the Privacy Rule and thus are permitted to exchange information necessary to conduct health care operations.* If the request concerns cases already referred to the OIG/OI, *PSCs or Medicare* contractor *BI units* shall refer the requesting *PSC or Medicare contractor BI unit* to the OIG/OI.

C - *Quality Improvement Organizations and State Survey and Certification Agencies*

PSCs and Medicare contractor BI units may furnish requested specific information on ongoing fraud investigations and on individually identifiable protected health information to the QIOs and State Survey and Certification Agencies. The functions QIOs perform for CMS are required by law, thus the Privacy Rule permits disclosures to them. State Survey and Certification Agencies are required by law to perform inspections, licensures, and other activities necessary for appropriate oversight of entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards, thus the Privacy Rule permits disclosures to them. If the request concerns cases already referred to the OIG/OI, PSCs and Medicare contractor BI units shall refer the requestor to the OIG/OI.

D - State Attorneys General and State Agencies

PSCs and Medicare contractor BI units may furnish requested specific information on ongoing fraud investigations to state Attorneys General and to state agencies. Releases of information to these entities in connection with their responsibility to investigate, prosecute, enforce, or implement a state statute, rule or regulation may be made as a

routine use under the Privacy Act of 1974, as amended; 5 USC § 552a(b)(3) and 45 CFR Part 5b Appendix B (5). See Section H below for further information regarding the Privacy Act requirements. If individually identifiable protected health information is requested, the disclosure shall comply with the Privacy Rule. See §G below and PIM Exhibit 25 for guidance on how requests should be structured to comply with the Privacy Rule. PSCs and Medicare contractor BI units may, at their discretion, share Exhibit 25 with the requestor as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, PSCs and Medicare contractor BI units shall refer the requestor to the OIG/OI.

E - Request from Medicaid Fraud Control Units

Under current Privacy Act requirements applicable to program integrity investigations, PSCs and Medicare contractor BI units may respond to requests from Medicaid Fraud Control Units (MFCUs) for information on current investigations. Releases of information to MFCUs in connection with their responsibility to investigate, prosecute, enforce, or implement a state statute, rule or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC § 552a(b)(3) and 45 CFR Part 5b Appendix B (5). See Section H below for further information regarding the Privacy Act requirements. If individually identifiable protected health information is requested, the disclosure shall comply with the Privacy Rule. See §G below and PIM Exhibit 25 for guidance on how requests should be structured to comply with the Privacy Rule. PSCs and Medicare contractor BI units may, at their discretion, share Exhibit 25 with the requestor as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, PSCs and Medicare contractor BI units shall refer the requestor to the OIG/OI.

F - Requests from OIG/OI for Data and Other Records

PSCs and Medicare contractor *BI units* shall provide the OIG/OI with requested information, and shall maintain cost information related to fulfilling these requests. If major/costly systems enhancements are required to fulfill a request, the *PSCs shall discuss the request with the GTL, Co-GTL, and SME before fulfilling the request, and the Medicare* contractor *BI units* shall discuss the request and the cost with the RO before fulfilling the request. These requests generally fall into one of the following categories:

> **Priority I –** This type of request is a top priority request requiring a quick turnaround. The information is essential to the prosecution of a provider. Information or material is obtained from the *PSC's or Medicare* contractor *BI unit's* files. *Based on review of its available resources, the PSC or Medicare contractor BI unit shall inform the requestor what, if any, portion of the request can be provided. The PSC or Medicare contractor BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.*

PSCs and Medicare contractors *BI units* shall respond to such requests within 30 days whenever possible. If that timeframe cannot be met, the *PSC or Medicare* contractor *BI unit* shall notify the requesting office as soon as possible (but not later than 30 days) after receiving the request. *PSCs and Medicare* contractor *BI units* shall include an estimate of when all requested *information* will be supplied. *This timeframe applies to all requests with the exception of those that require Data Extract Software System (DESY) access to NCH.*

Priority II – This type of request is less critical than a Priority I request. Development requests may require review or interpretation of numerous records, extract of records from retired files in a warehouse or other archives, or soliciting information from other sources. *Based on the review of its available resources, the PSC or Medicare contractor BI unit shall inform the requestor what, if any, portion of the request can be provided. The PSC or Medicare contractor BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.*

PSCs and Medicare contractor *BI units* shall respond to such requests within 45 calendar days, when possible. If that timeframe cannot be met, the *PSC or Medicare* contractor *BI unit* shall notify the requesting office within the 45-day timeframe, and include an estimate of when all requested *information* will be supplied. *This timeframe applies to all requests with the exception of those that require DESY access to NCH.*

Disclosures of information to the OIG/OI shall comply with the Privacy Rule and Privacy Act. To comply with the Privacy Act, the OIG/OI must make all data requests using the form entitled, Federal Agreement (Office of Inspector General) for Release of Data with Individual Identifiers (see Exhibit 37). To comply with the Privacy Rule, the paragraph below should be added to the form. If the OIG/OI requests protected health information that is not in a data format, e.g., copies of medical records that the PSC has in its possession, the OIG/OI should include the paragraph in its written request for the information.

The information sought in the request is required to be produced to the Office of Investigations pursuant to the Inspector General Act of 1978, 5 U.S.C. App. The information is also sought by the Office of Inspector General in its capacity as a health oversight agency, and this information is necessary to further health oversight activities. Disclosure is therefore permitted under the Health Insurance Portability and Accountability Act (HIPAA) Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.501; 164.512(a); and 164.512(d).

If the OIG provides language other than the above, the PSC shall contact the GTL, Co-GTL, and SME. The Medicare contractor BI unit shall contact the RO.

G - Procedures for Sharing CMS Data with the Department of Justice

In April 1994, CMS entered into an interagency agreement with the DHHS Office of the Inspector General and the DOJ that permitted CMS contractors *(PSCs and Medicare contractor BI units)* to furnish information, including data, related to the investigation of health care fraud matters directly to DOJ that previously had to be routed through OIG *(see PIM Exhibit 35). This agreement was supplemented on April 11, 2003, when in order to comply with the HIPAA Privacy Rule, DOJ issued procedures, guidance, and a form letter for obtaining information (see PIM Exhibit 25).* CMS and DOJ have agreed that DOJ requests for individually identifiable health information will follow the procedures that appear on the form letter (see PIM Exhibit 25). The *2003* form letter must be customized to each request.

The form letter mechanism is not applicable to requests regarding Medicare Secondary Payer (MSP) information, unless the DOJ requester indicates he or she is pursuing an MSP fraud matter.

PIM *Exhibit 25 contains the entire document issued by the DOJ on April 11, 2003. PSCs and Medicare contractor BI units shall familiarize themselves with the instructions contained in this document. Data requests for individually identifiable protected health information related to the investigation of health care fraud matters will come directly from an FBI agent or an Assistant United States Attorney. For example, data may be sought to assess allegations of fraud; examine billing patterns; ascertain dollar losses to the Medicare program for a procedure, service, or time period; or conduct a random sample of claims for medical review. The law enforcement agency should begin by consulting with the appropriate Medicare contractor (usually the PSC, but possibly also the Carrier, Fiscal Intermediary, or CMS) to discuss the purpose or goal of the data request. Requests for cost report audits and/or associated documents shall be referred directly to the appropriate FI.*

As part of the initial consultation process, the PSC or Medicare contractor BI unit and law enforcement agency shall develop appropriate language to insert in the data request form letter, including:

- *Type of data and data elements needed.*
- *Name and/or other identifying information for provider(s) (e.g., Tax Identification Number, Unique Physician Identification Number, etc.).*
- *Time period of data to be reviewed (approximate begin and end dates if the conduct is not ongoing currently).*
- *Preferred format or medium for data to be provided (i.e., tape, CD-ROM, paper, etc.).*

Once the language is formulated, the law enforcement agency will send the signed 2003 form letter, identifying the appropriate authority under which the information is being sought and specifying the details of the request described above, to the PSC or Medicare

contractor BI unit. A request for data that is submitted on the 2003 form letter is considered to be a Data Use Agreement (DUA) with CMS. In order for CMS to track disclosures that are made to law enforcement and health oversight agencies, PSCs and Medicare contractor BI units shall send a copy of all requests for data to the CMS Privacy Officer at the following address:

Centers for Medicare & Medicaid Services
Director of Division of Privacy Compliance Data Development
and CMS Privacy Officer
Mail Stop N2-04-27
7500 Security Blvd.
Baltimore, MD. 21244

Upon receiving a data request from DOJ, the PSC or Medicare contractor BI unit shall examine its sources of data for the most recent 36-month period for the substantive matter(s) in question or for the specific period requested by the DOJ, if necessary. Based on the review of its available data resources, the PSC or Medicare contractor BI unit shall inform the requestor what, if any, portion of the data can be provided. The PSC or Medicare contractor BI unit shall provide the relevant data, reports and findings to the requestor in the format(s) requested within 30 days when data for the most recent 36-month period is being sought directly from the PSC or Medicare contractor BI unit. If it is necessary for the PSC or Medicare contractor BI unit to seek and acquire data from CMS or another affiliated Medicare contractor, the time period required to provide the data to the requesting agency will extend beyond 30 days.

If appropriate, the PSC or Medicare contractor BI unit shall also use available analytic tools to look for other possible indicia of fraud in addition to the specific alleged conduct that was the cause of the DOJ data request.

If, in the view of the requesting DOJ, the PSC, the Medicare contractor BI unit, or CMS, the initial 36-month review generally verifies the fraud allegations, or if potential fraud is uncovered through the use of analytic tools, the PSC or Medicare contractor BI unit shall conduct a supplemental review of Medicare data if it receives a subsequent request. The supplemental review will meet the specific needs of the DOJ based on the allegations under investigation and/or findings of the initial 36-month review. Such supplemental reviews may involve retrieving information from original Carrier and/or Fiscal Intermediary data files, the National Claims History (NCH), the Common Working File (CWF), or other Medicare data files that may be archived, in order to cover the complete time frame involved in the allegations and/or allowed by the statute of limitations.

Every effort shall be made to fulfill all data requests within the time constraints faced by the DOJ. It may be necessary to negotiate a time period for fulfilling supplemental data requests on a case-by-case basis with the requestor when the scope of the request exceeds resources and/or current workload.

While the previous steps describe the usual process to be followed for handling DOJ requests for CMS Medicare data, exceptions to this process may be necessary on a case-by-case basis when the DOJ determines that conducting an initial review of the most recent 36 months of data would not be sufficient. For example, exceptions may be necessary if:

- *The most recent 36 months of data would not be helpful to the investigation because the fraud being investigated is alleged to have occurred prior, or in large part prior to, that period.*

- *Changes in the payment system used for the type(s) of claims in question cause the most current data to be inappropriate for attempting to verify allegations of possible fraud that occurred under a previous payment system.*

- *The purpose of the data request cannot be met using only the most recent 36 months of data (e.g., a statistical sampling plan that requires more than 36 months of data to implement the plan correctly and accurately).*

- *Litigation deadlines preclude conducting an initial review followed by a more comprehensive supplemental review.*

The prior items are illustrative, not exhaustive.

CMS has established a cost limit of $200,000 for any individual data request. If the estimated cost to fulfill any one request is likely to meet or exceed this figure, a CMS representative will contact the requestor to explore the feasibility of other data search and/or production options. Few, if any, individual DOJ requests will ever reach this threshold. In fact, an analysis of DOJ requests fulfilled by CMS's central office over the course of 1 year indicates that the vast majority of requests were satisfied with a minimum of expense. Nevertheless, CMS recognizes that *PSCs and Medicare* contractor *BI units* may not have sufficient money in their budgets to respond to DOJ requests. In such cases, *Medicare* contractor *BI units* are advised to submit to CMS a Supplementary Budget Request (SBR). *PSCs shall contact their GTLs, Co-GTLs, and SMEs.*

To facilitate CMS's ability to track the frequency and burden of DOJ requests, the *Medicare* contractor *BI unit shall* maintain and submit to CMS, on a quarterly basis, a log of DOJ data requests that has been itemized to show costs for filling each request. This report should be in the form of an Excel spreadsheet (see PIM Exhibit 26) and *shall* include, at a minimum, the following fields:

1. *Medicare* contractor name and identification number

2. Date of DOJ request

3. Nature of DOJ request and DOJ tracking number, if provided

4. Cost to fulfill request

5. *Medicare* contractor's capacity to fill request, including date of SBR submission, if necessary

The report *shall* be sent to the following address:

Director, Division of Benefit Integrity and Law Enforcement Liaison
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C3-02-16
Baltimore, Maryland 21244

H. Law Enforcement Requests for Medical Review

PSCs and Medicare contractor BI units shall not send document request letters or go on site to providers to obtain medical records solely at the direction of law enforcement. However, if law enforcement furnishes the medical records and requests the PSC or Medicare contractor BI unit to review and interpret medical records for them, the PSC and Medicare contractor BI unit shall require law enforcement to put this request in writing. At a minimum, this request shall include the following information:

- *The nature of the request (e.g., what type of service is in question and what should the reviewer be looking for in the medical record)*
- *The volume of records furnished*
- *Due dates*
- *Format required for response*

The PSC shall present the written request to the GTL, Co-GTL, and SME and the Medicare contractor BI unit shall present the written request to their RO prior to fulfilling the request. Each written request will be considered on a case-by-case basis to determine whether the request will be approved.

I – Requests from Law Enforcement for Information Crossing Several PSC Jurisdictions

If a PSC receives a request from law enforcement for information that crosses several PSC jurisdictions, the PSC shall respond back to the requestor specifying that they will be able to assist them with the request that covers their jurisdiction. However, for the information requested that is covered by another PSC jurisdiction, the PSC shall provide the requestor with the correct contact person for the inquiry, including the person's name

and telephone number. Furthermore, the PSC shall inform the requestor that the Director of the Division of Benefit and Law Enforcement Liaison at CMS CO is the contact person in case any additional assistance is needed. The PSC shall also copy their GTLs and SMEs on their response back to law enforcement for these types of cross jurisdictional requests.

J - Privacy Act Responsibilities

The *1994 Agreement and the 2003 form letter (see PIM Exhibits 35 and 25 respectively)* are consistent with the Privacy Act. Therefore, requests that *appear on the 2003 form letter* do not violate the Privacy Act. The Privacy Act of 1974 requires federal agencies that collect information on individuals that will be retrieved by the name or another unique characteristic of the individual to maintain this information in a system of records.

The Privacy Act permits disclosure of a record, without the prior written consent of an individual, if at least one of twelve disclosure provisions apply. Two of these provisions, the "routine use" provision and/or another "law enforcement" provision, may apply to requests from DOJ and/or FBI.

Disclosure is permitted under the Privacy Act if a routine use exists in a system of records.

Both the Intermediary Medicare Claims Records, System No., 09-70-0503, and the Carrier Medicare Claims Records, System No. 09-70-0501, contain a routine use that permits disclosure to:

"The Department of Justice for investigating and prosecuting violations of the Social Security Act to which criminal penalties attach, or other criminal statutes as they pertain to Social Security Act programs, for representing the Secretary, and for investigating issues of fraud by agency officers or employees, or violation of civil rights."

The CMS Utilization Review Investigatory File, System No. 09-70-0527, contains a routine use that permits disclosure to "The Department of Justice for consideration of criminal prosecution or civil action."

The latter routine use is more limited than the former, in that it is only for "consideration of criminal or civil action." It is important to evaluate each request based on its applicability to the specifications of the routine use.

In most cases, these routine uses will permit disclosure from these systems of records; however, each request should be evaluated on an individual basis.

Disclosure from other CMS systems of records is not permitted (i.e., use of such records compatible with the purpose for which the record was collected) unless a routine use exists or one of the 11 other exceptions to the Privacy Act applies.

The law enforcement provision may apply to requests from the DOJ and/or FBI. This provision permits disclosures "to another agency or to an instrumentality of any jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought."

The law enforcement provision may permit disclosure from any system of records if all of the criteria established in the provision are satisfied. Again, requests should be evaluated on an individual basis.

To be in full compliance with the Privacy Act, all requests must be in writing and must satisfy the requirements of the disclosure provision. *PSCs* shall refer requests that raise Privacy Act concerns and/or issues to the *GTL, Co-GTL, and SME* for further consideration*, and Medicare contractor BI units shall refer requests to their CMS RO.*

***K* – Duplicate Requests for Information**

The DOJ and the OIG will exchange information on cases they are working on to prevent duplicate investigations. If the *PSC or Medicare contractor BI unit* receives duplicate requests for information, the *PSC or Medicare contractor BI unit shall* notify the requestors. If the requestors are not willing to change their requests, the *PSC or Medicare contractor BI unit shall* ask the *GTL, Co-GTL, and SME (if a PSC) or CMS* RO *employee (if a Medicare contractor BI unit)* for assistance.

***L* - Reporting Requirements**

For each *data* request received *from DOJ, PSCs and Medicare* contractor *BI units* shall maintain a record that includes:

- The name and organization of the requestor
- The date of the written request (all requests must be in writing)
- The nature of the request
- Any subsequent modifications to the request
- Whether the RO*, GTL, Co-GTL, or SME* had to intervene on the outcome (request fulfilled or not fulfilled)
- The cost of furnishing a response to each request

The *Medicare* contractor shall report the data to the RO when requested by the RO. This data will be used to assess budget requirements.

4.4.1.1 - *Sharing Fraud Referrals Between the Office of the Inspector General and the Department of Justice*

(Rev. 71, 04-09-04)

PSCs and Medicare contractor BI units shall include two copies of the summary page with each fraud referral made to the OIG. As of October 18, 1999, the OI will provide a copy of the *PSC or Medicare* contractor *BI unit* fraud referral and all related information within 5 working days to the FBI Headquarters. The referral information received from the *PSC or* Medicare contractor *BI unit* includes all the information relevant to the potential fraud case. The OI will copy the *PSC or Medicare* contractor *BI unit* fraud referral to the FBI and will notify the FBI of any action they will take on the referral. The OI field offices will no longer forward health care fraud referrals directly to the local FBI field office. The OI will notify *PSCs and* Medicare contractor *BI units* of its decision on the fraud referral, with specific instructions on all matters related to the referral, within 90 calendar days.

Upon receipt of fraud referrals, the OI regional field offices are required to perform one or more of the following:

- Open an investigation
- Return the matter to the *PSC or Medicare* contractor *BI unit* for further development
- Forward the referral to the local FBI office or other law enforcement agency for investigation
- Close the case with no action necessary and refer the case back to the *PSC or Medicare* contractor *BI unit* for administrative action

The *PSC or Medicare* contractor *BI unit* shall follow the instructions *in PIM, Chapter 4, §4.18.1,* to follow up with the OI to determine their decision after the 90-calendar-day period. The *PSC or Medicare* contractor *BI unit* is encouraged to have dialogue with law enforcement during *investigations*, and to discuss fraud referrals at periodic meetings. If the OI does not give the *PSC or Medicare* contractor *BI unit* a definite answer after the 90-day period, the *PSC or Medicare* contractor *BI unit* shall contact the RO to help obtain the needed information, *and the PSC shall contact the GTL, Co-GTL, and the SME.* The FBI will notify the *PSC or Medicare* contractor *BI unit* of their action on the *PSC or Medicare* contractor *BI unit* fraud referral within 45 calendar days from the day the FBI receives referral from the OI. However, if the *PSC or Medicare* contractor *BI unit* has not received feedback at the end of the 45-calendar-day period, the *PSC or Medicare*

contractor *BI unit* may contact the applicable local FBI field office for a status. The *PSC or Medicare* contractor *BI unit* shall not contact the FBI Headquarters for a status of the fraud referral. In the case of multiple providers or servicing *PSCs or Medicare* contractor *BI units*, the FBI will notify the *PSC or* Medicare contractor *BI unit* that initiated the referral as to the decision.

4.4.2 - *Program Safeguard Contractor and Medicare* Contractor Coordination with Other *Program Safeguard Contractors and Medicare* Contractors

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* coordinate with other *PSCs and Medicare contractor BI units* within their service area. This includes sharing Local Medical Review Policies (LMRPs), and collaborating on abusive billing situations that may be occurring in multi-state *PSCs or Medicare* contractor *BI units*. Coordination is also necessary because certain findings of fraud involving a provider could have a direct effect on payments made by *ACs or Medicare* contractors. *Medicare* contractors *may* use the MFIS when there is a need to share information with Medicare contractors not in contiguous states, *and PSCs use the appropriate staff member(s) to share information*.

4.4.2.1 - *Program Safeguard Contractor and Medicare* Contractor Coordination with Other Entities

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* establish and *should* maintain formal and informal communication with state survey agencies, OIG, *DOJ,* General Accounting Office (GAO), Medicaid, other *Medicare* contractors (intermediaries with carriers and vice versa), *other PSCs,* and other organizations as applicable to determine information that is available and that should be exchanged to enhance PI activities.

If a *PSC or Medicare* contractor *BI unit* identifies a potential quality problem with a provider or practitioner in its area, it *shall* refer such cases to the appropriate entity, be it the *QIO*, state medical board, state licensing agency, etc. Any provider-specific information *shall* be handled as confidential information.

4.4.3 - Beneficiary, Provider, Outreach Activities

(Rev. 71, 04-09-04)

PSCs and Medicare *contractor BI units should* produce a wide variety of outreach items and materials for beneficiary and provider education and awareness. These items *should* include: brochures, flyers, stuffers, pens, pencils, newspaper advertisements, public service announcements, pamphlets, and videos, to list a few.

4.5 - The ARGUS System

(Rev. 71, 04-09-04)

ARGUS is a user-friendly personal computer software package developed by the OIG both to access provider claims data and to limit the need for the OIG to submit multiple requests to carriers for claims data. ARGUS is a useful tool for reviewing relationships of data that carriers have available. The billing practices of physicians, for example, can be compared to that of their peers as a means of detecting aberrant behavior.

OIG has trained a representative from each *Medicare* contractor *BI* unit to use ARGUS.

OIG and other authorized federal law enforcement agencies request claims data as they have in the past, but do not specify how the data is to be sorted. They specify the providers and the dates of service. ARGUS, which is written in DBASE, utilizes line item claims data provided by Medicare carriers in a simple ASCII format and separates the incoming data into database fields.

An investigative file in ARGUS is a database file consisting of individual line items of service taken from health insurance claims forms. Each line item consists of 29 fields and 160 bytes of information. Line items from a single provider or from multiple providers involved in a specific investigation may be combined into one ARGUS file.

PSCs are not required to have ARGUS, but they may obtain it if they wish.

When *PSCs and Medicare* contractor *BI units* receive a request for data *utilizing ARGUS*, they complete the data elements contained in *PIM Exhibit 34* (ARGUS Field Descriptions and Codes), in the order shown, and consistent with the following data conventions:

- All character fields are left-justified
- Leading zeros and blanks are omitted
- All numeric fields are right-justified
- Money fields are shown as $$$cc (no decimal point)
- All dates are shown as YYMMDD

Data are to be furnished in the above format on 3½-inch, high-density floppy disks *or a compact disk*. If the data does not fit on the 3½-inch disk without data compression, carriers compress the data using the PKZIP compression utility. Data will be transmitted to OIG *in a format consistent with CMS's security requirements*.

4.6 - Complaints

(Rev. 71, 04-09-04)

4.6.1 - Definition of a Complaint

(Rev. 71, 04-09-04)

A complaint is a statement, oral or written, alleging that a provider, supplier, or beneficiary received a Medicare benefit of monetary value, directly or indirectly, overtly or covertly, in cash or in kind, to which he or she is not entitled under current Medicare law, regulations, or policy. Included are allegations of misrepresentation and violations of Medicare requirements applicable to persons or entities that bill for covered items and services. Examples of complaints include:

- Allegations that items or services were not received.
- Allegations that items or services were not furnished as shown on the Explanation of Medicare Benefits (EOMB), Notice of Utilization (NOU), or Medicare Summary Notice (MSN), or that the services were not performed by the provider shown.
- Allegations that a provider is billing Medicare for a different item or service than that furnished.
- Allegations that a provider or supplier has billed both the beneficiary and Medicare for the same item or service.
- Allegations regarding waiver of co-payments or deductibles.
- Allegations that a supplier or provider has misrepresented itself as having an affiliation with an agency or department of the state, local, or federal government, whether expressed or implied.
- Beneficiary inquiries concerning payment for an item or service, that in his/her opinion, far exceeds reasonable payment for the item or service that the beneficiary received (e.g., the supplier or physician has “up-coded” to receive higher payment).

The following are not examples of a fraud complaint:

- Complaints or inquiries regarding Medicare coverage policy;
- Excessive charges;

- Complaints regarding the appeals process;
- Complaints over the status of a claim;
- Requests for an appeal or reconsideration; or
- Complaints concerning providers or suppliers (other than those complaints meeting the criteria established above) that are general in nature and are policy- or program-oriented.

Complaints alleging malpractice or poor quality of care may or may not involve a fraudulent situation. These *shall* be reviewed and determined on a case-by-case basis. Refer complaints alleging poor quality of care to the Medicare/Medicaid survey and certification agencies and the *QIO*.

4.6.2 - Complaint Screening

(Rev. 71, 04-09-04)

This section delineates the responsibility for PSCs, ACs, and Medicare contractors with regard to screening complaints alleging fraud and abuse. This supersedes any language within the Joint Operating Agreements (JOAs).

A - Medicare Contractor and Affiliated Contractor Responsibilities

The AC and the Medicare contractor shall be responsible for screening all complaints of potential fraud and abuse. This screening shall occur in the two phases described below.

Initial Screening

Customer Service Representatives (CSRs) shall try to resolve as many inquiries as possible in the Initial Screening with data available in their desktop system. If CSRs are able to resolve the inquiry, they shall send a resolution letter within 7 calendar days of the resolution. If a resolution takes longer than 45 calendar days, they shall send an interim acknowledgement letter within 45 calendar days of the receipt date stamped in the mailroom. The following are some scenarios that a CSR may receive and resolve in the initial phone call rather than refer to second-level screening (this is not an all-inclusive list):

- *Lab Tests – CSRs shall ask the caller if they recognize the referring physician. If they do, remind the caller that the referring physician may have ordered some lab work for them. The beneficiary usually does not have contact with the lab because specimens are sent to the lab by the referring physician office. (Tip: ask if they remember the doctor withdrawing blood or obtaining a tissue sample on their last visit.)*

- *Anesthesia Services - CSRs shall check the beneficiary claims history for existing surgery or assistant surgeon services on the same date. If a surgery charge is on file, explain to the caller that anesthesia service is part of the surgery rendered on that day.*

- *Injections - CSRs shall check the beneficiary claim history for the injectable (name of medication) and the administration. Most of the time, administration is not payable (bundled service) (Part B only). There are very few exceptions to pay for the administration.*

- *Services for Spouse - If the beneficiary states that services were rendered to his/her spouse and the Health Insurance Claim Numbers (HICNs) are the same, with a different suffix, the CSR shall initiate the adjustment and the overpayment process.*

- *Billing Errors - If the beneficiary states that he/she already contacted his/her provider and the provider admitted there was a billing error, and the check is still outstanding, the CSR shall follow the normal procedures for resolving this type of billing error.*

- *Services Performed on a Different Date - The beneficiary states that service was rendered, but on a different date. This is not a fraud issue. An adjustment to the claim may be required to record the proper date on the beneficiary's file.*

- *Incident to Services - Services may be performed by a nurse in a doctor's office as "incident to." These services are usually billed under the physician's provider identification number (PIN) (e.g., blood pressure check, injections, etc.). These services may be billed under the minimal Evaluation and Management codes.*

- *Billing Address vs. Practice Location Address - The CSR shall check the practice location address, which is where services were rendered. Many times the Medicare Summary Notice will show the billing address and this causes the beneficiary to think it is fraud.*

- *X-Rays with Modifier 26 - The CSRs shall ask the caller if he/she recognizes the referring physician. If so, the CSR shall explain to the caller that whenever modifier 26 is used, the patient has no contact with the doctor. The CSR shall further explain that the provider billing with modifier 26 is the one interpreting the test for the referring physician.*

Initial Screening activities shall be charged to Activity Code 13002 (Beneficiary and Provider Written Inquiries), Activity Code 13003 (Beneficiary and Provider Walk-in Inquiries), Activity Code 13005 (Beneficiary Telephone Inquiries), or Activity Code 33001 (Provider Telephone Inquiries), whichever is the most applicable. In fiscal year 2004, there is a separate Activity Code for Provider Written Inquiries (33002) and Provider Walk-in inquiries (33003). The current Beneficiary Inquiries Manual

Instructions will be revised and the FY2004 Budget and Performance Requirements will be developed to reflect the following Performance Priorities: 1) Telephones, 2) Second Level Screening, 3) Written, and 4) Walk-in, and 5) Customer Service Plan Activities.

CSRs shall use proper probing questions and shall utilize claim history files to determine if the case needs to be referred for second-level screening.

Any provider inquiries regarding potential fraud and abuse shall be forwarded immediately to the second-level screening staff for handling.

Any immediate advisements (e.g., inquiries or allegations by beneficiaries or providers concerning kickbacks, bribes, a crime by a Federal employee, indications of contractor employee fraud (e.g., altering claims data or manipulating it to create preferential treatment to certain providers; improper preferential treatment in collection of overpayments; embezzlement)) shall be forwarded immediately to the second-level screening staff for handling.

The initial screening staff shall maintain a log of all potential fraud and abuse inquiries. At a minimum, the log shall contain the following information:

- *Beneficiary name*
- *Provider Name*
- *Beneficiary HIC#*
- *Nature of the Inquiry*
- *Date of the Inquiry*
- *Internal Tracking Number*
- *Date Referred to the Second Level Screening Staff*
- *Date Closed*

<u>Second-Level Screening</u>

When the complaint/inquiry cannot be resolved by the CSR, the issue shall be referred for more detailed screening, resolution, or referral, as appropriate, within the AC or Medicare contractor. If the second level screening staff is able to resolve the inquiry without referral, they shall send a resolution letter within 7 calendar days of the resolution. If a resolution takes longer than 45 calendar days, they shall send an interim acknowledgement letter within 45 calendar days of receipt from the initial screening staff. The second-level screening staff shall maintain a log of all potential fraud and

abuse inquiries received from the initial screening staff. At a minimum, the log shall include the following information:

- *Beneficiary name*
- *Provider name*
- *Beneficiary HIC#*
- *Nature of the Inquiry*
- *Date received from the initial screening staff*
- *Date referral is forwarded to the Medicare contractor BI unit or the date it is sent to the PSC*
- *Destination of the referral (i.e., name of PSC or Medicare contractor BI unit)*
- *Documentation that an inquiry received from the initial screening staff was not forwarded to the PSC or Medicare Contractor BI Unit and an explanation why (e.g., inquiry was misrouted or inquiry was a billing error that should not have been referred to the second-level screening staff)*
- *Date inquiry is closed*

The AC or Medicare contractor staff shall call the beneficiary or the provider, check claims history, and check provider correspondence files for educational/warning letters or contact reports that relate to similar complaints, to help determine whether or not there is a pattern of potential fraud and abuse. The AC or Medicare contractor shall request and review certain documents, as appropriate, from the provider, such as itemized billing statements and other pertinent information. If the AC or Medicare contractor is unable to make a determination on the nature of the complaint (e.g., fraud and abuse, billing errors) based on the aforementioned contacts and documents, the AC or Medicare contractor shall order medical records and limit the number of medical records ordered to only those required to make a determination. If the medical records are not received within 45 calendar days, the claim(s) shall be denied. The second-level screening staff shall only perform a billing and document review on medical records to verify and validate that services were rendered. If fraud and abuse is suspected after performing the billing and document review, the medical record shall be forwarded to the PSC (if BI work was transitioned to a PSC) or Medicare contractor BI unit for clinician review. If the AC or Medicare contractor staff determines that the complaint is not a fraud and/or abuse issue, and if the staff discovers that the complaint has other issues (e.g., medical review, enrollment, claims processing, etc.), it shall be referred to the appropriate department. In these instances, the AC or Medicare contractor shall also be

responsible for acknowledging these complaints, and sending appropriate resolution letters to the beneficiary or complainant.

If the AC or Medicare contractor second-level screening staff determines that the complaint is a potential fraud and abuse situation, the second-level screening staff shall forward it to the PSC or Medicare contractor BI unit for further development within 30 calendar days of receipt in the AC or Medicare contractor mailroom, or within 30 calendar days of receiving medical records and/or other documentation, whichever is later.

The AC or Medicare contractor shall refer immediate advisements received by beneficiaries or providers and potential fraud or abuse complaints received by current or former provider employees immediately to the PSC or Medicare contractor BI unit for further development.

The AC or Medicare contractor shall be responsible for screening all Harkin Grantee complaints for fraud. If after conducting second level screening, the AC or Medicare contractor staff determines that the complaint is a potential fraud and abuse situation, the complaint shall be sent to the PSC or Medicare contractor BI unit within 30 calendar days of receipt in the AC or Medicare contractor mailroom, or within 30 calendar days of receiving medical records and/or other documentation, whichever is later. The complainant shall be clearly identified to the PSC or Medicare contractor BI unit as a Harkin Grantee complaint. The AC or Medicare contractor shall be responsible for entering all initial referrals identified in the second-level screening area and any updates received from the PSC or Medicare contractor BI unit into the Harkin Grantee Tracking System (HGTS).

The AC or Medicare contractor shall be responsible for downloading and screening complaints from the OIG Hotline Database, and for updating the database with the status of all complaints. If the AC or Medicare contractor determines that the complaint is a potential fraud and abuse situation, the second-level screening staff shall forward it to the PSC or Medicare contractor BI unit for further development within 30 calendar days of receipt, or within 30 calendar days of receiving medical records and/or other documentation, whichever is later, just like all other complaints. The PSC or Medicare contractor BI unit shall be responsible for updating the valid cases that have been referred. PSCs and Medicare contractors shall control all OIG Hotline referrals by the OIG Hotline number (the "H" or "L" number) as well as by any numbers used in the tracking system. PSCs and Medicare contractors shall refer to this number in all correspondence to the RO.

Complaints shall be forwarded to the Medicare contractor BI unit or PSC for further investigation under the following circumstances (this is not intended to be an all inclusive list):

- *Claims forms may have been altered or upcoded to obtain a higher reimbursement amount.*

- *It appears that the provider may have attempted to obtain duplicate reimbursement (e.g., billing both Medicare and the beneficiary for the same service or billing both Medicare and another insurer in an attempt to be paid twice). This does not include routine assignment violations. An example for referral might be that a provider has submitted a claim to Medicare, and then in two days resubmits the same claim in an attempt to bypass the duplicate edits and gain double payment. If the provider does this repeatedly and the AC or Medicare contractor determines this is a pattern, then it shall be referred.*

- *Potential misrepresentation with respect to the nature of the services rendered, charges for the services rendered, identity of the person receiving the services, identity of persons or doctor providing the services, dates of the services, etc.*

- *Alleged submission of claims for non-covered services are misrepresented as covered services, excluding demand bills and those with Advanced Beneficiary Notices (ABNs).*

- *Claims involving potential collusion between a provider and a beneficiary resulting in higher costs or charges to the Medicare program.*

- *Alleged use of another person's Medicare number to obtain medical care.*

- *Alleged alteration of claim history records to generate inappropriate payments.*

- *Alleged use of the adjustment payment process to generate inappropriate payments.*

- *Any other instance that is likely to indicate a potential fraud and abuse situation.*

When the above situations occur, and it is determined that the complaint needs to be referred to the PSC or Medicare contractor BI unit for further development, the AC or Medicare contractor shall prepare a referral package that includes, at a minimum, the following:

- *Provider name, provider number, and address.*

- *Type of provider involved in the allegation and the perpetrator, if an employee of the provider.*

- *Type of service involved in the allegation.*

- *Place of service.*

- *Nature of the allegation(s).*

- *Timeframe of the allegation(s).*

- *Narration of the steps taken and results found during the AC's or Medicare contractor's screening process (discussion of beneficiary contact, if applicable, information determined from reviewing internal data, etc.).*

- *Date of service, procedure code(s).*

- *Beneficiary name, beneficiary HICN, telephone number.*

- *Name and telephone number of the AC or Medicare contractor employee who received the complaint.*

NOTE: *Since this is not an all-inclusive list, the PSC or Medicare contractor BI unit has the right to request additional information in the resolution of the complaint referral or the subsequent development of a related case (e.g., provider enrollment information).*

When a provider inquiry or complaint of potential fraud and abuse or immediate advisement is received, the second-level screening staff will not perform any screening, but will prepare a referral package and send it immediately to the PSC or Medicare contractor BI unit. The referral package shall consist of the following information:

- *Provider name and address.*

- *Type of provider involved in the allegation and the perpetrator, if an employee of a provider.*

- *Type of service involved in the allegation.*

- *Relationship to the provider (e.g., employee or another provider).*

- *Place of service.*

- *Nature of the allegation(s).*

- *Timeframe of the allegation(s).*

- *Date of service, procedure code(s).*

- *Name and telephone number of the AC or Medicare contractor employee who received the complaint.*

The AC and Medicare contractor shall maintain a copy of all referral packages.

The AC or Medicare contractor shall report all costs associated with second-level screening of inquiries for both beneficiaries and providers in Activity Code 13201. Report the total number of second-level screening of beneficiary inquiries that were closed in workload column 1; report the total number of medical records ordered for beneficiary inquiries that were closed in workload column 2; and report the total number of potential fraud and abuse beneficiary complaints identified and referred to the PSC or Medicare contractor BI unit in workload column 3. The AC or Medicare contractor shall keep a record of the cost and workload for all provider inquiries of potential fraud and abuse that are referred to the PSC or Medicare contractor BI unit in Activity Code 13201/01.

B – Program Safeguard Contractor and Medicare Contractor Benefit Integrity Unit Responsibilities

At the point the complaint is received from the AC or Medicare contractor screening staff, it shall be the responsibility of the PSC or Medicare contractor BI unit to further investigate the complaint, resolve the complaint investigation, or make referrals as needed to appropriate law enforcement entities or other outside entities.

It shall be the responsibility of the PSC or the Medicare contractor BI unit to send out acknowledgement letters for complaints received from the AC or Medicare contractor. The AC or Medicare contractor shall be responsible for screening and forwarding the complaints, within 30 calendar days of receipt in the AC or Medicare contractor mailroom, or within 30 calendar days of receiving medical records and/or other documentation, whichever is later, to the PSC or Medicare contractor BI unit. The PSC or Medicare contractor BI unit shall send the acknowledgement letter within 15 calendar days of receipt of the complaint referral from the AC or Medicare contractor second-level screening staff, unless it can be resolved sooner. The letter shall be sent out on PSC or Medicare contractor BI unit letterhead and shall contain the telephone number of the PSC or Medicare contractor BI unit analyst handling the case.

If the PSC or Medicare contractor BI unit staff determines, after investigation of the complaint, that it is not a fraud and/or abuse issue, but has other issues (e.g., medical review, enrollment, claims processing, etc.), it shall be referred to the AC or Medicare contractor area responsible for second-level screening, or if applicable, the appropriate PSC unit for further action. This shall allow the AC or Medicare contractor screening area to track the complaints returned by the PSC or Medicare contractor BI unit. However, the PSC or Medicare contractor BI unit shall send an acknowledgement to the complainant, but indicate that a referral is being made, if applicable, to the appropriate PSC, or to the appropriate AC or Medicare contractor unit for further action.

The PSC or Medicare contractor BI unit shall be responsible for communicating any updates as a result of their investigation on Harkin Grantee complaints to the AC or Medicare contractor second-level screening staff, who shall update the database accordingly.

The PSC or Medicare contractor BI unit shall be responsible for updating valid cases that have been referred from the OIG Hotline Database by the AC or Medicare contractor second-level screening area.

The PSC or Medicare contractor BI unit shall be responsible for sending the complainant a resolution within 7 calendar days of the resolution on the complaint investigation and/or case in accordance with PIM Chapter 4, §4.8.

4.6.3 -Filing Complaints

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units file complaints in the investigation file (refer to the sections below on investigations) that originated from the complaint,* and check each against *PSC or Medicare contractor BI* unit files for other complaints involving the same provider.

PSCs and Medicare contractor *BI units* resolve any potential fraud or abuse situations without referral to OIG/OI, if possible, and maintain all documentation on these *complaint investigations* for subsequent review by *CMS personnel or* OIG/OI.

A - Source of Complaint

Record the name *and telephone number* of the individual (or organization) that provided the information concerning the alleged fraud or abuse. Also list the provider's name, address, and ID number.

B - Nature of Complaint

Briefly describe the nature of the alleged fraud or abuse (e.g., "Provider billed for services not furnished," or "Beneficiary alleged provider billed for more than deductible and coinsurance").

Also include the following information:

- The date the complaint was received.
- A brief description of the action taken to close out the complaint. For example, "Reviewed records and substantiated amounts billed beneficiary." Insure that sufficient information is provided to enable the OIFO or the RO to understand the reason for the closeout.
- The date the complaint was closed.

- The number of complaints received to date concerning this provider, including the present complaint. This information is useful in identifying providers that are involved in an undue number of complaints.

4.7 - Investigations

(Rev. 71, 04-09-04)

An investigation is the analysis performed on both proactive and reactive leads (e.g., complaints, data analysis, newspaper articles, etc.) in an effort to substantiate the lead or allegation as a case. However, not all investigations will result in cases.

When *PSCs or Medicare* contractor *BI units* receive an allegation of fraud, or identify a potentially fraudulent situation, they *shall investigate* to determine the facts and the magnitude of the alleged fraud. They *shall* also conduct a variety of reviews to determine the appropriateness of payments, even when there is no evidence of fraud. Prioritization of the *investigation* workload is critical to ensure that the resources available are devoted primarily to high-priority *investigations*. (Complaints by current or former *employees require immediate advisement to the* OIG/OI. OIG/OI may request that *PSCs or Medicare* contractor *BI units* perform only limited internal *investigation* and then immediately refer the case to them.)

PSCs and Medicare contractor BI units shall maintain files on all investigations. The files shall be organized by provider or supplier and shall contain all pertinent documents, e.g., original referral or complaint, *investigative* findings, reports of telephone contacts, warning letters, documented discussions, and decision memoranda regarding final disposition of the investigation *(refer to §4.2.2.4.2 for retention of these documents).*

Under the terms of their contract, PSCs shall investigate potential fraud on the part of providers, suppliers, and other entities who receive reimbursement under the Medicare program for services rendered to beneficiaries. PSCs shall refer potential fraud cases to law enforcement and provide support for these cases. In addition, PSCs may provide data and other information related to potential fraud cases initiated by law enforcement when the cases involve entities who receive reimbursement under the Medicare program for services rendered to beneficiaries.

The work a PSC performs under its contract does not extend to investigations of ACs and Medicare contractors. PSCs are not authorized to assist a law enforcement agency that may be investigating allegations of fraud or other misconduct against an AC or a Medicare contractor. Requests for assistance of this nature shall be directed to the CMS CO Contractor Compliance Officer, Acquisitions and Grants Group.

4.7.1 – Conducting Investigations

(Rev. 71, 04-09-04)

When the complaint cannot be dismissed *by the AC or Medicare contractor second-level screening staff* as *an* error or a misunderstanding*, PSCs and Medicare* contractor *BI units shall* use one or more of the following *investigative* methods to determine whether or not there is a pattern of submitting false claims. (The list is not intended to be all-inclusive.)

- Review a small sample of claims submitted within recent months. Depending on the nature of the problem, the *PSC or Medicare* contractor *BI unit* may need to request medical documentation or other evidence that would validate or cast doubt on the validity of the claims.

- Interview by telephone a small number of beneficiaries. Do not alarm the beneficiaries or imply that the provider did anything wrong. The purpose is to determine whether there appear to be other false claims or if this was a one-time occurrence.

- Look for past contacts by the *PSC or the Medicare contractor BI unit, or the MR* unit concerning comparable violations. Also, check provider correspondence files for educational/warning letters or for contact reports that relate to similar complaints. Review the complaint file. Discuss suspicions with MR and audit staff, as appropriate.

- *Perform data analysis.*

- *Review* telephone calls or written questionnaires to physicians, confirming the need for home health services or DME.

- *Perform* random validation checks of physician licensure.

- Review original CMNs.

- *Perform an* analysis of high frequency/high cost, high frequency/low cost, low frequency/low cost, and low frequency/high cost procedures and items.

- *Perform an* analysis of local patterns/trends of practice/billing against national and regional trends, beginning with the top 30 national procedures for focused medical review and other kinds of analysis that help to identify cases of fraudulent billings.

- Initiate other analysis enhancements to authenticate proper payments.

- *Perform a* compilation of documentation, e.g., medical records or cost reports.

Using internal data, *PSCs and Medicare* contractor *BI units may* determine the following:

- Type of provider involved in the allegation and the perpetrator, if an employee of the provider.
- Type of services involved in the allegation.
- Places of service.
- Claims activity (including assigned and non-assigned payment data in the area of the fraud complaint).
- The existence of statistical reports generated for the Provider Audit List (PAL) or other MR reports, to establish if this provider's practice is exceeding the norms established by their peer group (review the provider practice profile).
- Whether there is any documentation available on prior complaints. Obtain the appropriate CMS-1490s and/or 1500s, UB-92s, electronic claims and/or attachments. Review all material available.

NOTE: Due to evidentiary requirements, do not write on these forms/documents in any manner.

After reviewing the provider's background, specialty and profile, *PSCs and Medicare* contractor *BI units* decide whether the situation, although it involves potentially fraudulent activity, may be more accurately categorized as a billing error. For example, records indicate that a physician has billed, in some instances, both Medicare and the beneficiary for the same service. Upon review, a *PSC or Medicare contractor BI unit* determines that, rather than attempting to be paid twice for the same service, the physician made an error in his/her billing methodology. Therefore, this would be considered a *determination* of improper billing, rather than fraud involving intentional duplicate billing.

The purpose of these activities is to decide whether it is reasonable to spend additional investigative resources. If there appears to be a pattern*, the PSC and Medicare contractor BI unit shall discuss it with* OIG/OI *at the onset of the investigation*. *The PSC and Medicare contractor BI unit shall* discuss with OIG/OI the facts of the *investigation* and *obtain OIG's recommendation on* whether or not the *investigation* should be further developed for *possible case* referral to OIG/OI.

Once a case has been referred to law enforcement, *the PSC and Medicare contractor BI unit shall* not contact the provider or their office personnel. If there is belief that provider contact is necessary, *the PSC and Medicare contractor BI unit shall* consult with OIG/OI. OIG/OI will consider the situation and, if warranted, concur with such contact. Additionally, if the suspect provider hears that its billings are being reviewed or learns of

the complaint and contacts the *PSC or the Medicare* contractor *BI unit*, *they shall* report such contact immediately to OIG/OI.

NOTE: *If investigations do not result in a case*, *the PSC and Medicare contractor BI unit shall* take all appropriate action in order to prevent any further payment of inappropriate claims and to recover any overpayments that may have been made.

4.7.2 – Closing Investigations

(Rev. 71, 04-09-04)

An investigation shall be closed if it becomes a case (i.e., it is referred to OIG, DOJ, FBI, or AUSA), if it is referred back to the AC or to another PSC due to an incorrect referral or misrouting, or if it is closed with administrative action (refer to §4.11.2.8 for FID instructions on closing investigations).

4.8 - Disposition of *Cases*

(Rev. 71, 04-09-04)

A case exists when the PSC or Medicare contractor BI unit has *referred a fraud* allegation *to law enforcement, including but not limited to documented allegations that:* a provider, beneficiary, supplier, or other subject a) engaged in *a pattern of* improper billing, b) submitted improper claims with actual knowledge of their truth or falsity, or c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity. This *definition of a case* includes any and all *allegations* (regardless of dollar threshold or subject matter) where PSC or Medicare contractor BI unit staff verify to their own satisfaction that *there is potential Medicare fraud (the* allegation is likely to be true*)* and a referral to law enforcement has been performed. PSCs and Medicare contractor BI units do not prove fraud; such action is within the purview of the Department of Justice. *Immediate advisements shall not be considered cases (see PIM Chapter 4, §4.18.1.2).*

PSCs and Medicare contractor *BI units shall* summarize the case and *shall* send *two copies of the summary*, with the case file, to OIG/OI. *PSCs and Medicare contractor BI units shall* ensure that case material is filed in an organized manner (*e.g.,* chronological order, all pages attached with prongs or other binding material, and in the same order as summarized). *When necessary,* include copies of the claims (with attachments) at issue as well as copies of documentation of all educational/warning contacts with the provider that relate to this issue. See *PIM Chapter 4, §4.18.1ff (Referral of Cases to Office of Inspector General/Office of Investigations) for further instruction on referrals to OIG/OI.*

Once the case has been referred to OIG/OI, inform the complainant *within 7 calendar days* that the case has been referred to OIG/OI, and that further requests concerning the matter should be referred to OIG/OI. *However,* some cases may be sensitive and the

complainant is not to be informed of the referral to OIG/OI. The *PSC and Medicare contractor BI* unit *shall* contact OIG/OI before responding to the complainant if the case is a sensitive one. Otherwise, provide the complainant with the address of OIG/OI and the name of a contact person.

Also, PSCs and Medicare contractor *BI units* should notify the complainant *within 7 calendar days of* OIG/OI completing the case. OIG/OI will make a determination as to whether or not the case is to be referred to the FBI or other law enforcement agency for disposition. If adverse action is subsequently taken against the provider, explain to the complainant the action taken. Thank the complainant for his/her interest and diligence.

4.8.1 – Reversed Denials by Administrative Law Judges on Open Cases

(Rev. 71, 04-09-04)

If a case is still pending at the OIG, FBI, or AUSA, and denials are reversed by an Administrative Law Judge (ALJ), *PSCs and Medicare* contractor *BI units* should recommend to *CMS* that it consider protesting the ALJ's decision to pay to the DHHS Appeals Council, which has the authority to remand or reverse the ALJ's decision. *PSCs and Medicare* contractor *BI units* should be aware, however, that ALJs are bound only by statutory and administrative law (federal regulations), *CMS* rulings, and National Coverage Determinations.

The New York and Dallas CMS ROs coordinate these protests. *Medicare* contractor *BI units shall* consult with their ROs before initiating a protest of an ALJ's decision, *and PSCs shall consult with their GTL, Co-GTL, and SMEs*. They should be aware that the Appeals Council has only 60 days in which to decide whether to review an ALJ's decisions. Thus, CMS needs to protest the ALJ decision within 30 days of the decision, to allow the Appeals Council to review within the 60-day limit. *PSCs and Medicare* contractor *BI units shall* notify all involved parties immediately if they learn that claims/claim denials have been reversed by an ALJ in a case pending prosecution.

4.9 - Incentive Reward Program

(Rev. 71, 04-09-04)

Section 203(b)(1) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) instructs the Secretary to establish a program to encourage individuals to report information on individuals and entities that are engaged in or have engaged in acts or omissions that constitute grounds for the imposition of a sanction under §§1128, 1128A, or 1128B of the Act, or who have otherwise engaged in sanctionable fraud and abuse against the Medicare program under title XVIII of the Act.

The Incentive Reward Program (IRP) was established to pay an incentive reward to individuals who provide information on Medicare fraud and abuse or other sanctionable

activities. This rule adds a new Subpart E to 42 CFR 420 ("Program Integrity: Medicare"), which consists of §§420.400 - 420.405. This new Subpart E includes provisions to implement §203(b) of Public Law 104-191 and is entitled "Rewards for Information Relating to Medicare Fraud and Abuse." The final rule was effective on July 8, 1998. The following information is intended as guidance *for implementing IRP*.

4.9.1 - Incentive Reward Program General Information

(Rev. 71, 04-09-04)

The Medicare program will make a monetary reward only for information that leads to a minimum recovery of $100 of Medicare funds from individuals and entities determined by the *CMS* to have committed sanctionable offenses. Referrals from *PSCs or Medicare contractor BI units* to the OIG made pursuant to the criteria set forth in PIM Chapter 4, §*4.19ff* are considered sanctionable for the purpose of the IRP.

4.9.2 - Information Eligible for Reward

(Rev. 71, 04-09-04)

The information must relate to a specific situation, individual, or entity, and must specify the time period of the alleged activities. It must be relevant material information that directly leads to the imposition of a sanction, and non-frivolous. *CMS* does not give a reward for information relating to an individual or entity that, at the time the information is provided, is already the subject of a review or investigation by *CMS*, its *PSCs, Medicare* contractor *BI units,* the OIG, the DOJ, the FBI, or any other federal, state or local law enforcement agency.

4.9.3 - Persons Eligible to Receive a Reward

(Rev. 71, 04-09-04)

The complainant *shall* be determined to be eligible for a reward only if the initial complaint was received on or after July 8, 1998 and provides information that leads to a sanctionable offense as described in PIM Chapter *4*, §*4.19*ff and Chapter *4*, §*4.6*ff. In general, a reward is payable to all eligible individuals whose complaints were integral to the opening of a *BI* case. Where multiple complaints have been received, the following guidelines *shall* be used:

- Only complaints directly relevant to the issue/allegation investigated are eligible.
- In situations where two or more complaints of the same nature concerning the same provider/entity are received, all complaints may be eligible to share an equal portion of the reward not to exceed the maximum amount of the reward.

- The reward *shall* be paid to the complainant*(s)* who provided sufficient, specific information to open the case as discussed above.

The *PSC or Medicare* contractor *BI unit shall* make a determination of eligibility for a reward as appropriate.

4.9.4 - Excluded Individuals

(Rev. 71, 04-09-04)

The following individuals are not eligible to receive a reward under the IRP:

- An individual who was, or is, an immediate family member of an officer or employee of the Department of Health and Human Services, its *PSCs, ACs, Medicare* contractors or subcontractors, the Social Security Administration (SSA), the OIG, a state Medicaid agency, the DOJ, the FBI, or any other federal, state, or local law enforcement agency at the time he or she came into possession, or divulged information leading to a recovery of Medicare funds. Immediate family is as defined in 42 CFR 411.12(b), which includes any of the following:
    - Husband or wife
    - Natural or adoptive parent, child, or sibling
    - Stepparent, stepchild, stepbrother, or stepsister
    - Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law
    - Grandparent or grandchild.
- Any other federal or state employee, *PSC, AC, Medicare* contractor or subcontractor, or DHHS grantee, if the information submitted came to his/her knowledge during the course of his/her official duties.
- An individual who received a reward under another government program for the same information furnished.
- An individual who illegally obtained the information he/she submitted.
- An individual who participated in the sanctionable offense with respect to which payment would be made.
-

4.9.5 - Amount and Payment of Reward

(Rev. 71, 04-09-04)

The amount of the reward *shall* not exceed 10 percent of the overpayments recovered in the case, or $1,000, whichever is less. Collected fines and penalties are not included as part of the recovered money for purposes of calculating the reward amount. If multiple complainants are involved in the same case, the reward will be shared equally among each complainant but not to exceed the maximum amount of the reward.

4.9.6 - *Program Safeguard Contractor and Medicare* Contractor Responsibilities

(Rev. 71, 04-09-04)

For PSCs and ACs, the IRP responsibilities explained below shall be worked out in the Joint Operating Agreement.

4.9.6.1 - Guidelines for Processing Incoming Complaints

(Rev. 71, 04-09-04)

On or after July 8, 1998, any complaints received that pertain to a potentially sanctionable offense as defined by §§1128, 1128A, or 1128B of the Act, or that pertain to those who have otherwise engaged in sanctionable fraud and abuse against the Medicare program under title XVIII of the Act, are eligible for consideration for reward under the IRP. While the complainant may not specifically request to be included in the IRP, *the PSC or Medicare* contractor *BI unit* should consider the complainant for the reward program. Complaints may originate from a variety of sources such as the OIG Hotline, the *PSC, the Medicare* contractor *BI* unit, customer service representatives, etc. *PSCs, ACs, and Medicare* contractors *shall* inform their staff of this program so they will respond to or refer questions correctly. PIM Exhibit 5 provides IRP background information to assist staff who *handle* inquiries. *PSCs, ACs, and Medicare* contractors, *shall* treat all complaints as legitimate until proven otherwise. They *shall* refer incoming complaints to the *PSC or Medicare contractor BI* unit for *investigation.* Complaints *shall* either be resolved by the *PSC or Medicare contractor BI* unit or, if determined to be a sanctionable offense, referred to the OIG for investigation. Complaints that belong in another *PSC's or Medicare* contractor's jurisdiction *shall be* recorded and forwarded to the appropriate *PSC or Medicare* contractor. All information *shall be* forwarded to them according to existing procedures.

If an individual registers a complaint about a Medicare Managed Care provider, *PSCs, ACs, and Medicare* contractors *shall* record and forward all information to:

Centers for Medicare & Medicaid Services
Centers for Medicare Management
Performance Review Division
Mail Stop C4-23-07
7500 Security Blvd.
Baltimore, MD 21244

4.9.6.2 - Guidelines for *Incentive Reward Program* Complaint Tracking

(Rev. 71, 04-09-04)

PSCs and Medicare contractors *shall* continue to track all incoming complaints potentially eligible for reward in their existing internal tracking system. The following complainant information *shall* be included:

- Name;
- Health insurance claim number or Social Security number (for non-beneficiary complaints);
- Address;
- Telephone number; or
- Any other requested identifying information needed to contact the individual.

PSCs and Medicare contractor *BI units shall* refer *cases* to the OIG for investigation if referral criteria are met according to PIM Chapter *4*, *§4.18.1* - Referral of Cases to the Office of the Inspector General (OIG). The case report *shall* also be forwarded to the OIG.

The *PSC or Medicare contractor BI unit shall* enter all available information into the IRP tracking database. Information that *shall* be maintained on the IRP tracking database includes:

- Date the *case* is referred to the OIG.
- OIG determination of acceptance.
- If accepted by OIG, the date and final disposition of the *case* by the OIG (e.g., civil monetary penalty (CMP), exclusion, referral to DOJ).

- Any provider identifying information required in the FID, e.g., the Unique Physician Identification Number (UPIN).

The OIG has 90 calendar days from the referral date to make a determination for disposition of the case. If no action is taken by the OIG within the 90 calendar days, the *PSC or Medicare* contractor *BI unit* should begin the process for recovering the overpayment and issuance of the reward, if appropriate.

4.9.6.3 - Overpayment Recovery

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* initiate overpayment recovery actions according to PIM Chapter 3, §3.8ff, if it is determined an overpayment exist. *For PSCs, only ACs shall issue demand letters and recoup the overpayment.*

4.9.6.4 - Eligibility Notification

(Rev. 71, 04-09-04)

After all fraudulently obtained Medicare funds have been recovered and all fines and penalties collected, if appropriate, the *PSC or Medicare* contractor *BI unit* will send a reward eligibility notification letter and a reward claim form to the complainant by mail at the most recent address supplied by the individual. PIM Exhibit 5.1 provides a sample eligibility notification letter and Exhibit 5.2 provides a sample reward claim form that may be used as guides.

4.9.6.5 - Incentive Reward Payment

(Rev. 71, 04-09-04)

After the complainant has returned the reward claim form with appropriate attachments, the *PSC or Medicare contractor BI* unit *shall* determine the amount of the reward and initiate payment. The reward payment should be disbursed to the complainant from the overpayment money recovered. Payments made under this system are considered income and subject to reporting under Internal Revenue Service tax law. No systems changes to implement these procedures are to be made.

For Medicare contractors who have transitioned their BI work to a PSC, only the AC shall make IRP payments. The PSC shall provide the necessary documentation to the AC to initiate the IRP payment.

4.9.6.6 - Reward Payment Audit Trail

(Rev. 71, 04-09-04)

The *PSC or Medicare contractor* BI unit *shall* maintain an audit trail of the disbursed check. The following data *shall* be included:

- Amount of the disbursed check
- Date issued
- Check number
- Overpayment amount identified
- Overpayment amount recovered
- Social Security number of complainant
- Party the complaint is against

The *PSC or Medicare contractor BI* unit *shall* update the IRP tracking database to reflect disbursement of the reward check to the complainant*, and the PSC shall work with the AC via the JOA to disburse the reward check.*

4.9.7 - CMS Incentive Reward Winframe Database

(Rev. 71, 04-09-04)

The IRP database was designed to track rewards that could be paid for information about fraud or abuse of the Medicare Trust Fund. Access to the IRP database is through the Winframe file server located at the *CMS* data center and is controlled through password and access codes. Cases can be entered into the IRP system by any *PSC*, Medicare contractor *BI unit*, or managed care organization contractor, or by the OIG. When the *PSC or Medicare contractor BI* unit refers a case to the OIG, *for which the complaint is eligible for the IRP,* they *shall* update the IRP system with all available information. The database contains the current status of all Medicare fraud/abuse cases pending reward. Some cases may be closed without a reward, based on final disposition of the case. *PSCs and* Medicare contractor *BI units* and *CMS* ROs have oversight responsibility for this system. The database provides the following information:

- On-demand management reports
- Duplicate complaints submitted for reward

- Audit trail of overpayments recovered as a result of the reward program

The IRP database user instructions are found in PIM Exhibit 5.3.

4.9.8 - Updating the Incentive Reward Database

(Rev. 71, 04-09-04)

The *PSCs and Medicare* contractor *BI units shall be* responsible for updating the incentive reward database on overpayment recovery and reward amounts. *PSCs and Medicare* contractor *BI units shall* regularly follow up with the OIG to obtain information on recovery of complaints referred to them that originated from an IRP complainant. The *PSCs and Medicare* contractor *BI units shall* follow up on referrals to the OIG when no action is taken within 90 calendar days. The tracking system database *shall* be updated as information becomes available. Updates *shall* be entered*, at a minimum,* on a quarterly basis.

IRP screens may be viewed in PIM Exhibit 5.9

4.10 - Fraud Alerts

(Rev. 71, 04-09-04)

Fraud Alerts are issued when there is a need to advise the *PSCs,* Carriers, Fiscal Intermediaries, law enforcement*, QIOs*, and beneficiary communities about an activity that resulted in the filing of inappropriate and potentially false Medicare claims.

The Fraud Alert describes the particular billing, merchandising practice, or activity in enough detail to enable the *PSC and Medicare* contractor *BI unit* to determine whether the practice exists in their jurisdiction.

When one of these Fraud Alerts is received, the *PSC or Medicare* contractor *BI unit* shall determine whether the scheme exists within their jurisdiction. If it does, *PSCs and Medicare contractor BI units* shall take appropriate action to protect the Medicare Trust Fund. Action may include denials, suspensions, overpayment recovery, and*/or conducting of an investigation* for *case* referral to OIG. In each case, the action the *PSC or Medicare* contractor *BI unit* takes *shall* be based on findings developed independently of the Alert. Once the Alert has been investigated, the results of the investigation *shall be reported* to the *CMS* RO *SME* (i.e., whether the scheme exists in the *PSC's or Medicare* contractor *BI unit's* jurisdiction) and the steps that were taken to safeguard the Medicare Trust Fund.

4.10.1 - Types of Fraud Alerts

(Rev. 71, 04-09-04)

Below are the various types of Fraud Alerts that are issued:

A - National Medicare Fraud Alert

The most commonly issued Fraud Alert is the National Medicare Fraud Alert (NMFA). (See PIM Exhibit 27 for the NMFA template). NMFAs do not identify specific providers or other entities suspected of committing fraud. They focus on a particular scheme or scam and are intended to serve as a fraud detection lead.

The CMS CO issues an NMFA when a fraudulent or abusive activity is perceived to be, or has the potential for being widespread, i.e., crossing *PSC or Medicare* contractor *BI unit* jurisdictions. These Alerts are numbered sequentially. Because CMS and OIG use a comparable numbering system, CMS National Medicare Fraud Alerts are identified as "CMS NMFA," followed by the Alert number appearing in the bottom left-hand corner. OIG Alerts are identified by "OIG," followed by the Alert number appearing in parenthesis in the bottom left-hand corner. The National Medicare Fraud Alert *shall* be put on the blue *CMS fraud stationery*. The MFISs *and PSCs shall* distribute Alerts to all agencies in their jurisdiction within 15 working days of receipt by the *PSC or Medicare* contractor *BI unit*.

Draft National Medicare Fraud Alerts to CO *shall* be password protected and emailed to *the CMS CO Director of the Division of Benefit Integrity and Law Enforcement Liaison.*

An NMFA *shall* contain the two following disclaimers, in bold print:

> **Distribution of this Fraud Alert is Limited to the Following Audience:**
>
> **CMS Regional Offices, All Medicare Carrier and Fiscal Intermediary Benefit Integrity Units, Program Safeguard Contractors, Medicare Integrity Program Units, Quality Improvement Organizations, Medicaid Fraud Control Units, the Office of Inspector General, the Defense Criminal Investigation Service, the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney Offices, U.S. Postal Inspectors, the Internal Revenue Service, State Surveyors, State Attorneys General, and the *State Medicaid Program Integrity Directors.***
>
> **This Alert is provided for educational and informational purposes only. It is intended to assist interested parties in obtaining additional information concerning potential fraud and to alert affected parties to the nature of the suspected fraud. It is not intended to be used as a basis for denial of claims or**

any adverse action against any provider or supplier. Such decisions must be made based on facts developed independent of this Alert.

The NMFA does not include a sanitized version, because it does not identify specific providers or entities. The sharing of NMFAs with individuals or groups that are not on the approved distribution list will be left to the discretion of the MFISs *and/or PSCs*. However, if the MFISs *or PSCs* choose to share the NMFAs beyond the approved list, the discovery and detection methodology sections shall not be included. These sections *shall* be disclosed only to the entities appearing on the audience line of the Fraud Alert.

B - Restricted Medicare Fraud Alert

CMS issues an RMFA when specific providers are identified as being suspected of engaging in fraudulent or abusive practices or activities. *PSCs and Medicare contractor BI units* prepare this type of Alert (see PIM Exhibit 28 for the RMFA template) when advising other Medicare carriers, intermediaries, *PSCs*, QIOs, MFCUs, OIG, DCIS, FBI, or DOJ of a particular provider or providers suspected of fraud. These Alerts are numbered sequentially. Because CMS and OIG use a comparable numbering system, CMS Restricted Medicare Fraud Alerts are identified by "CMS RMFA," followed by the Alert number appearing in the bottom left-hand corner. Distribution is limited to *PSCs,* Medicare contractors, CMS, QIOs, OIG/OI, DCIS, FBI, MFCUs, U.S. Postal Service, IRS, and the Offices of the U.S. Attorney. The CMS CO will issue each MFIS one copy of an RMFA along with a sanitized version. Each MFIS *and PSC shall* distribute said Alert to the *agencies* in their jurisdiction for reproduction on the red *CMS fraud stationery within 15 working days of receipt by the PSC or Medicare contractor BI unit.*

Draft Restricted *Medicare* Fraud Alerts *shall be emailed password protected via the secure email system. If problems occur with the secure email system, RMFAs shall be mailed to the following address:*

Centers for Medicare & Medicaid Services
OFM/PIG/DBIL
Mail Stop C3-02-16
7500 Security Blvd.
Baltimore, MD 21244
Attention: Fraud Alert Lead

The envelope *shall* be marked "personal and confidential" and "do not open in mailroom." *All RMFAs shall be password protected when mailed on diskette or CD-ROM.* The content of this Alert is not disclosable to the public even under the Freedom of Information Act. Public disclosure of information protected by the Privacy Act has serious legal consequences for the disclosing individual. It is intended solely for the use of those parties appearing on the audience line. It contains the names and other identifying information of provider or suppliers who are suspected of fraud.

A Restricted *Medicare* Fraud Alert *shall* contain the following disclaimer exactly as below:

> **THIS ALERT IS CONFIDENTIAL. It is not intended to be used as a basis for the denial of any claim or adverse action against any provider. Such decisions must be based on facts independent of this Alert.**
>
> **Distribution is Limited to the Following Audience:**
>
> **Centers for Medicare & Medicaid Services Regional Offices, Medicare Carrier and Fiscal Intermediary Benefit Integrity Units, Program Safeguard Contractors, Quality Improvement Organizations, Medicaid Fraud Control Units, the Office of the Inspector General, the Defense Criminal Investigation Service, the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney Offices, U.S. Postal Inspector Offices, the Internal Revenue Service, *and the State Medicaid Program Integrity Directors.***

C - *CMS Central Office Alert*

PSCs and Medicare contractor *BI units shall* prepare a CMS CO Alert when:

- *PSCs or Medicare* contractor *BI units* need to notify CMS of a scheme that is about to be publicized on the national media
- The case involves patient abuse or a large dollar amount (approximately $1 million or more or potential for widespread abuse), or
- The issues involved are politically sensitive, e.g., congressional hearings are planned to accept testimony on a fraudulent or abusive practice

The Alert is *shall be* prepared and submitted in the same manner as an NMFA but the audience line reads "CO Only." *This Alert shall be addressed to: the CMS CO Division of Benefit Integrity and Law Enforcement Liaison (DBILEL) Director, the CMS CO PIG Director, the CMS CO PIG Deputy Director, and the CMS CO Fraud Alert Lead.*

D - Medicare Fraud Information Specialist or Program Safeguard Contractor Alert

- *Initially, this Alert generally is sent to the CMS CO as a draft NMFA or RMFA.*
- *If CMS reviews the Alert and determines that it does not meet the NMFA or RMFA criteria, CMS will deny clearance and issuance.*
- *CMS notifies the MFIS or PSC of the Alert denial.*

- *If the MFIS or PSC does not provide CMS with any additional information to justify reconsideration, the denial is final. However, the MFIS/PSC communication network may issue denied Alerts as MFIS/PSC Alerts.*

- *The MFIS and PSC shall provide the CMS CO Fraud Alert Lead with a copy of this Alert.*

4.10.2 - Alert Specifications

(Rev. 71, 04-09-04)

All Alerts drafted shall meet the following criteria:

- The Alert *shall* be entitled "National Medicare Fraud Alert," "Restricted Medicare Fraud Alert," "CMS CO Alert," *or "MFIS or PSC Alert."*

- It *shall* include an audience line that indicates the audience that needs to be made aware.

- It *shall have* a subject line that briefly describes the issue or subject of the Alert, including the provider's UPIN, Tax ID number, and FID case number (if applicable).

- It *shall* include the source of the information that defines the alleged improper/suspect behavior (e.g., PIM, Medicare Carrier Manual (MCM), Medicare Intermediary Manual (MIM) section, National Coverage Determinations (NCD), LMRP, etc.).

- The body of the Alert *shall* describe the matter in enough detail to enable readers to determine their susceptibility to the activity and what they need to do to protect themselves. It includes diagnosis, Current Procedural Terminology (CPT), and Healthcare Common Procedure Coding System (HCPCS) codes, the dollar amount involved, the states affected, and applicable policy references, as appropriate.

- It *shall* include a discovery line that indicates how the *PSC or Medicare* contractor *BI unit* who initiated the Alert discovered the problem. (See note below.) This *shall* be a clear, detailed explanation that will enable others to determine what to look for in their systems. If a previous Fraud Alert was issued addressing a similar situation, *it shall* include the Fraud Alert reference.

- It *shall* include a detection methodology detailing the steps or approaches other *PSCs or Medicare* contractor *BI units* can use to determine whether this practice

is occurring in their jurisdiction (see note below), including the reports run, the edits used, and the timeframes followed.

- It *shall* include a status that details the current position of the case (e.g., with OIG or FBI, overpayment identified and amount, etc.).

- It *shall* include the name and telephone number of a person or organization to be contacted in the event of a complaint or question.

- It *shall* contain the appropriate disclaimer, depending on the type of Alert. *CMS* CO Alerts *and MFIS and PSC Alerts* do not need a disclaimer.

NOTE: Do not include the "discovery" and "detection methodology" sections when distributing an Alert to a provider professional organization or other outside group. These sections are disclosable only to ROs, *PSCs, Medicare* contractors, and federal law enforcement agencies. Restricted Alerts *shall* not be distributed beyond the approved distribution list.

4.10.3 - Editorial Requirements

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* adhere to the following requirements when drafting a Fraud Alert:

- Avoid an emotional writing style such as frequent exclamation points, underlining, and bold type. State the issue in as matter-of-fact a way as possible.

- Avoid generalizing the problem to groups, specialties, or types of providers. Focus on the billing practice or issue.

- Do not state that performance of the activity is fraud, even if the practice does violate Medicare requirements. Couch the message in terms of "alleged," "suspected," "potential," and "possible," fraud, or say it "may be fraud."

- When stating applicable penalties, use "may" (e.g., "may result in exclusion from the Medicare and Medicaid programs"). Do not state that certain penalties will be applied.

- Avoid programmatic jargon or unnecessary terms of art. Use plain English, whenever possible, while remaining technically accurate. If technical terms are necessary, explain them.

Be certain the Alert is technically accurate. Have it reviewed by the MFIS*/PSC communication network* prior to submitting a proposed Alert to CMS CO for publication. Consult with RO and OIG, as necessary. Do not sacrifice technical accuracy in the interest of a speedy issuance or writing in plain English.

Issue portions of Alerts in Spanish or other appropriate foreign language if there is a non-English-speaking population that is potentially affected by the scheme, and there are plans to distribute the Alert to such groups.

4.10.4 - Coordination

(Rev. 71, 04-09-04)

Before preparing an Alert, *the PSC or MFIS shall* consult with the applicable CMS RO and/or MFIS*, PSC network, GTL, Co-GTL, SME,* and *Medicare contractor* BI unit manager. The *PSC or MFIS shall* determine whether or not a similar Alert has been issued by contacting MFISs *or PSCs* in contiguous jurisdictions. If so, that Alert *shall* be used and the name and address of your organization *shall be added* to the contact section. If there is no such Alert, the Alert *shall be* forwarded in draft to the MFIS*/PSC communication network for input*. The MFIS/PSC *shall* forward the draft to CMS Program Integrity Group *or the GTL, Co-GTL, and SME (if a PSC)* for review and clearance. The Program Integrity Group reviews the draft, acknowledges the Alert, and notifies the *PSC or Medicare* contractor *BI unit* whether:

- A National Medicare Fraud Alert will be issued
- A Restricted Medicare Fraud Alert will be issued, or
- The Alert should be issued as a MFIS *or PSC* Alert

The CMS CO keeps the MFIS *or PSC* informed of the progress of the Alert throughout the clearance process.

4.10.5 - Distribution of Alerts

(Rev. 71, 04-09-04)

CMS issues the Alert to the *MFISs or PSCs* for further distribution. Approved NMFAs are sent through the electronic mail system *(password protected)* and approved RMFAs are mailed *(password protected diskette, CD ROM)*. Upon receipt of an approved Alert, the MFIS *or PSC shall* add their name and telephone number to the existing contact

information on the Alert. They *shall* then reproduce the Alert on their own *supply of CMS approved* stationery. MFISs *or PSCs shall* distribute the Alert to the entities that appear on the audience line.

4.11 – Fraud Investigation Database Entries

(Rev. 71, 04-09-04)

The *Fraud Investigation Database (*FID*)* is a nationwide *database of Medicare* fraud and abuse *investigations, cases, and payment suspensions by the PSC or Medicare contractor BI unit*.

The following agencies/organizations currently have access to the FID:

- *Medicare Program Safeguard Contractors*
- Medicare *Contractor Benefit Integrity units that have not transitioned to a PSC*
- *Medicare Contractor Provider Enrollment units*
- CMS
- FBI
- DOJ
- *DHHS/*OIG
- *Medicaid Program Integrity Directors, SURs (State Utilization Review) officials, and Provider Enrollment units*
- Medicaid Fraud Control Units
- Other federal and state partners seeking to address program integrity concerns in judicial or state health care programs

4.11.1 - Background

(Rev. 71, 04-09-04)

The FID *shall* capture information on *investigations that have been initiated by the PSC or Medicare contractor BI unit and on* cases that *have been referred to law enforcement* by the *PSC or* Medicare contractor *BI unit. The FID shall also capture information on payment suspensions that have been imposed. As available, the FID shall also capture information on cases/investigations initiated by law enforcement.*

Investigations initiated by the PSC or Medicare contractor BI unit shall be saved in the FID, and contain identifying information on the potential subject of a case.

Cases initiated by the PSC or Medicare contractor BI unit shall contain a summary of the pertinent information *on the case referral. At a minimum, the following data shall be included* in the case:

- Subject of *the case* (e.g., physician, hospital, Skilled Nursing Facility, Home Health Agency, Comprehensive Outpatient Rehabilitation Facility, etc.).
- Allegation information/nature of the scheme.
- Status of the case.
- Disposition of a case (e.g., administrative action, prosecution, exclusion, settlement, etc.).
- Contact information for *PSC, Medicare* contractor *BI unit,* and/or law enforcement.

Payment suspensions shall contain a summary of the pertinent information on the suspension, including date implemented, rebuttal information, and amounts in suspense.

Cases/investigations initiated by law enforcement shall contain available information.

The FID also has monitoring *and* reporting capabilities*, and contains Medicare Fraud Alerts and a Resource Guide, by state, of contacts at PSCs, Medicare contractor BI units, MFIS/PSC Network members, Medicaid Program Integrity Directors and Medicaid Fraud Control Units, and law enforcement agencies.*

4.11.1.1 - Information not Captured in the FID

(Rev. 71, 04-09-04)

Individual complaints (statements alleging improper entitlement), simple overpayment recoveries (*not involving potential* fraud), and medical review abuses *shall* not *be captured in the FID.*

4.11.1.2 - Entering OIG Immediate Advisements into the FID

(Rev. 71, 04-09-04)

All available information *shall* be entered into the FID*, as an investigation,* concurrent with, or within *15 calendar* days after, the "*immediate* advisement" *and shall be converted to a case if the OIG accepts it*.

4.11.2 – Investigation, Case, and Suspension Entries

(Rev. 71, 04-09-04)

It is not appropriate for an OIG or FBI agent, DOJ, or an Assistant United States Attorney (AUSA), to request that a PSC or Medicare contractor BI unit not enter or update an investigation, case, or payment suspension initiated by the PSC or Medicare contractor BI unit in the FID, except in rare circumstances. PSCs and Medicare contractor BI units shall inform law enforcement agents making such requests that they are required by CMS to maintain the FID and that they do not have the discretion to do otherwise. The PSC or Medicare contractor BI unit shall contact the GTL, Co-GTL, and SME (if a PSC) or CMS RO employee (if a Medicare contractor BI unit) in order to resolve the matter.

However, for both PSC or Medicare contractor BI unit initiated and law enforcement initiated cases/investigations, information regarding law enforcement activities that are or could be considered to be of a sensitive nature, including but not limited to, planned search warrants, undercover operations and activities and executed search warrants where only some of the search warrants have been executed, shall not be entered into the FID.

4.11.2.1 - Initial Entry *Requirements for Investigations*

(Rev. 71, 04-09-04)

Investigations shall capture information on ongoing work in the PSC or Medicare contractor BI unit. For PSCs, investigations are entered when they are reported on the PSC's ART report. For Medicare contractor BI units, investigations are entered when they are being worked in the BI unit, regardless of level of effort, but have not been referred to law enforcement as a case.

Law enforcement initiated investigations or law enforcement data requests shall only be entered as Investigations in the FID. They shall not be entered as FID cases. They shall be entered the same as for PSC or Medicare contractor BI unit initiated investigations, except for under the Actions tab, the specific Action selected shall be: "Support for LE-initiated investigation". They shall be entered within 15 calendar days of the request for support.

Investigations initiated by the PSC or Medicare contractor BI unit shall be entered into the FID within 15 calendar days of the start of the investigation (Investigations are defined in PIM Chapter 4, §4.7). Such investigations shall be saved in the FID and shall not be converted to a case until and unless the investigation results in a referral as a case

to the OIG or other law enforcement agency. When an investigation is saved, the FID will assign it an investigation number, starting with the letter N.

The minimum initial data entry requirements into the FID for an Investigation shall be (by Tab):

SUBJECT INFORMATION Tab:

- *Subject's Name*

- *Subject's Address (City, State, and Zip Code)*

- *Subject Type and Subtype*

CASE INFORMATION Tab:

- *Allegation*

- *Allegation Source*

- *Dates of Services (if known)*

ACTIONS Tab:

- *Actions Taken by: Contractor*

- *Action Date: [enter the date the investigation was opened]*

- *Action Narrative: [enter brief statement on the investigation]*

- *Action: Under Investigation (for PSC or Medicare contractor BI unit initiated investigations) or*

- *Action: Support for LE-Initiated Investigation*

CONTACTS Tab:

[Confirm contact information is accurate]

4.11.2.2 – Initial Entry Requirements for Cases

(Rev. 71, 04-09-04)

Once the *PSC or Medicare* contractor *BI unit* has *referred a case to the OIG or other law enforcement agency, the investigation shall then be saved as a Case* within *15 days of referral. The investigation actually converts to a FID case.*

4.11.2.3 – Initial Entry Requirements for Payment Suspension

(Rev. 71, 04-09-04)

For payment suspensions, the information shall be entered into the FID Suspension Module no later than the effective date of the suspension.

4.11.2.4 – Update Requirements for Investigations

(Rev. 71, 04-09-04)

There are no mandatory update requirements for investigations, but the PSC and Medicare contractor BI unit shall enter updates as necessary. Should the PSC or Medicare contractor BI unit add information during the investigation phase, it shall still be saved in FID as an investigation.

4.11.2.5 - Update Requirements for Cases

(Rev. 71, 04-09-04)

For cases referred to the OIG, the FBI, or other law enforcement agency, updates to the FID case shall be made at least every three months (one month is a maximum of 31 days). If problems are encountered which undermine the PSCs' or Medicare contractor BI units' ability to get updated information, this shall be discussed with the appropriate GTL, Co-GTL, and SME (if a PSC) or CMS RO employee (if a Medicare contractor BI unit).

As applicable, the following tabs/sections shall be updated:

- Referrals accepted by OIG or FBI are assigned a case number *by the OIG or FBI*. It *shall be* the responsibility of the *PSC or Medicare* contractor *BI unit* to obtain and enter the case number into the FID *Case Information tab*;

- The *Case Narrative* section *in the FID Case Information tab shall* clearly identify *the alleged fraudulent activity, all investigation actions, and referral activities performed on the case* by the *PSC or Medicare* contractor *BI unit*. The sooner comprehensive case *information* is entered into FID, the more efficiently other *PSCs, Medicare* contractors, CMS, *Medicaid,* and law enforcement agencies can react to the *case* and perform related trend-data analysis;

- The *PSC or Medicare* contractor *BI unit shall enter updated summary* information in the FID *Actions tab* after the case is referred to the OIG/FBI. *The status of the case and, when appropriate,* actions taken by law enforcement *shall* be entered into the FID. If the *PSC or Medicare* contractor *BI unit* is not able to obtain status on cases referred to *and accepted by* law enforcement, this *shall* be brought to the attention of the *appropriate GTL, Co-GTL, and SME (if a PSC) or* CMS RO *employee (if a Medicare contractor BI unit). All corrective and/or administrative actions taken by the AC, PSC, or Medicare contractor shall be entered into the FID;*

- *Contact with* the FBI or an AUSA regarding their actions on a case;

- *Capturing and documenting* subsequent law enforcement referrals (e.g., OIG declines case, *PSC or Medicare* contractor *BI unit* refers case to FBI, FBI accepts case);

- Keeping apprised of MR/Provider Audit and Reimbursement actions if they are taking actions on a case;

- Updating the amount being withheld, denied, or paid;

- Entering information on convictions/sentences*; and/or,*

- *Adding to* the *case* narrative *section in the Case Information tab,* to incorporate any updated information *summarized in* the Actions *tab*.

It is extremely important to document in the FID any consultations with law enforcement as well as administrative actions and associated monetary assessments by the *PSC, Medicare* contractor *BI unit, or law enforcement*. *PSCs and Medicare contractor BI units shall be* responsible for providing such documentation.

4.11.2.6 – Update Requirements for Payment Suspensions

(Rev. 71, 04-09-04)

The first update following initial entry of the suspension shall be made within one month; the second update shall be made within two months. Thereafter, the amount being withheld and other pertinent information on the suspension shall be updated in the suspension module every two months, until the suspension is removed. For suspensions under unlimited extension, updates shall be made every three months. (For all references to a month in this section, one month is a maximum of 31 days.)

4.11.2.7 - OIG Non-Response to or Declination of Case Referral

(Rev. 71, 04-09-04)

As per instructions found in PIM, Chapter 4, §4.18.1, if the PSC or Medicare contractor BI unit does not hear back from the OIG within the first 90 days following referral, and if repeated attempts by the PSC or Medicare contractor BI unit to find out the status of the case are unsuccessful, the PSC or Medicare contractor BI unit shall then refer the case first to the FBI and if FBI declines the case to any other law enforcement agency with interest in the case. If this subsequent referral to the FBI or any other investigative agency is not acted upon within 45 days, the PSC or Medicare contractor BI unit shall follow up with the FBI or other investigative agency. Subsequent to follow-up, the PSC or Medicare contractor BI unit may close the case in the FID if it is still not acted upon by the FBI or other law enforcement agency, but shall continue to enter any actions that it takes, including administrative actions. For FID tracking purposes, the PSC and Medicare contractor BI unit shall make any additional entries, based upon administrative or other actions taken, or, in the alternative, shall reopen the same FID case at some future time if the OIG, FBI, or other law enforcement agency accepts the case.

If the OIG formally declines a referral and does not *itself* refer the case to the FBI, the *PSC or Medicare* contractor *BI unit shall* refer the case *first* to *the FBI and then to another law enforcement agency if the FBI declines the case*. However, *when a case is referred to FBI in this situation,* it *shall be* considered an update *to the existing FID case,* reflecting a subsequent action *taken on the case*, and not a new *FID case. That is, subsequent* referrals *of the same case* to other law enforcement agencies *shall* not *be* count*ed* as new case entries in the FID, nor are they counted for workload purposes as new referrals to law enforcement.

4.11.2.8 – Closing Investigations

(Rev. 71, 04-09-04)

Investigations shall be closed when they are no longer reported as an investigation on the PSCs' ART or the Medicare contractor BI unit has determined that it will not result in a case (refer to §4.7.2 for a definition of when to close an investigation). The investigation that does not result in referral of a case shall be closed by entering the following action in the ACTIONS Tab in order to indicate that the investigation has been closed:

ACTIONS Tab:

- Action Taken by: Contractor

- Action: Investigation Closed

The PSC or Medicare contractor BI unit shall also enter administrative actions, if any, it has taken as part of disposition of the investigation.

Investigations initiated by law enforcement shall be closed when law enforcement indicates it requires no further support. Close the investigation by entering the following action:

ACTIONS Tab:

- Action Taken by: Contractor

- Action: LE-Initiated Investigation Closed

4.11.2.9 – Closing Cases

(Rev. 71, 04-09-04)

An active FID case shall be closed when law enforcement has ended all its activity on the case (whether through successful resolution of the case or otherwise) and no further action will be required of the PSC or Medicare contractor BI unit by law enforcement. Note that even after the case is closed, there may still be administrative actions that the PSC or Medicare contractor BI unit will take. Such administrative actions shall also be documented in the Case Information and Actions tabs of the closed FID case as they occur.

4.11.2.10 – Closing Payment Suspensions

(Rev. 71, 04-09-04)

When the payment suspension is removed, this information shall be entered into the payment suspension module within 15 calendar days of removal. This changes the status of the suspension from Active to Removed. Even after a suspension becomes inactive, updated information on the Actual Overpayment Amount, Amount Recovered, and other pertinent information shall be entered as it becomes available.

4.11.2.11 - Duplicate *Investigations, Cases, or Suspensions*

(Rev. 71, 04-09-04)

A duplicate *investigation,* case, *or suspension* exists when any given *PSC or Medicare* contractor *BI unit inadvertently* enters a provider, supplier, or beneficiary as the subject of *an investigation, case, or payment suspension* more than once, absent different allegations or other differentiating criteria requiring a separate *investigation, case*, *or suspension entry*.

For investigations, cases, and suspensions, it shall not *be* considered a duplicate *investigation,* case, or *suspension* if multiple *PSCs or Medicare* contractor *BI units* enter *investigations,* cases, *or suspensions* for the same provider as the subject of *an investigation, case, or suspension*. These *investigations,* cases, *and suspensions*, however, *shall* reflect a coordinated effort by all *PSCs and Medicare* contractor *BI units* involved and investigating the provider. Case numbers *shall* be referenced *in the Subject*

Information tab, Related FID Case No. field, and the case description summaries *shall* reflect this coordination. The FID now has the capability of cross-checking for related cases.

If a *new investigation or* case *is initiated* on a provider that was already the subject of a closed *investigation or* case, a new *investigation or case shall* be opened. The closed *investigation or* case, however, *shall* be mentioned in the Case Narrative screen *in the Case Information Tab* and cross-referenced to the old *investigation or* FID case number.

The target, whether entity or individual, *shall* be entered as the subject of the *investigation or* case. Any and all related providers, suppliers, beneficiaries, *etc.,* who *are in any way affiliated with the* subject of the case, *shall* be identified under "AKAs, DBAs, and Affiliates." However, if these individuals are the primary subjects/targets of the *investigation or case* and independent *investigations or* cases are made against them, then individual *investigations or* cases *shall* be established in the FID.

If a new payment suspension has been imposed on a provider that was already the subject of an earlier payment suspension, a new payment suspension shall be entered into the FID. The prior (now inactive) suspension, however, shall be cross-referenced in the Contacts/Narrative Information tab - Suspension Narrative section.

PSCs and Medicare contractor *BI units shall* check for potential duplicate entries of *investigations,* cases, *or suspensions*.

4.11.2.12 – Deleting Investigations, Cases, or Suspensions

(Rev. 71, 04-09-04)

Investigations, cases, or *suspensions* can be deleted from the FID only by users with the "File Manager" (system administrator) designation. As applicable and necessary, *the GTL, Co-GTL, SME, or* CMS RO will contact and discuss with the *PSC or Medicare* contractor *BI unit* the need to correct and/or delete *an investigation, a* case, *or suspension* from the database. In the event that a *PSC or Medicare* contractor decides that *an investigation,* a case, *or suspension* should be deleted from the FID*, the investigation number, case number, or suspension number shall* be forwarded to the *FID mailbox at* FID@cms.hhs.gov.

4.11.3 - Operational Issues

(Rev. 71, 04-09-04)

4.11.3.1 - Access

(Rev. 71, 04-09-04)

If *PSCs, Medicare contractor BI units, and others eligible to access the FID* have never applied for access to the FID system and require authorization, an "Application for Access to CMS Computer Systems" *shall* be completed, submitted, and approved.

This form may be acquired from http://www.cms.hhs.gov/mdcn/access.pdf. *It shall be submitted to the* appropriate RACF *(Resource Access Control Facility)* Group Administrator for all CMS central and regional offices, *Medicare contractor BI unit* users, or to the *CMS Central Office GTL for PSCs or to the* CMS Division of Benefit Integrity and Law Enforcement Liaison *for all* law enforcement personnel or other users.

The CMS Remote Access Guide can be found at the following website:
http://www.cms.hhs.gov/mdcn/cmsremoteaccessguide.pdf.

For those individuals who have received prior authorization, but are experiencing authorization lapses or password problems, the same contacts referenced above *shall* be contacted. Internet access problems *shall be* directed to *the CMS IT Service* Desk, at (410) 786-2580 *or 1-800-562-1963*.

4.11.3.2 - The Fraud Investigation Database User's Group

(Rev. 71, 04-09-04)

Membership in the FID User's Group is voluntary and open to all Users. The group discusses proposed enhancements, upgrades, current issues, matters of interest to users, etc. Anyone interested in joining the group can send an email to the FID mailbox:
FID@cms.hhs.gov

Notice of programming changes in the FID (e.g., enhancements, upgrades, changes to entry requirements) shall be issued by the FID User's Group, and disseminated as widely as possible. PSCs and Medicare contractor BI units shall refer to FID User's Group minutes for entry instructions. Programming changes are also communicated via News Items posted in the FID.

4.11.3.3 - DMERC MFIS *and Designated PSC Staff* and the Fraud Investigation Database

(Rev. 71, 04-09-04)

The DMERC Medicare Fraud Information Specialists and designated PSC staff receive training on how to input and maintain cases in the FID. The intent is to use these staff members as FID experts and points of contact for questions and comments on the FID. They *shall* be responsive to FID questions from *PSCs and Medicare contractor BI units* and law enforcement personnel within their jurisdiction.

The MFISs *shall* regularly share FID information and analysis (e.g., FID system reports) with the *Medicare contractor* BI unit manager, or their designee, for their applicable jurisdiction. MFISs *shall serve* as a resource to CMS on the FID, including FID training. While the *MFIS* should not enter cases into the FID or monitor FID quality, if the MFIS detect any inaccuracies or discrepancies they *shall* notify the respective *Medicare* contractor staff and/or management. Upon request, the MFIS *shall* furnish FID reports to the *Medicare contractor* BI unit manager*(s)* within their jurisdiction.

Designated staff at each PSC shall be responsible for sharing FID information and analysis (e.g., FID system reports) with the PSC BI manager and BI staff. The designated PSC staff shall also serve as a resource to CMS on the FID, including FID training. If the designated PSC staff detects any inaccuracies or discrepancies in cases entered by their PSC, they shall notify the PSC BI manager.

4.11.3.4 - The Fraud Investigation Database Mailbox

(Rev. 71, 04-09-04)

Anyone can send an email to the FID mailbox with a question, comment, or suggestion about the FID. The address is FID@cms.hhs.gov

4.12 - Harkin Grantees - Complaint Tracking System

(Rev. 71, 04-09-04)

This section provides instructions for implementing the Harkin Grantee Tracking System (HGTS).

4.12.1 - Harkin Grantee Project Description

(Rev. 71, 04-09-04)

The Harkin Grantees (named after Senator Tom Harkin) are part of a broad initiative to combat waste, fraud, and abuse within the Medicare program. The anti-abuse initiative is supported by the partnership between the Department of Health and Human Services, Office of Inspector General, and the Administration on Aging (AOA).

The Harkin Grantees are senior volunteers who focus on detecting and reporting fraudulent or improper Medicare activities, primarily in home health care, nursing facilities, hospice, and durable medical equipment suppliers.

4.12.2 - Harkin Grantee Tracking System Instructions

(Rev. 71, 04-09-04)

The *AC or* Medicare contractor *second-level screening staff shall be* responsible for collecting, tracking, and reporting the administrative and monetary results of fraud and abuse complaints generated by the Harkin Grantee state projects*, including those complaints referred to the PSC or Medicare contractor BI unit. The AC or Medicare contractor second-level screening staff shall develop aggregate reports available to the Harkin Grantee state project coordinators every 6 months.*

The Harkin Grantee state/local contact information is available at http://www.aoa.gov/smp/index.asp

4.12.3 - *System Access to Metaframe and* Data Collection

(Rev. 71, 04-09-04)

The Harkin Grantee Tracking System migrated from the Winframe to the Metaframe server. Access the Metaframe system as follows:

> *Download the new Citrix Client and upgrade. Download the Client software:* ***http://download2.citrix.com/files/en/products/client/ica/current/ica32.exe***

Each AC and Medicare contractor shall designate a person in the second-level screening staff to input the complaint into the HGTS database located on the Metaframe system. These designees shall enter data on a continuous basis related to complaints generated by the Harkin Grantee state projects.

The Harkin Grantees will report their complaints according to their usual procedure, using the model complaint form (PIM Exhibit 32).

Upon receiving Harkin Grantee complaints, the AC or Medicare contractor second-level screening staff shall enter the following information into the Metaframe database fields.

- *Project number*
- *Date of Report*
- *Provider Number*
- *Provider Name*
- *Provider City*
- *Provider State*
- *AC or Medicare Contractor Number*

- *Overpayment Identified*
- *Overpayment Recovered*
- *Action Taken*
- *Further Explanation*

If the PSC or Medicare contractor BI unit completes the complaint review, they shall provide the above information, as applicable, to the AC or Medicare contractor second-level screening staff for input.

4.12.4 - Data Dissemination/Aggregate Report

(Rev. 71, 04-09-04)

The *AC or Medicare* contractor *second-level screening staff shall* compile information in the database into an aggregate report. The *AC or Medicare* contractor *shall* distribute the aggregate report to the Harkin Grantees state project coordinators every 6 months. *Aggregate reports shall be distributed by the second week of July (covering January - June data) and the second week of January (covering July - December data).*

The January through June/July through December report cycle shall be continuous until further instruction.

The AC and Medicare contractors second-level screening staff *shall* forward copies of the aggregate reports to the *CMS CO Director of the Division of Benefit Integrity and Law Enforcement Liaison.*

4.13 - Administrative Relief from Benefit Integrity *Review* in the Presence of a Disaster

(Rev. 71, 04-09-04)

During a disaster, whether man-made or natural, the *PSC and Medicare* contractor *BI unit* shall continue every effort to identify cases of potential fraud. Therefore, if the *PSC or Medicare contractor BI* unit suspects fraud of a provider who cannot furnish medical records in a timely manner due to a disaster, the *PSC or Medicare contractor BI* unit shall ensure that the provider is not attempting to harm the Medicare Trust Fund by taking 6 months or more to furnish medical records. As such, the *PSC or Medicare* contractor *BI unit* shall request and review verification documentation in all instances where fraud is suspected.

In the case of complete destruction of medical records/documentations where backup records exist, *PSCs or Medicare contractor BI units shall* accept reproduced medical

records 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, *PSCs or Medicare contractor BI units shall* 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."

4.14 - Provider Contacts by the *Program Safeguard Contractor and Medicare Contractor Benefit Integrity* Unit

(Rev. 71, 04-09-04)

A *PSC or Medicare contractor BI unit* may determine that the resolution of an *investigation* does not warrant referral for criminal, CMP, or sanction, and that *an educational* meeting with the provider is more appropriate. The *PSC or Medicare* contractor *BI unit shall* inform the provider of the questionable or improper practices, the correct procedure to be followed, and the fact that continuation of the improper practice may result in administrative sanctions. The *PSC or Medicare* contractor *BI unit* shall document contacts and/or warnings with written reports and correspondence and place them in the *investigation* file. If the improper practices continue, the *PSC or Medicare* contractor *BI unit shall* consult with the OIG/OI contact person regarding sanction action.

If the provider continues aberrant billing practices during the period for which it is being investigated for possible sanction, the *PSC or Medicare* contractor *BI unit* shall *initiate the adjustment of* payments accordingly *with the AC or appropriate unit in the Medicare contractor*. After meeting with a provider, the *PSC or Medicare* contractor *shall* prepare a detailed report for the *investigation* file, and *shall* forward a copy to OIG/OI *along with a case referral*, if requested. The report *shall* include the information in A, B, and C below.

A - Background of Provider (Specialty)

PSCs and Medicare contractor *BI units shall* include a list of all enterprises in which the subject had affiliations, the states where the provider is licensed, all past complaints, and all prior educational contacts/notices.

B - Total Medicare Earnings

PSCs and Medicare contractor *BI units shall* include a report of the total Medicare earnings for the past 12 months, as well as total dollars for assigned and non-assigned claims in that period in the case file.

The report *shall* include the following:

- Earnings for the procedures or services in question
- Frequency of billing for these procedures/services
- Total number of claims submitted for these procedures/services

C - Extent of Audit Performed

PSCs and Medicare contractor *BI units shall* include:

- A report of your audit process and findings
- Overpayment identified
- Recommendation(s)

D – Report of Meeting

PSCs and Medicare contractor BI units include:

- *Minutes from the meeting describing the problems and/or aberrancies discussed with the provider and the education provided to the provider to correct those problems, and*
- *Copies of educational materials given to the provider before, during, or subsequent to the meeting.*

4.15 - Consent Settlement Instructions

(Rev. 71, 04-09-04)

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

The consent settlement is *a limited audit that is used as a* tool to modify a provider's billing practice while limiting *PSC and Medicare* contractor *BI unit* costs in monitoring provider practice patterns. 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. A 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 a consent settlement

When offering a provider a consent settlement, *PSCs and Medicare* contractor *BI units* may choose to present the consent settlement letter to the provider in a face-to-face meeting. The consent settlement correspondence describes the three options available to the provider.

A - Option 1 - Acceptance of Potential Projected Overpayment

Providers selecting Option 1 agree to refund the entire limited projected overpayment amount without submitting additional documentation. These providers forfeit their right to appeal the adjudication determinations made on the sampled cases and the potential projected overpayment that resulted from extrapolating to the universe. For providers who elect Option 1, any additional claims *shall* not be audited for the service under review within the time period audited. (If desired, waive Option 1.)

B - Option 2 - Acceptance of Capped Potential Projected Overpayment

Providers selecting Option 2 agree to submit additional pre-existing documentation. Review this additional documentation and adjust the potential projected overpayment amount accordingly. Any additional claims *shall* not be audited for the service under review within the time period audited for providers who elect Option 2.

C - Option 3 - Election to Proceed to Statistical Sampling for Overpayment Estimation

If a provider fails to respond, this option is selected by default. For providers who select this option knowingly or by default, thereby rejecting the consent settlement offer and retaining their full appeal rights, *PSCs and Medicare contractor BI units* shall:

- Notify the provider of the actual overpayment and refer to overpayment recoupment staff
- Initiate statistical sampling for overpayment estimation of the provider's claims for the service under review

If the review results in a decision to recoup overpayment through the consent settlement process, the consent settlement *shall* have been initiated within 12 months of the selection process.

A sample of consent settlement documents can be found in PIM Exhibit 15.

4.15.1 - Consent Settlement Budget and Performance Requirements *for Medicare Contractors*

(Rev. 71, 04-09-04)

In preparation for the BI BPR requirements, *Medicare* contractors who have not transitioned BI work to a PSC shall keep a record of the number of consent settlements offered and accepted, and the number of *times that statistical sampling for overpayment estimation is used*. These workload numbers *shall* be reported each fiscal year. (For example, BI develops a case and it is not accepted by law enforcement. BI should perform an overpayment estimation and offer the provider a consent settlement or *statistical sampling for overpayment estimation*.) BI shall track this information and record the counts in the Miscellaneous field for Activity Code 23007.) *ACs shall report these costs in the PSC support activity code 23201.*

4.16 - Voluntary Repayment *and Referral to Law Enforcement*

(Rev. 71, 04-09-04)

Through the JOA, PSCs shall establish a mechanism whereby the AC notifies the PSC on a regular basis of all voluntary repayments received by the AC. Medicare contractor BI units shall work with the appropriate area in the Medicare contractor to receive such notification. PSCs and Medicare contractor BI units shall send one letter annually to the same provider submitting a voluntary refund, advising the provider of the following:

> The acceptance of payment from _____of the sum of $_____ as repayment for the claims specified herein*, if applicable,* in no way affects or limits the rights of the Federal Government or any of its agencies or agents to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims.

PSCs shall advise providers to send voluntary repayments to the AC.

4.17 - Procedures for Benefit Integrity on Unsolicited/Voluntary Refund Checks

(Rev. 71, 04-09-04)

This section provides program integrity guidance on unsolicited/voluntary refunds from providers/suppliers (including physicians and other practitioners).

Voluntary refund checks payable to the Medicare program shall not be returned, regardless of the amount of the refund. *The PSC or Medicare contractor BI unit shall communicate with the AC or Medicare contractor staff responsible for processing voluntary refunds to obtain information on voluntary refund checks received. The PSC or Medicare contractor BI unit shall perform an investigation on any voluntary refunds where there is suspicion of inappropriate payment or if a provider is under an active investigation (see PIM Chapter 4, §4.16).*

Should the PSC or Medicare contractor BI unit receive a voluntary refund check in error, the PSC shall coordinate the transfer of voluntary refund checks to the AC through the JOA, and the Medicare contractor BI unit shall transfer the check to the appropriate Medicare contractor staff. For PSCs, voluntary refund checks shall be processed and deposited by the AC.

ACs and the appropriate Medicare contractor staff refer to the Financial Management Manual for instructions on processing and reporting unsolicited/voluntary refunds received from providers/physicians/suppliers and other entities.

This *PIM* section does not supersede PIM, *Chapter 4, §4.16* (Voluntary Repayment *and Referral to Law Enforcement*).

4.18 – Referral of Cases to Other Entities for Action

(Rev. 71, 04-09-04)

4.18.1 - Referral of Cases to the Office of the Inspector General/Office of Investigations

(Rev. 71, 04-09-04)

PSCs and Medicare contractor BI units shall identify cases of suspected fraud and to *shall* make referrals of all such cases to the OIG/OI, regardless of dollar thresholds or subject matter. Matters *shall* be referred when the *PSC or Medicare* contractor *BI unit* has *documented allegations, including but not limited to: a* provider, *beneficiary, supplier, or other subject,* a) engaged in *a pattern of* improper billing, b) submitted improper claims with actual knowledge of their falsity, or c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity. In cases where providers' employees submit complaints, such cases *shall* be forwarded to the OIG immediately.

Prior to a referral to law enforcement and within 60 calendar days of identifying the necessity for administrative action (e.g., payment suspension or recoupment of an

overpayment), the PSC and Medicare contractor BI unit shall consult with law enforcement prior to taking administrative action. If law enforcement is unwilling to render a decision on administrative action or advises the PSC or Medicare contractor BI unit against taking administrative action, the PSC shall consult the GTL, Co-GTL, and SME and the Medicare contractor BI unit shall contact the RO. The GTL, Co-GTL, and SME for a PSC and the RO for a Medicare contractor BI unit will decide whether or not to take administrative action.

If a case has been referred to OIG/OI, OIG/OI has 90 calendar days to accept the referral, refer the case to the DOJ (for example, the FBI, AUSAs, etc.), or to reject the case. If the *PSC or Medicare* contractor *BI unit* does not hear from OIG/OI within the *first 90 calendar days following referral, and repeated attempts by the PSC or Medicare contractor BI unit to find out the status of the case are unsuccessful*, the *PSC or Medicare contractor BI unit shall refer the case to the FBI and/or any other investigative agency with interest in the case. The PSC or Medicare contractor BI unit shall follow up on this second referral to the FBI and any other investigative agency within 45 calendar days. Refer to the FID section of the PIM for the requirements on entering and updating referrals in the FID.* If OIG/OI *or other law enforcement agencies* will not give a definite answer, contact the *GTL, Co-GTL, and SME (if a PSC) or* RO *(if a Medicare contractor BI unit)* for assistance. If *OIG/OI or other law enforcement agencies do not* accept the case or are still unwilling to render a decision on the case, even after the intercession of the *GTL/Co-GTL/SME or* RO*, PSCs and Medicare* contractor *BI units shall* proceed with action to ensure the integrity of the Medicare Trust Fund *(e.g., PSCs and Medicare contractor BI units shall discuss it with the AUSA and/or the OIG prior to taking administrative action).*

OIG/OI will usually exercise one or more of the following options when deciding whether to accept a case:

- Conduct a criminal and/or civil investigation
- Refer the case back to the *PSC or Medicare* contractor *BI unit* for administrative action/recovery of overpayment with no further investigation
- Refer the case back to the *PSC or Medicare* contractor *BI unit* for administrative action/recoupment of overpayment after conducting an investigation or after consulting with the appropriate AUSA's office
- Refer the case back to the *PSC or Medicare* contractor *BI unit* for administrative action/recoupment of overpayment after the AUSA's office has declined prosecution
- Refer the case to another law enforcement agency for investigation

Where OIG/OI conducts an investigation, OIG/OI will usually initiate ongoing consultation and communication with the *PSC or Medicare* contractor *BI unit* to establish

evidence (i.e., data summaries, statements, bulletins, etc.) that a statutory violation has occurred.

In addition to referral of such cases to the OIG, *PSCs and Medicare* contractor *BI units shall* also identify and take additional corrective action and prevent future improper payment (for example, by placing the provider's or supplier's claims on prepayment review). In every instance, whether or not the *investigation* is a potential *case and* law enforcement referral, the first priority is to minimize the potential loss to the Medicare Trust Fund and to protect Medicare beneficiaries from any potential adverse effect. Appropriate action varies from case to case. In one instance, it may be appropriate to suspend payment pending further development of the case. In another instance, suspending payment may alert the provider to detection of the fraudulent activity and undermine a covert operation already underway, or being planned, by federal law enforcement. *PSCs and Medicare* contractor *BI units shall develop appropriate administrative action prior to the elapsing of the 90 calendar days, but withhold final action until after* consult*ing* appropriately with the OIG *or other law enforcement agencies* when taking such measures. The OIG may provide the *PSC or Medicare* contractor *BI unit* with information that *shall* be considered in determining what corrective action should be taken. *If law enforcement is unwilling to render a decision on administrative action or advises the PSC or Medicare contractor BI unit against taking administrative action, the PSC shall contact the GTL, Co-GTL, and SME and the Medicare contractor shall contact the RO. The GTL, Co-GTL, and SME for a PSC and the RO for a Medicare contractor will decide whether or not to take administrative action.*

It is important to alert OIG/OI, FBI, the civil and criminal divisions in the U.S. Attorney's Office, and the RO, of contemplated suspensions, denials, and overpayment recoveries where there is reliable evidence of fraud and a referral pending with the OIG/OI or FBI, or a case pending in a U.S. Attorney's Office.

If the case is the focus of a national investigation, *PSCs and Medicare* contractor *BI units shall* not take action without first consulting with the *GTL, Co-GTL, and SME (if a PSC) or the* RO *(if a Medicare contractor BI unit),* and the agency that has the lead for the investigation.

4.18.1.1 - Referral of Potential Fraud Cases Involving Railroad Retirement Beneficiaries

(Rev. 71, 04-09-04)

The DHHS OIG has jurisdiction over investigations involving Railroad Retirement Beneficiaries (RRB). OIG will refer them to the carrier for RRB claims.

RRB personnel occasionally can more readily obtain necessary information from beneficiaries, e.g., working through the Social Security Administration (SSA) office when the Part B beneficiary is a railroad annuitant with no SSA monthly benefit

involvement. When suspected violations come to the attention *of the RRB* in its processing of claims, it is expected to check for the possibility of similar violations in Medicare claims processed for RRB as well.

4.18.1.2 - Immediate Advisements to the OIG/OI

(Rev. 71, 04-09-04)

The PSC or Medicare contractor BI unit *shall* immediately advise *in writing* OIG/OI when it receives allegations with one or more of the following characteristics:

- Indications of PSC, AC, or Medicare contractor employee fraud.
- Cases involving an informant that is an employee or former employee of the suspect physician or supplier.
- Involvement of providers who have prior convictions for defrauding Medicare or who are currently the subject of an OIG fraud investigation.
- Situations involving the subjects of current program investigations.
- Multiple carriers involved with any one provider (OIFO coordinates activities with all involved carriers).
- Cases with, or likely to get, widespread publicity or involving sensitive issues.
- Allegations of kickbacks or bribes or a crime by a federal employee.
- Indications that organized crime may be involved.
- Indications of fraud by a third-party insurer that is primary to Medicare.

PSCs and Medicare contractor BI units *shall* not expend resources attempting to investigate the allegation until so directed by CMS and/or the OIG. For example, if a PSC or Medicare contractor BI unit receives an allegation of kickbacks, the PSC or Medicare contractor BI unit *shall* immediately advise *in writing* the OIG of the allegation, but *shall* not initiate an independent PSC or Medicare contractor BI unit query until requested to do so by the OIG and guidance on the parameters of the query are provided by the OIG.

When an "immediate advisement" is required, all available *documentation received with the allegation shall* be forwarded, unless otherwise directed by OIG. However, the initial forwarding of the applicable information does not equate to the PSC or Medicare contractor BI unit completing the full referral package as defined in the PIM (see PIM Exhibit 16.1), *and does not equate to a case referral to law enforcement.*

Refer to the FID section of the PIM for entering immediate advisements into the FID.

4.18.1.3 - Program Safeguard Contractor and Medicare Contractor *BI Unit* Actions When Cases Are Referred to and Accepted by OIG/OI

(Rev. 71, 04-09-04)

Even though OIG/OI or another law enforcement agency has accepted a case, it is incumbent on the *PSC or Medicare* contractor *BI unit* to continue to monitor and document the suspect provider's activities. Additional complaints or other information received *shall* be immediately forwarded to the appropriate agency. Also, *PSCs and Medicare* contractor *BI units* may still *initiate* action to suspend payments, deny payments, or to recoup overpayments.

4.18.1.3.1 - Suspension

(Rev. 71, 04-09-04)

If payment has not been suspended before OIG/OI accepts a case, *PSCs and Medicare* contractor *BI units shall* discuss suspending payments with OIG/OI where there is reliable and substantive evidence that overpayments have been made and are likely to continue. Where OIG/OI disagrees with the suspension on the grounds that it will undermine their law enforcement action and there is disagreement, *PSCs and Medicare* contractor *BI units shall* discuss the matter with *their designated SME or* RO. The *SME or* RO will then decide, after consulting with OIG/OI, whether the *PSC or Medicare* contractor *BI unit* should proceed with the suspension. Suspension of payment should not be delayed in order to increase an overpayment amount in an effort to make the case more attractive to law enforcement.

Continuing to pay claims submitted by a suspect provider for this purpose is not an acceptable reason for not suspending payment.

A - Record of Suspended Payments Regarding Providers Involved in Litigation

PSCs or Medicare contractor *BI units shall* provide OIG/OI with current information, as requested, regarding total payments due providers on monies that are being withheld because those cases are being referred for fraud prosecution. (The OIG/OI sends notification of which potential fraud cases have been referred for prosecution.) These monies represent potential assets, against which offset is made to settle overpayments or to satisfy penalties in any civil action brought by the government. The total amount of withheld payments is also pertinent to any determination by the DOJ whether civil fraud prosecution action is pursued or a negotiated settlement attempted.

4.18.1.3.2 - Denial of Payments for Cases Referred to and Accepted by OIG/OI

(Rev. 71, 04-09-04)

Where it is clear that the provider has not furnished the item or services, denial is the appropriate action. (See PIM Exhibit 14.) Before *recommending* denying payments, *PSCs consult with their GTL, Co-GTL and SME, and Medicare* contractor *BI units* consult with their RO.

4.18.1.3.3 - Recoupment of Overpayments

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* seek to *initiate recoupment of* overpayments whenever there is a determination that Medicare has erroneously paid. Once an overpayment has been determined, the statute and regulations require that the overpayment be recovered, especially if the overpayment is not related to the matter that was referred to law enforcement (see PIM Chapter 3, *§3.8ff*). *Upon transition of BI work to a PSC, the AC shall perform recoupment of all overpayments including sending the demand letter.*

4.18.1.4 - OIG/OI Case Summary and Referral

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units* should use the following format when preparing summaries for referral to OIG/OI *including* where additional *civil,* criminal, Civil Monetary Penalty Law (CMPL), or sanctions action appears appropriate. They *shall forward two copies of the referral and fact sheet to the OIG, and shall* retain a copy of the summary in the case file.

A Case Referral Fact Sheet Format can be found in PIM Exhibit 16.1.

A Case Summary Format can be found in PIM Exhibit 16.2.

4.18.1.5 - Actions to be Taken When *a* Fraud Case is Refused by OIG/OI

(Rev. 71, 04-09-04)

4.18.1.5.1 - Continue to Monitor Provider and Document Case File

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* not close a case simply because it is not accepted by OIG/OI. Since the subject is likely to continue to demonstrate a pattern of fraudulent activity, they *shall* continue to monitor the situation and to document the file, noting all instances of suspected fraudulent activity, complaints received, actions taken, etc. This will strengthen the case if it is necessary to take further administrative action or there is a wish to resubmit the case to OIG/OI at a later date. If *PSCs and Medicare* contractor *BI units* do resubmit the case to OIG/OI, they *shall* highlight the additional information collected and the increased amount of money involved.

4.18.1.5.2 - Take Administrative Action on Cases Referred to and Refused by OIG/OI

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units* take immediate action to implement appropriate administrative remedies, including the suspension or denial of payments, and the recovery of overpayments (see PIM Chapter 3, §3.8ff). Because the case has been rejected by law enforcement, *PSCs shall* consult with the *GTL, Co-GTL, and SME and Medicare contractor BI units shall consult with their* RO concerning the imposition of suspension. They pursue administrative and/or civil sanctions by OIG where law enforcement has declined a case.

A - Denial/Referral Action for Erroneous Payment(s), Cases Not Meeting the Referral Threshold

Many instances of erroneous payments cannot be attributed to fraudulent intent. There will also be cases where there is apparent fraud, but the case has been refused by law enforcement. Where there is a single claim, deny the claim and collect the overpayment. Where there are multiple instances, deny the claims, collect the overpayment, and warn the provider. *PSCs and Medicare* contractor *BI units shall* refer the provider, as appropriate, to provider relations, medical review, audit, etc.

4.18.1.5.3 - Refer to Other Law Enforcement Agencies

(Rev. 71, 04-09-04)

If the OIG/OI declines a case that the *PSC or Medicare* contractor *BI unit* believes has merit, the *PSC or Medicare* contractor *BI unit* may refer the case to other law enforcement agencies, such as the FBI, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), RRB/OIG, and/or the MFCU.

PSCs and Medicare contractor *BI units should* recommend administrative and/or civil sanctions *(including exclusions) to the* OIG where law enforcement has declined the case.

4.18.2 - Referral to State Agencies or Other Organizations

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* refer instances of apparent unethical or improper practices or unprofessional conduct to state licensing authorities, medical boards, the *QIO*, or professional societies for review and possible disciplinary action. If a case requires immediate attention, they *shall* refer it directly to the state licensing agency or medical society and send a copy of the referral to the *QIO*.

Some state agencies may have authority to terminate, sanction, or prosecute under state law. It may be appropriate to refer providers to the state licensing agency, to the MFCU, or to another administrative agency that is willing and able to sanction providers that either bill improperly or mistreat their patients (see PIM *Chapter 4, §4.18.1.5.3 and §4.19ff*). This option is strongly recommended in instances where federal law enforcement is not interested in the case.

In each state there is a Medicare survey and certification agency. It is typically within the Department of Health. The survey agency has a contract with *CMS* to survey and certify institutional providers as meeting or not meeting applicable Medicare health and safety requirements, called Conditions of Participation. Providers not meeting these requirements are subject to a variety of adverse actions, ranging from bans on new admissions to termination of their provider agreements. These administrative sanctions are imposed by the RO, typically after an onsite survey by the survey agency.

Ordinarily, *PSCs and Medicare* contractor *BI units* do not refer isolated instances of questionable professional conduct to medical or other professional societies and state licensing boards. However, in flagrant cases, or where there is a pattern of questionable practices, a referral is warranted. The MR and *BI* units *shall* confer before such referrals, to avoid duplicate referrals. There is no need to compile sufficient weight of evidence so that a conclusive determination of misconduct is made prior to the referral. Rather, *PSCs and Medicare* contractor *BI units* ascertain the probability of misconduct, gather available information, and leave any further investigation, review, and disciplinary action to the appropriate professional society or state board. Consultation and agreement between the MR and *BI* unit *shall* precede any referral to these agencies.

The *PSC shall work closely with their GTLs, Co-GTLs, and SMEs, and Medicare contractor BI* units *shall* work closely with their RO *BI* coordinator on these referrals. The *BI* coordinator *shall* involve the necessary staff in *CMS*.

Concurrently, *PSCs or Medicare* contractor *BI units shall* notify OIG/OI of any referral to medical or other professional societies and state licensing boards in cases involving unethical or unprofessional conduct. They *shall* include with the notification to OIG/OI copies of all materials referred to the society or board. *PSCs or Medicare* contractor *BI units shall* send OIG/OI and the MFIS*/PSC network* a follow-up report on significant

developments. They *shall* notify OIG/OI about possible abuse situations when it appears that a harmful medical practice or a sanctionable practice is occurring or has occurred.

Notice of suspension should also be given to the Medicaid SURs since a significant percent of Medicare beneficiaries are eligible for both Medicare and Medicaid and Medicaid is paying co-payments

4.18.3 - Referral to *Quality Improvement Organizations*

(Rev. 71, 04-09-04)

Communication with the *QIO* is essential to discuss the potential impact of efforts to prevent abuse as well as efforts to ensure quality and access. More specifically, *CMS* expects dialogue between *PSCs* and the *QIO* to:

- Ensure that an LMRP does not set up obstacles to appropriate care
- Articulate the program safeguard concerns or issues related to *QIO* activities
- Be aware of *QIO* initiatives (e.g., a *QIO* project to encourage Medicare beneficiaries to get eye exams), so they do not observe an increase in utilization and label it overutilization

PSCs should continue exchanging additional information such as data analysis methods, data presentation methods, and successful ways to interact with providers to change behavior. This includes special projects that *PSCs* and the *QIO* have determined to be mutually beneficial.

It is essential that the *PSC* manager maintain an ongoing dialogue with his/her counterpart(s) at other *PSCs,* particularly in contiguous states. This ensures that a comprehensive investigation is initiated in a timely manner and prevents possible duplication of investigation efforts.

PSCs should maintain an ongoing dialogue with the *QIOs*. Intermediaries may make referrals to the *QIO* for review of inpatient claims when outpatient claims reveal a problem provider. If the *PSC* refers a provider to the state licensing agency or medical society, i.e., those referrals that need immediate response from the state licensing agency, it should also send a copy of the referral to the *QIO*. Also, *PSCs shall* notify the *QIO on utilization and quality issues for* Part A providers and physicians that are suspected of fraud and of referrals to OIG/OI.

The PSC shall coordinate the review of Part A acute care inpatient hospital claims for benefit integrity purposes with the QIO. The PSC shall follow the definition of acute care inpatient prospective payment system (PPS) hospital found in PIM Chapter 1, §1.1.2 (http://www.cms.gov/manuals/108_pim/pim83c01.pdf). If the PSC investigation indicates

a need to review Part A acute care inpatient PPS hospital medical records, the PSC shall request the medical records directly from the provider and have them sent directly to the PSC. Upon receipt of the records, the PSC shall perform a billing and document review of the medical record. The PSC shall also review the medical records for medical necessity, as well as, any indications of potential fraud and abuse. The PSC shall not initiate any payment determination, provider education, overpayment calculation, or overpayment request based on these medical records. QIOs will conduct or initiate these activities as appropriate.

Following PSC review of the Part A acute care inpatient PPS hospital claims and medical records, if the PSC determines that no potential fraud and abuse has been committed, or if the PSC determines that potential fraud and abuse is likely but law enforcement rejects the case, the PSC shall refer the provider and medical records back to the QIO for further medical review, provider education, or the initiation of overpayment calculation, payment determination, and overpayment request.

If after the PSC reviews the Part A acute care inpatient PPS hospital claims and medical records, the PSC determines that potential fraud and abuse is likely, the PSC shall coordinate the case with law enforcement (per Law Enforcement Memorandum of Understanding). If law enforcement accepts the case, law enforcement may then coordinate directly with the QIO for any further medical review.

The PSC shall not involve the QIO in reviews at other types of hospitals.

4.19 - Administrative Sanctions

(Rev. 71, 04-09-04)

The term "sanctions" represents the full range of administrative remedies and actions available to deal with questionable, improper, or abusive practices of practitioners, providers, and suppliers under the Medicare and Medicaid programs or any state health care programs as defined under §1128(h) of the Act. There are two purposes for these sanctions. First, they are designed to be remedial, to ensure that questionable, improper, or abusive practices are dealt with appropriately. Practitioners, providers, and suppliers are encouraged to correct their behavior and operate in accordance with program policies and procedures. Second, the sanctions are designed to protect the programs by ensuring that improper payments are identified and recovered and that future improper payments are not made.

The primary focus of this section is sanctions authorized in §1128 *and §1128A* of the Act (exclusions *and CMPs*). Other, less severe administrative remedies may precede the more punitive sanctions affecting participation in the programs. The corrective actions *PSCs, ACs, and Medicare* contractors *shall* initially consider are:

- Provider education and warnings

- Revocation of assignment privileges
- *Suspension* of payments *(refer to PIM Chapter 3, §3.9ff)*
- Recovery of overpayments *(refer to PIM Chapter 3, §3.8ff)*
- Referral of situations to state licensing boards or medical/professional societies

4.19.1 - The Program Safeguard Contractor's, *AC's,* and *Medicare* Contractor's Role

(Rev. 71, 04-09-04)

The AC shall be responsible for:

- Ensuring that no payments are made to provider/suppliers for a salaried individual who is excluded from the program. OIG, as it becomes aware of such employment situations, notifies providers that payment for services furnished to Medicare patients by the individual is prohibited and that any costs (salary, fringe benefits, etc.) submitted to Medicare for services furnished by the individual will not be paid. A copy of this notice is sent to the *PSC or Medicare* contractor *BI unit* and to the appropriate CMS RO.

The PSC and the AC shall work out the following in their JOA, and the Medicare contractor BI unit shall work out the following with the appropriate Medicare contractor unit(s):

- Furnishing any available information to the OIG/OI with respect to providers/suppliers requesting reinstatement.
- Reporting all instances where an excluded provider/supplier submits claims for which payment may not be made after the effective date of the exclusion.

The *PSC or Medicare* contractor *BI unit shall also be* responsible for:

- Contacting OIG/OI when it determines that an administrative sanction against an abusive provider/supplier is appropriate.
- Providing OIG/OI with appropriate documentation in proposed administrative sanction cases.
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4.19.2 - Authority to Exclude Practitioners, Providers, and Suppliers of Services

(Rev. 71, 04-09-04)

Section 1128 of the Act provides the Secretary of DHHS the authority to exclude various health care providers, individuals, and businesses from receiving payment for services that would otherwise be payable under Medicare, Medicaid, *and all federal health care programs.* This authority has been delegated to the OIG.

When an exclusion is imposed, no payment is made to anyone for any items or services *in any capacity* (other than an emergency item or service provided by an individual who does not routinely provide emergency health care items or services) furnished, ordered, or prescribed by an excluded party under the Medicare, Medicaid, *and all federal health care programs*. In addition, no payment is made to any business or facility, e.g., a hospital, that submits claims for payment of items or services provided, ordered, prescribed, or referred by an excluded party.

OIG also has the authority under §1128(b)(6) of the Act to exclude from coverage items and services furnished by practitioners, providers, or other suppliers of health care services who have engaged in certain forms of program abuse *and quality of care issues. In order to prove such cases, the PSC or Medicare contractor BI unit shall document a long-standing pattern of care where educational contacts have failed to change the abusive pattern. Isolated instances and statistical samples are not actionable. Medical doctors must be willing to testify.*

Authority under §1156 of the Act is delegated to OIG to exclude practitioners and other persons who have been determined by a *QIO* to have violated their obligations under §1156 of the Act. To exclude, the violation of obligation under §1156 of the Act must be a substantial violation in a substantial number of cases or a gross and flagrant violation in one or more instances. Payment is not made for items and services furnished by an excluded practitioner or other person. Section 1156 of the Act also contains the authority to impose a monetary penalty in lieu of exclusion. Section 1156 exclusion actions and monetary penalties are submitted by *QIOs* to the OIG/OI.

Payment is not made for items and services furnished by an excluded practitioner or other person.

4.19.2.1 - Basis for Exclusion Under §1128(b)(6) of the Social Security Act

(Rev. 71, 04-09-04)

Exclusions under §1128(b)(6) of the Act are effected upon a determination that a provider has done one of the following:

- Submitted or caused to be submitted claims or requests for payment under Medicare or a state health care program containing charges (or costs) for items or services furnished substantially in excess of its usual charges (or costs).

- Furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under Medicare or under a state health care program) substantially in excess of the needs of such patients or of a quality that does not meet professionally recognized standards of health care.

For purposes of the exclusion procedures, "furnished" refers to items or services provided *or supplied, directly or indirectly, by any individual or entity. This includes items or services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.*

4.19.2.2 - Identification of Potential Exclusion Cases

(Rev. 71, 04-09-04)

The *PSC or Medicare contractor BI* unit *shall* review and evaluate abuse cases to determine if they warrant exclusion action. Examples of abuse cases suitable for exclusion include, but are not limited to:

- Providers who have been the subject of an adverse *QIO* finding.

- Providers whose claims must be reviewed continually because of repeated instances of overutilization.

- Providers who have been the subject of previous cases that were not accepted for prosecution because of the low dollar value, or who were the subject of previous cases that were settled without exclusion.

- Providers who furnish or cause to be furnished items or services that are substantially in excess of the patient's needs or are of a quality that does not meet professionally recognized standards of health care (whether or not eligible for benefits under Medicare, Medicaid, title V or title XX).

- Providers who are the subject of prepayment review for an extended period of time (longer than 6 months) who have not corrected their pattern of practice after receiving educational/warning letters.

- *Providers who have been convicted of a program related offense (§1128(a) of the Social Security Act).*

- *Providers who have been convicted of a non-program related offense (e.g., a conviction related to neglect or abuse of a patient, or related to a controlled substance) (§1128(a) of the Social Security Act).*

Also, §1833(a)(1)(D) of the Act provides that payment for clinical diagnostic laboratory tests is made on the basis of the lower of the fee schedule or the amount of charges billed for such tests. Laboratories are subject to exclusion from the Medicare program under §1128(b)(6)(A) of the Act where the charges made to Medicare are substantially in excess of their customary charges to other clients. This is true regardless of the fact that the fee schedule exceeds such customary charges.

Generally, to be considered for exclusion due to abuse, the practices have to consist of a clear pattern that the provider/supplier refuses or fails to remedy in spite of efforts on the part of the *PSC, AC, Medicare* contractor, or *QIO* groups. An exclusion recommendation is implemented only where efforts to get the provider/supplier to change the pattern of practice are unsuccessful. The educational or persuasive efforts are not necessary or desirable when the issues involve life-threatening or harmful care or practice.

If a case involves the furnishing of items or services in excess of the needs of the individual or of a quality that does not meet professionally recognized standards of health care, *PSCs and Medicare* contractor *BI units shall* make every effort to obtain reports confirming the medical determination of their medical review from one or more of the following:

- The *QIO* for the area served by the provider/supplier
- State or local licensing or certification authorities
- *QIO* committees
- State or local professional societies
- Other sources deemed appropriate

4.19.2.3 - Development of Potential Exclusion Cases

(Rev. 71, 04-09-04)

A - Case Considerations

When *PSCs and Medicare* contractor *BI units* recommend cases to OIG/OI for exclusion, they *shall* consider:

- The nature and seriousness of the acts in question

- Actions taken to persuade the provider/supplier to abstain from further questionable acts

- The experience gained from monitoring payments to the provider/supplier after corrective action was taken

- The degree of deterrence that might be brought about by exclusion

- The effects of exclusion on the delivery of health care services to the community

- Any other factors deemed appropriate

In cases recommended to OIG/OI for exclusion where there has not been a conviction, *see 42 U.S.C. 1320 a-7(b).*

Documentation *for excessive services and charges shall* include the length of time that the problem existed and the dollars lost by the program. Documentation of excessive services or poor quality of care requires a medical opinion from a qualified physician *who must be willing to testify*. All cases involving excessive services or poor quality of care *shall* also contain documentation of prior unsuccessful efforts to correct the problem through the use of less serious administrative remedies.

B - Notification to Provider

If, as a result of development of potential fraud or abuse, a situation is identified that meets one or more of the criteria in PIM Chapter *4, §4.19.2.1,* PSCs and Medicare contractor *BI units shall* consult the OIG/OI*/OCIG (Office of Counsel to the Inspector General)* contact person. *The OIG prepares and sends a written notice to the provider* containing the following information:

- Identification of the provider.

- The nature of the problem.

- The health care services involved.

- The basis or evidence for the determination that a violation has occurred. In cases concerning medical services, make every effort to include reports and opinions from a *QIO* or a *QIO* committee, or a state/local professional society.

- The sanction to be recommended.

- An invitation to discuss the problem with *PSC, Medicare* contractor *BI unit,* and OIG/OI staff, or to submit written information regarding the problem.

- A statement that a recommendation for consideration of sanctions will be made to the OIG/OI within 30 days, if the problems are not satisfactorily resolved.

If the provider/supplier accepts the invitation to discuss the issues, *PSCs and Medicare* contractor *BI units shall* make a report of the meeting for the record. This does not have to be a professionally transcribed report. Copies of the letter to the provider/supplier and the provider response, or the summary of the meeting, *shall* be in the file.

PSCs and Medicare contractor *BI units shall* refer cases that demonstrate a strong fraud potential to OIG/OI for investigation.

They notify OIG/OI of any cases that reach the level where a provider/supplier is notified of a problem in accordance with this section, even if the provider is convinced that there was a legitimate reason for the problem or that the problem has been corrected. *PSCs and Medicare* contractor *BI units* do not refer these cases to OIG/OI unless requested to do so.

PSCs and Medicare contractor *BI units* document and refer cases involving harmful care as rapidly as possible. They handle OIG/OI requests for additional information as priority items.

C - Additional Information

Additional information that may be of value in supporting a proposal to exclude includes any adverse impact on beneficiaries, the amount of damages incurred by the programs, and potential program savings.

D - Mitigating Circumstances

Any significant factors that do not support a recommendation for exclusion or that tend to reduce the seriousness of the problem *may be found in 42 CFR Part 1001 and* are also considered. One of the primary factors is the impact of the sanction action on the availability of health care services in the community. *PSCs and Medicare* contractor *BI units shall* bring mitigating circumstances to the attention of OIG/OI when forwarding their sanction recommendation.

4.19.2.4 - Contents of Sanction Recommendation

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* include in the sanction recommendation (to the extent appropriate) the following information:

- Identification of the subject, including the subject's name, address, date of birth, social security number, and a brief description of the subject's special field of

medicine. If the subject is an institution or corporation, include a brief description of the type of services it provides and the names of its officers and directors.

- A brief description of how the violation was discovered.

- A description of the subject's fraudulent or abusive practices and the type of health service(s) involved.

- A case-by-case written evaluation of the care provided, prepared by the *PSC's, AC's, or Medicare* contractor's MR staff, which includes the patient's medical records. This evaluation *shall* cite what care was provided and why such care was unnecessary and/or of poor quality. (The reviewer may want to consult with someone from their RO OCSQ.) Medicare reimbursement rules *shall not be* the basis for a determination that the care was not medically necessary. The reviewer *shall* identify the specific date, place, circumstance, and any other relevant information. If possible, the reviewer should review the medical records of the care provided to the patient before and after the care being questioned.

NOTE: A minimum of 10 *examples shall* be submitted in support of a sanction recommendation under §1128(b)(6)(B). In addition, none of the services being used to support the sanction recommendations *shall* be over 2 years old.

- Documentation supporting the case referral, e.g., records reviewed, copies of any letters or reports of contact showing efforts to educate the provider, profiles of the provider who is being recommended for sanction, and relevant information provided by other program administrative entities.

- Copies of written correspondence and written summaries of the meetings held with the provider regarding the violation.

- Copies of all notices to the party.

- Information on the amount billed and paid to the provider for the 2 years prior to the referral.

- Data on program monies on an assigned/non-assigned basis for the last 2 years, if available.

- Any additional information that may be of value in supporting the proposal to exclude or that would support the action in the event of a hearing.

NOTE: All documents and medical records should be legible.

4.19.2.5 - Notice of Administrative Sanction Action

(Rev. 71, 04-09-04)

When OIG receives the sanction recommendation, it is reviewed by medical and legal staff to determine whether the anticipated sanction action is supportable.

OIG then develops a proposal and sends it to the provider, advising it of the recommended sanction period, the basis for the determination that excessive or poor-quality care has been provided, and its appeal rights. The provider is also furnished with a copy of all the material used to make the determination. This is the material that was previously forwarded to OIG with the initial sanction recommendation.

The provider has 30 days from the date on the proposal letter to submit:

- Documentary evidence and written argument against the proposed action, or
- A written request to present evidence or argument orally to an OIG official

OIG may extend the 30-day period. All additional information is reviewed by OIG, as well as by medical and/or legal personnel when necessary. In the event the provider requests an in-person review, it is conducted by OIG in *Washington, D.C.*

When a final determination is made to exclude a provider, OIG sends a written notice to the provider at least 20 days prior to the effective date of the action *(see 42 CFR §1001.2003 for exceptions to the 20 day notice)*. The notice includes:

- The basis for the exclusion.
- The duration of the exclusion and the factors considered in setting the duration.
- The earliest date on which OIG accepts a request for reinstatement, and the requirements and procedures for reinstatement.
- Appeal rights.
- A statement that, should claims continue to be submitted during the period of sanction for which payments may not be made, the provider/supplier may be *criminally prosecuted,* subject to a CMP action *and/or denied reinstatement*.

4.19.2.5.1 - Notification to Other Agencies

(Rev. 71, 04-09-04)

Concurrent with the mailing of the notice to the provider, OIG sends a notice to the state agency administering or supervising the administration of each state health care program, *the appropriate state licensing board, and CMS*. *CMS* is responsible for ensuring proper effectuation of sanction actions.

OIG also notifies the appropriate licensing agency, the public, and all known employers of the sanctioned provider.

The effective date of exclusion is 20 days from the date of the notice to the provider *(see 42 CFR §1001.2003 for exceptions to the 20 day notice)*.

4.19.2.6 - Denial of Payment to an Excluded Party

(Rev. 71, 04-09-04)

PSCs shall not recommend payments to the AC, Medicare contractor BI units shall not recommend payments to the appropriate unit within the Medicare contractor, and ACs and Medicare contractors shall not make *payment on* any excluded *individual or entity* for items or services furnished, ordered, or prescribed *in any capacity* on or after the effective date of exclusion, except in the following cases:

- For inpatient hospital services or post-hospital SNF care provided to an individual admitted to a hospital or SNF before the effective date of the exclusion, make payment, if appropriate, for up to 30 days after that date.

- For home health services provided under a plan established before the effective date of exclusion, make payment, if appropriate, for 30 days after the date on the notice.

- For emergency items and services furnished, ordered, or prescribed (other than an emergency item or service furnished, ordered, or prescribed in a hospital emergency room) payment may be made to an excluded provider on or after the effective date of exclusion.

4.19.2.6.1 - Denial of Payment to Employer of Excluded Physician

(Rev. 71, 04-09-04)

If an excluded physician is employed in a hospital setting and submits claims for which payment is prohibited, the *AC or Medicare contractor* Part B carrier surveillance process usually detects and investigates the situation.

However, in some instances an excluded physician may have a salary arrangement with a hospital or clinic, or work in group practice, and may not directly submit claims for payment. If this situation is detected, *Part B ACs or Part B Medicare contractors*:

- Contact the hospital/clinic/group practice and inform them that they are reducing the amount of their payment by the amount of federal money involved in paying the excluded physician

- Develop *and refer to the PSC or Medicare contractor BI unit as a CMP case.*

Upon referral from the AC or Medicare contractor, the PSC or Medicare contractor BI unit shall finalize the case and refer it to the OIG.

4.19.2.6.2 - Denial of Payment to Beneficiaries and Others

(Rev. 71, 04-09-04)

If claims are submitted after the effective date of the exclusion by a beneficiary for items or services furnished, ordered, or prescribed by an excluded provider *in any capacity*, *ACs or Medicare* contractors *shall*:

- Pay the first claim submitted by the beneficiary and immediately give notice of the exclusion.

- Do not pay the beneficiary for items or services provided by an excluded party more than 15 days after the date of the notice to the beneficiary or after the effective date of the exclusion, whichever is later. The regulatory time frame is 15 days; however, *CMS* allows an additional 5 days for mailing.

If claims are submitted by a laboratory or DME company for any items or services ordered by a provider *in any capacity* excluded under §1156, or any items or services ordered or prescribed by a physician excluded under §1128, *ACs or Medicare* contractors *shall* handle the claims as above.

A - Notice to Beneficiaries

To ensure that the notice to the beneficiary indicates the proper reason for denial of payment, *ACs or Medicare* contractors *shall* include the following language in the notice:

"We have received your claim for services furnished *or ordered* by _____ on _____. Effective _____, _____was excluded from receiving payment for *any* items and services furnished *in any capacity* to Medicare beneficiaries. This notice is to advise you that no payment will be made for any items or services furnished by _____ if rendered more than 20 days from the date of this notice."

B - Notice to Others

The Medicare Patient and Program Protection Act of 1987 provides that payment is denied for any items or services ordered or prescribed by a provider excluded under §§1128 or 1156. It also provides that payment cannot be denied until the supplier of the items and services has been notified of the exclusion.

If claims are submitted by a laboratory or a DME company for any items or services ordered or prescribed by a provider excluded under §§1128 or 1156, *ACs and Medicare* contractors *shall*:

- Pay the first claim submitted by the supplier and immediately give notice of the exclusion.

- Do not pay the supplier for items or services ordered or prescribed by an excluded provider *in any capacity* if such items or services were ordered or prescribed more than 20 days after the date of notice to the supplier, or after the effective date of the exclusion, whichever is later.

To ensure that the notice to the supplier indicates the proper reason for denial of payment, *ACs and Medicare* contractors *shall* include the following language in the notice:

"We have received your claim for services ordered or prescribed by _____ on _____. Effective _____, _____was excluded from receiving payment for items or services ordered or prescribed *in any capacity* for Medicare beneficiaries. This notice is to advise you that no payment will be made for any items or services ordered or prescribed by _____ if ordered or prescribed more than 20 days from the date of this notice."

4.19.3 - Appeals Process

(Rev. 71, 04-09-04)

An excluded provider may try to have the decision reversed or modified, through the appeals process. The *Departmental Appeals Board* is responsible for processing hearing requests received from sanctioned providers *except in very limited circumstances*. *Exclusions remain in effect during the appeals process (see 42 CFR §§1001.901 (false claims), 1001.951 (kickbacks), 1001.1601 (violations of the limitation on physician charges), or 1001.1701 (billing for services of assistant-at-surgery during cataract operations)).*

4.19.4 - Reinstatements

(Rev. 71, 04-09-04)

A provider may apply for reinstatement *when the basis for exclusion has been removed,* at the expiration of the sanction period, or any time thereafter. *PSCs and Medicare* contractor *BI units shall* refer all requests *they receive* for reinstatement to *the Office of Investigation of the OIG.* Also, they furnish, as requested, information regarding the subject requesting reinstatement. OIG notifies the *PSC and Medicare* contractor *BI unit in the state where the subject lives/practices* of all reinstatements.

4.19.4.1 - Monthly Notification of Sanction Actions

(Rev. 71, 04-09-04)

The Medicare Exclusion Database is a standard format, cumulative exclusion database that contains information on all exclusions and reinstatement actions in Medicare, Medicaid, and other federal health care programs. CMS receives this information from the Office of Inspector General monthly.

PSCs, ACs, and Medicare contractors *shall* use the information contained in *the MED and the GAO Debarment list* to:

- Determine whether a physician/practitioner/provider or other health care supplier who seeks approval as a provider of services in the Medicare/Medicaid programs is eligible to receive payment

- Ensure that sanctioned providers are not being inappropriately paid

The dates reflected on the *MED* are the effective dates of the exclusion. Exclusion actions are effective 20 days from the date of the notice. Reinstatements or withdrawals are effective as of the date indicated.

The *MED* shows the names of a number of individuals and entities where the sanction period has expired. These names appear on *the MED* because the individual or entity has not been granted reinstatement. Therefore, the sanction remains in effect until such time as reinstatement is granted.

PSCs, ACs, and Medicare contractor*s shall* check their systems to determine whether any physician, practitioner, provider, or other health care *worker or* supplier is being paid for items or services provided subsequent to the date they were excluded from participation in the Medicare program. In the event a situation is identified where inappropriate payment is being made, they *shall* notify OIG and take appropriate action to correct the situation. Also, *PSCs and Medicare* contractor *BI units shall* consider the instructions contained in the *CMP section of the PIM (PIM Chapter 4, §4.20ff)*.

PSCs shall work with ACs to document a process in the JOA to make the AC aware of any payments to an excluded provider.

ACs and Medicare contractors *shall* ensure that no payments are made after the effective date of a sanction, except as provided for in regulations at 42 CFR 1001.1901(c) and 489.55.

ACs and Medicare contractors *shall* check payment systems periodically to determine whether any *individual or entity* who has been excluded since January 1982 is submitting claims for which payment is prohibited. If any such claims are submitted by *any individual in any capacity or any entity* who has been sanctioned under §§1128, 1862(d), 1156, 1160(b) or 1866(b) of the Act, *PSCs and Medicare* contractor *BI units shall* forward them to OIG/OI.

Also, *ACs and Medicare contractors shall* refer to the RO all cases that involve habitual assignment violators. In cases where there is an occasional violation of assignment by a provider, they *shall* notify the provider in writing that continued violation could result in a penalty under the CMPL.

4.20 - Civil Monetary Penalties

(Rev. 71, 04-09-04)

4.*20*.1 - Background

(Rev. 71, 04-09-04)

Background includes Basis of Authority, Purpose, Administrative Actions, and Documents.

4.20.1.1 - Basis of Authority

(Rev. 71, 04-09-04)

In 1981, Congress added §1128A (42 U.S.C. 1320a-7a) to the Social Security Act to authorize the Secretary of Health and Human Services to impose civil monetary penalties (CMPs). Since the enactment of the first CMP authority in 1981, Congress has increased both the number and types of circumstances under which CMPs may be imposed. Most of the specific statutory provisions authorizing CMPs also permit the Secretary to impose an assessment in addition to the CMP. An assessment is an additional monetary payment in lieu of damages sustained by the government because of the improper claim. Also, for many statutory violations, the Secretary may exclude the individual or entity violating the statute from participating in Medicare and other federal health care programs for specified periods of time.

In October 1994, the Secretary realigned the responsibility for enforcing these CMP authorities between the Centers for Medicare & Medicaid Services and the Office of the Inspector General. CMS was delegated the responsibility for implementing CMPs that involve program compliance. The OIG was delegated the responsibility for implementing CMPs that involve threats to the integrity of the Medicare or Medicaid programs, i.e., those that involve fraud or false representations. On August 21, 1996, the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) was enacted. This law provides for higher maximum CMPs ($10,000 per false item or service on a claim or instance of non-compliance, instead of $2,000 per item or service), and higher assessments (three times the amount claimed, instead of twice the amount) for some of the violations.

4.20.1.2 - Purpose

(Rev. 71, 04-09-04)

The central purpose of the CMP process is to promote compliance with the program rules and regulations. To achieve this, CMS and its *PSCs, ACs, and Medicare* contractors *shall* enforce the regulatory standards and requirements.

ACs and Medicare contractors *shall* educate the industry and the public regarding compliance. *PSCs, ACs, and Medicare* contractors *shall* have a statutory obligation to ensure compliance with regulations. Therefore, the efforts of *ACs and Medicare* contractors to achieve compliance *shall* be directed toward promoting a clear awareness and understanding of the program through education. When these efforts for achieving voluntary compliance have failed, formal enforcement action *shall* be referred to the appropriate agency.

4.20.1.3 - Enforcement

(Rev. 71, 04-09-04)

An essential part of enforcement is that potential violations be discovered at the earliest possible time. Every alleged violation should be identified, developed, and processed in a timely manner. Delays in developing and/or processing the violations affect the program in several ways. First, such delays may permit an unsafe medical condition to prevail if prompt corrective action is not taken. Second, delays tend to improperly de-emphasize the seriousness of the violation. Lastly, delays diminish the deterrent effect.

4.20.1.4 - Administrative Actions

(Rev. 71, 04-09-04)

PSCs, ACs, and Medicare contractors shall ensure that the program rules and regulations are being appropriately followed. If violations are noted (either through internal reviews

or through a complaint process), *ACs and Medicare* contractors *shall* take the appropriate steps to inform and educate the provider of the non-compliance and encourage future compliance.

If, after a period of time, there is no significant change by the provider (the non-compliance continues), then a final warning notice of plans to propose a corrective action (such as a CMP) *shall be* issued by the *AC or Medicare* contractor. This notice *shall* be sent by certified mail (return receipt required) to ensure its receipt by the provider. The notice *shall* indicate that previous notifications sent to the provider failed to correct the problem, and that this is a final warning. Additionally, it *shall* indicate that any further continuation of the non-compliance will result in the matter being forwarded to CMS or the OIG for administrative enforcement. While not specifically assessing a monetary penalty amount, the notice *shall* indicate that this is one type of sanction that may be applied.

4.20.1.5 - Documents

(Rev. 71, 04-09-04)

Documentary evidence is extremely important in the CMP process. It is not only the evidence needed to support the administrative actions, but also a tool used for cross-referencing, verifying statements, and/or providing backup or background information.

Documentary evidence *shall* be identified, accounted for, and protected from loss, damage, or alteration. When copies of documents are made, care *shall* be taken to ensure that all copies are legible and accurate. Wherever possible, documents or copies *shall* be preserved in their original state; making marks on the face of the documents *shall be* avoided. If marks or explanations are necessary for explanation or clarification, include an additional copy of the document with marks on the copy.

4.20.2 - Civil Monetary Penalty Authorities

(Rev. 71, 04-09-04)

The following sections list the authorities under which CMS's Program Integrity Group and the OIG may impose civil money penalties, assessments, and/or exclusions for program non-compliance.

4.20.2.1 - Civil Monetary Penalties Delegated to CMS

(Rev. 71, 04-09-04)

The following is a brief description of authorities from the Social Security Act:

- Section 1806(b)(2)(B) - Any person or entity that fails to provide an itemized statement describing each item or service requested by a Medicare beneficiary.

- Section 1833(h)(5)(D) - Any person billing for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also cause an assessment and an exclusion.)

- Section 1833(i)(6) - Any person billing for an intraocular lens inserted during or after cataract surgery for which payment may be made for services in an ambulatory surgical center.

- Section 1833(q)(2)(B) - When seeking payment on an unassigned basis, any entity failing to provide information about a referring physician, including the referring physician's name and unique physician identification number. (This violation may also cause an exclusion.)

- Sections 1834(a)(11)(A) and 1842(j)(2) - Any supplier of durable medical equipment charging for covered items (furnished on a rental basis) after the rental payments may no longer be made (except for maintenance and servicing) as provided in §1834(a)(7)(A) of the Act. (This violation may also cause an assessment and an exclusion.)

- Section 1834(a)(17)(C) - Unsolicited telephone contacts by any supplier of durable medical equipment to Medicare beneficiaries regarding the furnishing of covered services. (This violation may only cause an exclusion.)

- Sections 1834(a)(18)(B) and 1842(j)(2) - Any durable medical equipment supplier that fails to make a refund to Medicare beneficiaries for a covered item for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also cause an assessment and an exclusion.)

- Sections 1834(b)(5)(C) and 1842(j)(2) - Any non-participating physician or supplier that charges a Medicare beneficiary more than the limiting charge as specified in §1834(b)(5)(B) of the Act for radiologist services. (This violation may also cause an assessment and an exclusion.)

- Sections 1834(c)(4)(C) and 1842(j)(2) - Any non-participating physician or supplier charging a Medicare beneficiary more than the limiting charge for mammography screening, as specified in §1834(c)(3) of the Act. (This violation may also cause an assessment and an exclusion.)

- Sections 1834(h)(3) and 1842(j)(2) - Any supplier of durable medical equipment, prosthetics, orthotics, and supplies charging for a covered prosthetic device, orthotic, or prosthetic (furnished on a rental basis) after the rental payment may

no longer be made (except for maintenance and servicing). (This violation may also cause an assessment and an exclusion.)

- Section 1834(h)(3) - Unsolicited telephone contacts by any supplier of durable medical equipment, prosthetics, orthotics to Medicare beneficiaries regarding the furnishing of prosthetic devices, orthotics, or prosthetics. (This violation may only cause an exclusion.)

- Section 1834(j)(2)(A)(iii) - Any durable equipment supplier that completes the medical necessity section on the certificate of medical necessity or fails to provide the fee schedule amount and the supplier's charge for the medical equipment or supply prior to distributing the certificate to the physician.

- Sections 1834(j)(4) and 1842(j)(2) - Any supplier of durable medical equipment, prosthetics, orthotics, and supplies that fails to make refunds in a timely manner to Medicare beneficiaries (for items or services billed on a non-assigned basis) if the supplier does not possess a Medicare supplier number, if the item or service is denied in advance, or if the item or service is determined not to be medically necessary or reasonable. (This violation may also cause an assessment and an exclusion.)

- Sections 1834(k)(6) and 1842(j)(2) - Any practitioner or other person that bills or collects for outpatient therapy services or comprehensive outpatient rehabilitation services on a non-assigned basis. (This violation may also cause an assessment and an exclusion.)

- Section 1842(b)(18)(B) - For practitioners specified in §1842(b)(18)(C) of the Act (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists), any practitioner billing (or collecting) for any services on a non-assigned basis. (This violation may also cause an assessment and an exclusion.)

- Section 1842(k) - Any physician presenting a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987. (This violation may also cause an assessment and an exclusion.)

- Section 1842(l)(3) - Any non-participating physician who does not accept payment on an assigned basis and who fails to refund beneficiaries for services that are not reasonable or medically necessary or are of poor quality. (This violation may also cause an assessment and an exclusion.)

- Section 1842(m)(3) - Any non-participating physician billing for an elective surgical procedure on a non-assigned basis, who charges at least $500, fails to disclose charge and coinsurance amounts to the Medicare beneficiary prior to rendering the service, and fails to refund any amount collected for the procedure

in excess of the charges recognized and approved by the Medicare program. (This violation may cause an assessment and an exclusion.)

- Section 1842(n)(3) - Any physician billing diagnostic tests in excess of the scheduled fee amount. (This violation may cause an assessment and an exclusion.)

- Section 1842(p)(3)(A) - Any physician that fails to promptly provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill submitted on a non-assigned basis.

- Section 1842(p)(3)(B) - Any physician failing to provide the diagnosis code or codes after repeatedly being notified by CMS of the obligations on any request for payment or bill submitted on a non-assigned basis. (This violation is only subject to an exclusion.)

- Section 1848(g)(1)(B) - Any non-participating physician, supplier, or other person who furnishes physicians' services and bills on a non-assigned basis, or collects in excess of the limiting charge, or fails to make an adjustment or refund to the Medicare beneficiary. (This violation may cause an assessment and an exclusion.)

- Section 1848(g)(3) - Any person billing for physicians' services on a non-assigned basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may cause an assessment and an exclusion.)

- Section 1848(g)(4) - Any physician, supplier, or other person (except one excluded from the Medicare program) that fails to submit a claim for a beneficiary within one year of providing the service; or imposes a charge for completing and submitting the standard claims form. (This violation may cause an exclusion.)

- Section 1862(b)(5)(C) - Any employer who (before October 1, 1998) fails to provide an employee's group health insurance coverage information to the Medicare contractor.

- Section 1862(b)(6)(B) - Any entity that fails to complete a claim form relating to the availability of other health benefit plans, or provides inaccurate information relating to the availability of other health plans on the claim form.

- Section 1877(g)(5) - Any person failing to report information concerning ownership, investment, and compensation arrangements. (This violation may cause an assessment and an exclusion.)

- Section 1879(h) - Any durable medical equipment supplier (including a supplier of durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies) failing to make refunds to Medicare beneficiaries for items or services billed on an assigned basis if the supplier did not possess a Medicare supplier number, if the item or service is denied in advance, or if the item or service is determined to be not medically necessary or reasonable. (This violation may cause an assessment and an exclusion.)

- Section 1882(a)(2) - Any person who issues a Medicare supplemental policy that has not been approved by the state regulatory program or does not meet federal standards. (This violation may cause an assessment and an exclusion.)

- Section 1882(p)(8) - Any person who sells or issues non-standard Medicare supplemental policies. (This violation may cause an assessment and an exclusion.)

- Section 1882(p)(9)(C) - Any person who sells a Medicare supplemental policy and fails to make available the core group of basic benefits as part of its product line; or fails to provide the individual (before the sale of the policy) an outline of coverage describing the benefits provided by the policy. (This violation may cause an assessment and an exclusion.)

- Section 1882(q)(5)(C) - Any person who fails to suspend a Medicare supplemental policy at the policyholder's request (if the policyholder applies for and is determined eligible for Medicaid); or to automatically reinstate the policy as of the date the policyholder loses medical assistance eligibility (and the policyholder provides timely notice of losing his or her Medicaid eligibility). (This violation may cause an assessment and an exclusion.)

- Section 1882(r)(6)(A) - Any person that fails to refund or credit as required by the supplemental insurance policy loss ratio requirements. (This violation may cause an assessment and an exclusion.)

- Section 1882(s)(4) - Any issuer of a Medicare supplemental policy that does not waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare policy; or denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria. (This violation may cause an assessment and an exclusion.)

- Section 1882(t)(2) - Any issuer of a Medicare supplemental policy who fails to provide medically necessary services to enrollees through the issuer's network of entities; imposes premiums on enrollees in excess of the premiums approved by the state; acts to expel an enrollee for reasons other than non-payment of premiums; does not provide each enrollee at the time of enrollment with specific information regarding policy restrictions; or fails to obtain a written

acknowledgment from the enrollee of receipt of the information. (This violation may cause an assessment and an exclusion.)

4.20.2.2 - Civil Monetary Penalties Delegated to OIG

(Rev. 71, 04-09-04)

The following is a brief description of authorities from the Social Security Act:

Section 1128(a)(1)(A), (B)	False or fraudulent claim for item or service including incorrect coding (upcoding) or medically unnecessary services.
Section 1128A(a)(1)(C)	Falsely certified specialty.
Section 1128A(a)(1)(D)	Claims presented by excluded party.
Section 1128A(a)(1)(E)	Pattern of claims for unnecessary services or supplies.
Section 1128A(a)(2)	Assignment agreement, Prospective Payment System (PPS) abuse violations.
Section 1128A(a)(3)	PPS false/misleading information influencing discharge decision.
Section 1128A(a)(4)	Excluded party retaining ownership or controlling interest in participating entity.
Section 1128A(a)(5)	Remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.
Section 1128A(a)(6)	Contracting with an excluded individual.
Section 1128A(a)(7)	Improper remuneration; i.e., kickbacks.
Section 1128A(b)	Hospital physician incentive plans.
Section 1128A(b)(3)	Physician falsely certifying medical necessity for home health benefits.
Section 1128E(b)	Failure to supply information on adverse action to the Health Integrity and Protection Data Bank (HIPDB).
Section 1140(b)(1)	Misuse of Departmental symbols/emblems.
Section 1819(b)(3)(B) Section 1919(b)(3)(B)	False statement in assessment of functional capacity of skilled nursing facility (SNF) resident.
Section 1819(g)(2)(A)	Notice to SNF/nursing facility of standard scheduled

Section 1919 (g)(2)(A)	survey.
Section 1857(g)(1)(F)	Managed care organization (MCO) fails to comply with requirements of §1852(j)(3) or §1852(k)(2)(A)(ii). (Prohibits MCO interference with the provider's advice to an enrollee; mandates that providers not affiliated with the MCO may not bill or collect in excess of the limiting charge.)
Section 1862(b)(3)(c)	Financial incentives not to enroll in a group health plan.
Section 1866(g)	Unbundling outpatient hospital costs.
Section 1867	Dumping by hospital/responsible physician of patients needing emergency medical care.
Section 1876(i)(6)(A)(i) Section 1903(m)(5)(A)(i) Section 1857(g)(1)(A)	Failure by Health Maintenance Organization (HMO)/competitive medical plan/MCO to provide necessary care affecting beneficiaries.
Section 1876(i)(6)(A)(ii) Section 1903(m)(5)(A)(ii) Section 1857(g)(1)(B)	Premiums by HMO/competitive medical plan/MCO in excess of permitted amounts.
Section 1876(i)(6)(A)(iii) Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(C)	HMO/competitive medical plan/MCO expulsion/refusal to re-enroll individual per prescribed conditions.
Section 1876(i)(6)(A)(iv) Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(D)	HMO/competitive medial plan/MCO practices to discourage enrollment of individuals.
Section 1876(i)(6)(A)(v) Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(E)	False or misrepresenting HMO/competitive medical plan/MCO information to Secretary.
Section 1876(i)(6)(A)(vi) Section 1903(m)(5)(A)(v) Section 1857(f)	Failure by HMO/competitive medical plan/MCO to assure prompt payment for Medicare risk-sharing contracts only or incentive plan provisions.
Section 1876(i)(6)(A)(vii) Section 1857(g)(1)(G)	HMO/competitive medical plan/MCO hiring/employing person excluded under §1128 or §1128A.
Section 1877(g)(3)	Ownership restrictions for billing clinical lab services.
Section 1877(g)(4)	Circumventing ownership restriction governing clinical labs and referring physicians.

Section 1882(d)(1)	Material misrepresentation referencing compliance of Medicare supplemental policies (including Medicare + Choice).
Section 1882(d)(2)	Selling Medicare supplemental policy (including Medicare + Choice) under false pretense.
Section 1882(d)(3)(A)	Selling health insurance that duplicates benefits.
Section 1882(d)(3)(B)	Selling or issuing Medicare supplemental policy (including Medicare + Choice) to a beneficiary without obtaining a written statement from beneficiary with regard to Medicaid status.
Section 1882(d)(4)(A)	Use of mailings in the sale of non-approved Medicare supplemental insurance (including Medicare + Choice).
Section 1891(c)(1)	Notifying home health agency of scheduled survey.
Section 1927(b)(3)(B)	False information on drug manufacturer survey from manufacturer/wholesaler/seller.
Section 1927(b)(3)(C)	Provision of untimely or false information by drug manufacturer with rebate agreement.
Section 1929(i)(3)	Notifying home- and community-based care providers/settings of survey.
Section 421(c) of the Health Care Quality Improvement Act (HCQIA)	Failure to report medical malpractice liability to National Practitioner Data Bank.
Section 427(b) of HCQIA	Breaching confidentiality of information report to National Practitioner Data Bank.

4.20.3 - Referral Process

(Rev. 71, 04-09-04)

4.20.3.1 - Referral Process to CMS

(Rev. 71, 04-09-04)

Compliance is promoted through both administrative and formal legal actions. Administrative compliance action *shall* first be attempted by *ACs and Medicare* contractors through education and warning letters that request the provider to comply

with Medicare's rules and regulations. If the provider fails to take corrective action and continues to remain non-compliant, the *AC shall make a referral to the PSC who shall forward it to the GTL, Co-GTL, SME, and the CMS CO Director of the Division of Benefit Integrity and Law Enforcement Liaison (see PIM Chapter 4, §4.20.3.2). The Medicare contractor shall make a referral to the Medicare contractor BI unit who* shall prepare a referral of a CMP case and *shall* forward it to its respective CMS RO component that has oversight of the Medicare Integrity Program *and CMS CO DBILEL (see PIM Chapter 4, §4.20.3.2).*

It is important for *ACs and Medicare* contractors to promote program compliance in their respective jurisdictions. The *ACs and Medicare* contractors shall ensure that all materials presented to providers through education, published bulletins, or written communication are clear and concise and accurately represent the facts of compliance versus non-compliance. Providers *shall* also be allowed the opportunity to present additional facts that may represent mitigating circumstances. *PSCs and Medicare* contractor *BI units* shall consider this information in an objective manner before proceeding with a CMP referral to CMS.

When a *PSC or Medicare* contractor *BI unit* elects to make a CMP referral to CMS, the initial referral package *shall* consist of a brief overview of the case; supportive documentation is not required at such time. The initial referral package shall consist of:

1. Identification of the provider, including the provider's name, address, date of birth, Social Security number, Medicare identification number(s), and medical specialty. If the provider is an entity, include the names of its applicable owners, officers, and directors.

2. Identification of the CMP authorities to be considered (use the authorities identified in PIM Chapter *4*, *§4.20.2.1*).

3. Identification of any applicable Medicare manual provisions.

4. A brief description of how the violations identified above were discovered, and the volume of violations identified.

5. Total overpayments due the program or the beneficiary(ies), respectively.

6. A brief chronological listing of events depicting communication (oral and written) between *the AC or Medicare* contractor and the provider.

7. A brief chronological listing of bulletins addressing the non-compliant area (starting with the bulletin released immediately prior to the first incident of non-compliance by the provider).

8. Any additional information that may be of value to support the referral.

9. The name and phone number of contacts at the *PSC or Medicare* contractor *BI unit*.

Upon receipt of the above information, CMS staff will review the materials and conduct follow-up discussions with the *PSC or Medicare* contractor *BI unit* regarding the referral. Within 90 days of receipt of the referral, CMS will notify the *PSC or Medicare* contractor *BI unit* of its decision to accept or decline the referral.

If CMS declines the referral, the *PSC or Medicare contractor shall communicate this to the AC or the appropriate Medicare contractor unit to* continue *in their* efforts to educate and promote compliance by the provider. The *PSC or Medicare* contractor *BI unit shall* also consider other (less severe) administrative remedies, which, at a minimum, may include revocation of assignment privileges, establishing prepayment or postpayment medical reviews, and referral of situations to state licensing boards or medical/professional societies, where applicable. In all situations where inappropriate Medicare payments have been identified, *ACs and Medicare* contractors shall initiate the appropriate steps for recovery.

If CMS accepts the referral, the *PSC and Medicare* contractor *BI unit* shall provide any supportive documentation that may be requested, and be able to clarify any issues regarding the data in the case file or *PSC, AC, and Medicare* contractor processes.

4.20.3.2 - Referrals to OIG

(Rev. 71, 04-09-04)

Upon discovery of any case that may implicate any of the OIG's delegated CMP authority, regardless of whether there is any other pending activity, or whether the fraud case was closed, the *PSC or Medicare* contractor *BI unit* shall contact the OIG/OI Field Office to discuss the potential case. If this contact results in a referral, the *PSC or Medicare* contractor *BI unit* shall follow the same referral format as described in PIM Chapter *4, §4.18.1.4*. If a referral is not made or a referral is declined, the *PSC or Medicare* contractor *BI unit* shall consider other administrative remedies, which, at a minimum, may include revocation of assignment privileges, establishing prepayment or postpayment medical reviews, and referral of situations to sate licensing boards or medical/professional societies, where applicable. In all situations where appropriate Medicare payments have been identified, *ACs and Medicare* contractors shall initiate the appropriate steps for recovery.

The *PSC and Medicare* contractor *BI unit* shall send to the OIG all cases, as appropriate, where an excluded provider or individual has billed or caused to be billed to the Medicare or Medicaid program for the furnishing of items or services after exclusion. Such misconduct is sanctionable under §1128A(a)(C)(1) of the Social Security Act.

The PSC or Medicare contractor BI unit shall send to CMS DBILEL all cases where the PSC or the Medicare contractor BI unit believes that misuse has occurred of the

Medicare name, symbols, emblems, or other violations as described in §1140 of the Social Security Act and in 42 CFR 1003.102(b)(7). CMS will be responsible for referring these types of cases to OIG. All such cases shall be sent to the following CMS address:

Centers for Medicare & Medicaid Services
Division of Benefit Integrity & Law Enforcement Liaison
Mail Stop C3-02-16
7500 Security Blvd
Baltimore, MD 21244

4.20.4 - CMS Generic Civil Monetary Penalties Case Contents

(Rev. 71, 04-09-04)

The following information, if available, shall be included as part of the CMP case package and made available upon request by CMS:

1. Background information:

    a. All known identification numbers (PIN, UPIN, etc.).

    b. Provider's first and last name or entity name (if subject is an entity, also include the full name of the principal operator).

    c. Provider's address (street, city, state, and zip code). If violator is an entity, identify address where principal operator personally receives his/her mail.

2. Copies of any interviews, reports, or statements obtained regarding the violation.

3. Copies of documentation supporting a confirmation of the violation.

4. Copies of all applicable correspondence between beneficiary and provider.

5. Copies of all applicable correspondence (including telephone contacts) between *the AC or Medicare* contractor and provider.

6. Copies of provider's applicable bills to beneficiaries and/or *ACs and* Medicare contractors, and associated payment histories.

7. Copies of any complaints regarding provider and disposition of the complaint.

8. Copies of all publications (e.g., bulletins, newsletters) sent to provider by the *PSC, AC, or Medicare* contractor *who* discuss the type of violation being addressed in the CMP case.

9. Copies of any monitoring reports regarding the provider.

10. Name and telephone number of *PSC or Medicare* contractor *BI unit* contact.

4.20.5 - Additional Guidance for Specific Civil Monetary Penalties

(Rev. 71, 04-09-04)

4.20.5.1 - Beneficiary Right to Itemized Statement

(Rev. 71, 04-09-04)

The following is background information for developing specific CMS CMP cases:

Effective for services or items provided on or after January 1, 1999, §4311 of the Balanced Budget Act (BBA) provides that Medicare beneficiaries have the right to request and receive an itemized statement from their health care provider of service (e.g., hospital, nursing facility, home health agency, physician, non-physician practitioner, DMEPOS supplier). Upon receipt of this request, providers have 30 days to furnish the itemized statement to the beneficiary. Health care providers who fail to provide an itemized statement may be subject to a CMP of not more than $100 for each failure to furnish the information (§1806(b)(2)(B) of the Social Security Act). An itemized statement is defined as a listing of each service(s) or item(s) provided to the beneficiary. Statements that reflect a grouping of services or items (such as a revenue code) are not considered an itemized statement.

A beneficiary who files a complaint with an *AC or Medicare* contractor regarding a provider's failure to provide an itemized statement must initially validate that his/her request was in writing (if available), and that the statutory 30-day time limit (calendar days) for receiving the information has expired. In most cases, an additional 5 calendar days should be allowed for the provider to receive the beneficiary's written request. If the beneficiary did not make his/her request in writing, inform him/her that he/she must first initiate the request to the provider in writing. It is only after this condition and the time limit condition are met that the *AC or Medicare* contractor may contact the provider.

Once the *AC or Medicare* contractor confirms that the complaint is valid, the *AC or Medicare* contractor *shall* initiate steps to assist the beneficiary in getting the provider to furnish the itemized statement. *ACs and Medicare* contractors *shall* initiate the same or similar procedures when receiving complaints regarding mandatory submission of claims (i.e., communicating with the provider about their non-compliance and the possibility of the imposition of a CMP).

If the intervention of the *AC or Medicare* contractor results in the provider furnishing an itemized statement to the beneficiary, the conditions for the statute are considered met, and a CMP case should not be developed. Should the intervention of the *AC or Medicare*

contractor prove unsuccessful, the *AC or Medicare* contractor shall *consider referral to the PSC or Medicare contractor BI unit for subsequent referral of* the potential CMP case to CMS, following the guidelines established in PIM Chapter *4, §§4.20.3.1 and 4.20.4.* There may be instances where a beneficiary receives an itemized statement and the *AC or Medicare* contractor receives the beneficiary's request (written or oral) to review discrepancies on his/her itemized statement. *ACs and Medicare* contractors *shall* follow their normal operating procedures in handling these complaints. *ACs and Medicare* contractors *shall* determine whether itemized services or items were provided, or if any other irregularity (including duplicate billing) resulted in improper Medicare payments. If so, the *AC or Medicare* contractor shall recover the improper payments.

4.20.5.2 - Medicare Limiting Charge Violations

(Rev. 71, 04-09-04)

The Omnibus Budget Reconciliation Act of 1989 (OBRA) established a limitation on actual charges (balanced billing) by non-participating physicians. (Refer to §1848(g) of the Act, and Medicare Carriers Manual §§5000ff. and 7555, respectively, for further information.)

As a result of the reduction in limiting charge monitoring activities (i.e., the discontinuance of the Limiting Charge Exception Report and the Limiting Charge Monitoring Report, the discontinuance of sending compliance monitoring letters and Refund/Adjustment Verification Forms), developing a Limiting Charge CMP case *shall* require the following additional information:

- Contact with the provider - Based on CMS instructions, *ACs and Medicare* contractors are to assist beneficiaries in obtaining overcharge refunds from the providers. This assistance reinstates the activity of sending the refund verification forms and compliance monitoring letters respective to the beneficiary(ies) who request assistance. Copies of these communications will become part of the CMP case file. Ensure that the communication includes language that reminds the provider that the limiting charge amounts for most physician fee schedule services are listed on the disclosure reports they receive in their yearly participation enrollment packages. (This constitutes "notice" of the Medicare charge limits for those services.) The provider's letter should also include information that describes "what constitutes a violation of the charge limit," and that providers are provided notification on their copy of the remittance statements when they exceed the limiting charge. Providers who elected not to receive remittance statements for non-assigned claims should be reminded that they are still bound by the limiting charge rules, and that they are required to make refunds of overcharges. It may be appropriate at this time for providers to reconsider their decision not to receive remittance forms for non-assigned claims. Providers should also be informed of what action to take in order to receive these statements.

- Limiting Charge Monitoring Reports (LCMRs) - Produce LCMRs for all limiting charge violations respective to the provider and which encompasses the last three years. *ACs and Medicare* contractors shall also identify those beneficiaries appearing on the reports who have requested assistance in obtaining a refund from their provider.

4.21 - Monitor Compliance

(Rev. 71, 04-09-04)

PSCs and Medicare contractor *BI units shall* follow-up on all incidences of documented false claims to ensure that the problem has not recurred and no longer exists. They *shall* send a letter to the provider indicating that they are monitoring their actions.

4.21.1 - Resumption of Payment to a Provider - Continued Surveillance After Detection of Fraud

(Rev. 71, 04-09-04)

After completion of the investigation and appropriate legal action, all determined overpayments are recouped by either direct refund or offset against payments being held in suspense. Once recoupment is completed, *PSCs and Medicare* contractor *BI units shall* release any suspended monies that are not needed to recoup determined overpayments and, if applicable, penalties.

PSCs and Medicare contractor *BI units shall* monitor future claims and related actions of the provider for at least 6 months, to assure the propriety of future payments. In addition to internal screening of the claims, if previous experience or future billings warrant, they *shall* periodically interview a sampling of the provider's patients to verify that billed services were actually furnished.

If, at the end of a 6-month period, there is no indication of a continuing aberrant pattern, *PSCs and Medicare* contractor *BI units shall* discontinue the monitoring.

4.22 - Discounts, Rebates, and Other Reductions in Price

(Rev. 71, 04-09-04)

A PSC or Medicare contractor that learns of a questionable discount program shall contact OIG/OI to determine how to proceed. OIG/OI may ask for immediate referral of the matter for investigation.

4.22.1 - Anti-Kickback Statute Implications

(Rev. 71, 04-09-04)

The Medicare and Medicaid anti-kickback statute provides as follows:

> Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, hospital incentive or bribe) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or a State health care program, or in return for purchasing, leasing, or ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Medicare, Medicaid or a State health program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both. 42 U.S.C. 1320a-7b(b), §1128B(b) of the Act.

Discounts, rebates, or other reductions in price may violate the anti-kickback statute because such arrangements induce the purchase of items or services payable by Medicare or Medicaid. However, some arrangements are clearly permissible if they fall within a safe harbor. One safe harbor protects certain discounting practices. For purposes of this safe harbor, a "discount" is the reduction in the amount a seller charges a buyer for a good or service based on an arms-length transaction. In addition, to be protected under the discount safe harbor, the discount must apply to the original item or service which is purchased or furnished, i.e., a discount cannot be applied to the purchase of a different good or service than the one on which the discount was earned. A "rebate" is defined as a discount that is not given at the time of sale. A buyer is the individual or entity responsible for submitting a claim for the item or service which is payable by the Medicare or Medicaid programs. A seller is the individual or entity that offers the discount.

4.22.1.1 - Marketing to Medicare Beneficiaries

(Rev. 71, 04-09-04)

This section explains marketing practices that could be in violation of the Medicare anti-kickback statute, 42 U.S.C. 1320a-7b(b). *These practices shall comply* with the Medicare anti-kickback statute and with the Office of the Inspector General's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry.

Marketing practices may influence Medicare beneficiaries who utilize medical supplies, such as blood glucose strips, on a repeated basis. Beneficiaries are advised to report any instances of fraudulent or abusive practices, such as misleading advertising and excessive

or non-requested deliveries of test strips, to their Durable Medical Equipment Regional Carriers

Advertising incentives that indicate or imply a routine waiver of coinsurance or deductibles could be in violation of 42 U.S.C. 1320a-7b(b). Routine waivers of coinsurance or deductibles are unlawful because they could result in 1) false claims, 2) violation of the anti-kickback statute, and/or 3) excessive utilization of items and services paid for by Medicare.

In addition, 42 U.S.C. 1320a-7a(a) (5) prohibits a person from offering or transferring remuneration. Remuneration is a waiver of coinsurance and deductible amounts, with exceptions for certain financial hardship waivers that are not prohibited.

Suppliers should seek legal counsel if they have any questions or concerns regarding waivers of deductibles and/or coinsurance or the propriety of marketing or advertising material.

Any supplier who routinely waives co-payments or deductibles can be criminally prosecuted and excluded from participating in federal health care programs.

4.22.2 - Cost-Based Payment (Intermediary Processing of Part A Claims): Necessary Factors for Protected Discounts

(Rev. 71, 04-09-04)

For a discount to be protected, certain factors must exist. These factors assure that the benefit of the discount or rebate will be reported and passed on to the programs. If the buyer is a Part A provider, it must fully and accurately report the discount in its cost report. The buyer may note the submitted charge for the item or service on the cost report as a "net discount." In addition, the discount must be based on purchases of goods or services bought within the same fiscal year. However, the buyer may claim the benefit of a discount in the fiscal year in which the discount is earned or in the following year. The buyer is obligated, upon request by DHHS or a state agency, to provide information given by the seller relating to the discount.

The following types of discounts may be protected if they comply with all the applicable standards in the discount safe harbor:

- Rebate check
- Credit or coupon directly redeemable from the seller
- Volume discount or rebate

The following types of discounts are not protected:

- Cash payment
- Furnishing one good or service free of charge or at a reduced charge in exchange for any agreement to buy a different good or service
- Reduction in price applicable to one payer but not to Medicare or a state health care program
- Routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary

NOTE: There is a separate safe harbor for routine waiver of co-payments for inpatient hospital services.

4.22.3 - Charge-Based Payment (Intermediary Processing of Part B Claims): Necessary Factors for Protected Discounts

(Rev. 71, 04-09-04)

For a discount program to be protected for Part B billing, certain factors *shall* exist. These factors assure that the benefit of the discount or other reduction in price is reported and passed on to the Medicare or Medicaid programs. A rebate rendered after the time of sale is not protected under any circumstances. The discount must be made at the time of sale of the good or service. In other words, rebates are not permitted for items or services if payable on the basis of charges. The discount must be offered for the same item or service that is being purchased or furnished. The discount must be clearly and accurately reported on the claim form.

Credit or coupon discounts directly redeemable from the seller may be protected if they comply with all the applicable standards in the discount safe harbor.

The following types of discounts are not protected:

- Rebates offered to beneficiaries
- Cash payment
- Furnishing an item or service free of charge or at a reduced charge in exchange for any agreement to buy a different item or service
- Reduction in price applicable to one payer but not to Medicare or a state health care program
- Routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary

NOTE: There is a separate safe harbor for routine waiver of co-payments for inpatient hospital services.

4.22.4 - Risk-Based Provider Payment: Necessary Factors for Protected Discounts

(Rev. 71, 04-09-04)

If the buyer is a health maintenance organization or a competitive medical plan acting in accordance with a risk contract or under another state health care program, it need not report the discount, except as otherwise required under the risk contract.

4.23 - Hospital Incentives

(Rev. 71, 04-09-04)

As many hospitals have become more aggressive in their attempts to recruit and retain physicians and increase patient referrals, physician incentives (sometimes referred to as "practice enhancements") are becoming increasingly common. Some physicians actively solicit such incentives. These incentives may result in reductions in the physician's professional expenses or an increase in their revenues. In exchange, the physician is aware that he or she is often expected to refer the majority, if not all, of his or her patients to the hospital providing the incentives.

OIG has become aware of a variety of hospital incentive programs used to compensate physicians (directly or indirectly) for referring patients to the hospital. These arrangements are prohibited by the anti-kickback statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid.

These incentive programs can interfere with the physician's judgment of what is the most appropriate care for a patient. They can inflate costs to the Medicare program by causing physicians to inappropriately overuse the services of a particular hospital. The incentives may result in the delivery of inappropriate care to Medicare beneficiaries and Medicaid recipients by inducing the physician to refer patients to the hospital providing financial incentives rather than to another hospital (or non-acute care facility) offering the best or most appropriate care for that patient. Indicators of potentially unlawful activity include:

- Payment of any sort by the hospital each time a physician refers a patient to the hospital.

- The use of free or significantly discounted office space or equipment (in facilities usually located close to the hospital).

- Provision of free or significantly discounted billing, nursing, or other staff services.

- Free training for a physician's office staff in areas such as management techniques, CPT coding, and laboratory techniques.

- Guarantees which provide that, if the physician's income fails to reach a predetermined level, the hospital supplements the remainder up to a certain amount.

- Low-interest or interest-free loans, or loans that may be "forgiven" if a physician refers patients (or some number of patients) to the hospital.

- Payment of the cost of a physician's travel and expenses for conferences.

- Payment for a physician's continuing education courses.

- Coverage on hospital's group health insurance plans at an inappropriately low cost to the physician.

- Payment for services (which may include consultations at the hospital) that require few, if any, substantive duties by the physician, or payment for services in excess of the fair market value of services furnished.

When *PSCs and Medicare* contractor *BI units* learn of a questionable hospital incentive program, the matter *shall* be referred to OIG/OI.

PSCs and Medicare contractor *BI units shall* not provide, in writing or orally, an opinion on whether or not a particular business arrangement is in violation of the kickback law.

4.24 - Breaches of Assignment Agreement by Physician or Other Supplier

(Rev. 71, 04-09-04)

A - Criminal Penalty

The law provides that any person who accepts an assignment of benefits under Medicare, and who "knowingly, willfully, and repeatedly" violates the assignment agreement, shall be guilty of a misdemeanor and subject to a fine of not more than $2,000, or imprisonment of not more than 6 months, or both.

B - Administrative Sanction

CMS may revoke the right of a physician (or other supplier, or the qualified reassignee of a physician or other supplier) to receive assigned benefits, if the physician (or other party) who has been notified of the impropriety of the practice:

- Collects or attempts to collect more than the Medicare-allowed charge as determined for covered services after accepting assignment of benefits for such items or services, or

- Fails to stop collection efforts already begun or to refund monies incorrectly collected.

C - Civil Monetary Penalties

The statute provides for CMPs of up to $2,000 per item or service claimed against any person who violates an assignment agreement.

D - Action by *ACs or Medicare* Contractor*s* on Receipt of Initial Complaint

Upon receipt of the initial assignment agreement violation complaint or complaints against a physician, *ACs and Medicare* contractors *shall* develop the facts to ascertain whether the allegation is valid, regardless of whether the complaint is referred from an SSA FO, an OIFO, a beneficiary, or the RO.

If a violation has occurred, the *AC or Medicare* contractor *shall* contact the physician in person, by phone, or by mail to explain the obligations assumed in accepting assignment and to obtain his/her assurance that improperly collected monies are being refunded and that further billings in violation of the assignment agreement will cease. *The AC or Medicare* contractor *shall* inform the physician of the possible criminal penalty discussed in subsection A (above), the possible administrative sanction (i.e., revocation of the assignment privilege) discussed in subsection B, and the possible CMPs discussed in subsection C. The dates and other particulars of the contact with the physician *shall* be recorded.

The AC or Medicare contractor *shall* supplement any personal or phone contact with a letter to the physician explaining his/her assignment obligations and the possible sanctions. The *AC or Medicare* contractor *shall* close the case with that letter if the physician response is satisfactory.

A satisfactory response *shall* include*, at a minimum,* the following:

- The physician acknowledges the obligations of the assignment agreement and agrees:

- To make any necessary refund
- To credit the refund due against other amounts owed, and
- To stop further incorrect billing and to refund or credit any amount due the complainant as verified by the *AC or Medicare* contractor.

If the physician response is unsatisfactory, the AC *or Medicare* contractor *shall* refer the case to the *PSC or* the *Medicare contractor* BI unit for further action. The action taken by the *PSC or Medicare contractor* BI unit depends on the circumstances. If the physician persists in billing the patient for the charges that gave rise to the complaint or fails to make any refund due, the *PSC or Medicare contractor* BI unit *shall* complete the SSA-2808 (see PIM Chapter *4, §4.24H*) and *shall* refer the case to the RO for initiation of steps to revoke the physician's assignment privilege. However, the RO may find it desirable to give the physician further written warning before undertaking such action.

If the physician, after having been warned, has violated his/her assignment agreement in connection with additional claims, see Section E, below.

E - Action by *Program Safeguard Contractor or Medicare Contractor* Benefit Integrity Unit When Violations Occur After Warning

Upon receipt of a new assignment violation complaint(s) after a physician has been given the warning described in subsection D, the *PSC or Medicare* contractor *BI unit shall* develop the facts and *shall* refer the case to the RO with a report, regardless of whether the complaint is referred from an SSA FO, OIFO, or RO. *PSCs or Medicare* contractor *BI units* may wish to substitute an oral report to the RO in situations where the *PSC or Medicare* contractor *BI unit* has resolved the repeat violation. The RO considers whether to initiate action to revoke the physician's assignment privilege.

F - Procedure for Revoking Assignment Privilege

The RO may revoke assignment privileges when prosecution is inappropriate or not feasible. The RO notifies the physician of the proposed revocation of his right to receive assigned benefits and gives him/her 15 days to submit a statement, including any pertinent evidence, explaining why his/her right to payment should not be revoked. After the statement is received, or the 15-day period expires without the filing of the statement, the RO determines whether to revoke the physician's right to receive payment. If the determination is to revoke the physician's right to receive payment, the RO notifies the *AC or Medicare* contractor to suspend payment on all assigned claims received after the effective date of the revocation. The RO also notifies the physician of the revocation, and of his/her right to request a formal hearing on the revocation within 60 days. (The RO may extend the period for requesting a hearing.)

If the physician requests a formal hearing (to be conducted by a member of the Hearing Staff of the Office of Budget and Administration, CMS) and the hearing officer reverses

the revocation determination, the RO instructs *the AC or Medicare* contractor to pay the physician's claims.

If the hearing officer upholds the revocation determination, or if no request for a hearing is filed during the period allowed, the RO instructs *the AC or Medicare* contractor to make any payments otherwise due the physician to the beneficiary who received the services or to another person or organization authorized under the law and regulations to receive the payments. (See Medicare Carrier Manual §7050ff for payment to a representative payee or legal representative.) If the beneficiary is deceased, *ACs or Medicare* contractors *shall* make payment in accordance with the requirements of Medicare Carrier Manual §§7200ff to the person who paid the claim, to the legal representative of the beneficiary's estate, or to his/her survivors. (*ACs or Medicare* contractors *shall* not make payment to the physician.) The revocation remains in effect until the RO finds that the reason for the revocation has been removed and there is reasonable assurance that it will not recur. The RO's decision to continue the revocation is not appealable.

When the right of a person or organization to receive assigned payment is revoked, the revocation applies to any benefits payable to that person or organization throughout the country. The RO is responsible for notifying those *ACs or Medicare* contractors who are likely to receive claims.

See Medicare Carrier Manual §3060.9B for the effect of revocation of a physician's or other person's assignment privileges on the right of a hospital or other entity to accept assignment for his/her services. This section also contains information concerning the effect of revocation of a hospital's or other entity's assignment privileges on the right of a physician or other person for whom it has been billing to bill for his/her own services.

G - Other Considerations

Because of the government's responsibility to prosecute persons who repeatedly violate the assignment agreement, effective monitoring of such offenses is very important. The factors involved in each case may vary, and *PSCs and Medicare* contractor *BI units shall* discuss with the RO, OIFO as appropriate, any situation where the *PSCs and Medicare* contractor *BI units* believe that legal or administrative action is necessary. In addition, *PSCs and Medicare* contractor *BI units shall* utilize the specific control measures and referral procedures in accordance with RO/OIG-OI direction. The RO may review the *AC's or Medicare* contractor's actions to assure that assignment violations are being properly tracked and reported.

ACs and Medicare contractors *shall* notify physicians and other suppliers of the implications of §1842(b)(3)(ii) of the Act, since the penalties for violations of the assignment agreement are significant. *ACs and Medicare* contractors *shall* use the language contained in these letters, or similar language, when contacting providers regarding assignment violation. *ACs and Medicare* contractors *shall* ensure that all physicians are made aware of the penalties that can be imposed. This deters assignment

violations and works against a defense by physicians that they had no knowledge of these laws.

H - Form for Reporting Assignment Agreement Violations

Form SSA-2808, Notice of Reported Assignment Agreement Violation, is specifically designed for SSA FOs and *ACs and Medicare* contractors to use in handling assignment agreement violations. SSA FOs use this form for referral and control of complaints. *ACs and Medicare* contractors use it to report action on complaints.

SSA FOs are responsible for completing sections one and two completely and clearly. They are to forward the original plus one copy and a second copy is to be sent to the servicing RO. A third copy is kept by the SSA FO for control and follow-up purposes. A fourth copy is sent to the appropriate RO for informational purposes.

In the event that there is an undue delay (in excess of 45 days) by the *AC or Medicare* contractor in processing complaints, the SSA FO sends periodic interim reports (monthly) to beneficiaries/complainants informing them that as soon as action is taken, notification will be sent to them. This action precludes excessive inquiries to the *AC or Medicare* contractor. If an SSA FO wishes to determine the status of the complaint, it contacts the RO.

ACs or Medicare contractors *shall* complete §3 of the SSA-2808 and forward a copy to the RO when appropriate action is completed. The RO notifies the originating SSA FO of the action taken.

4.25 - Participation Agreement and Limiting Charge Violations

(Rev. 71, 04-09-04)

Section 2306 of the Deficit Reduction Act of 1984 established a physician/supplier participation program. The Omnibus Budget Reconciliation Act of l989 established a limitation on actual charges by non-participating physicians (see §1848(g) of the Act). Participating physicians/suppliers who violate their participation agreements, and non-participating physicians who knowingly, willfully, and repeatedly increase their charges to Medicare beneficiaries beyond the limits, are liable for action in the form of CMPs, assessments, and exclusion from the Medicare program for up to 5 years, or both. Criminal penalties also apply to serious violations of the participation agreement provisions.

For further discussion of the participation agreement and limiting charge provisions, see Medicare Carrier Manual §§5000ff. and 7555, respectively.

4.26 – Supplier Proof of Delivery Documentation Requirements

(Rev. 71, 04-09-04)

Suppliers are required to maintain proof of delivery documentation in their files. Documentation must be maintained in the supplier's files for 7 years.

Proof of delivery is required in order to verify that the beneficiary received the DMEPOS. Proof of delivery is one of the supplier standards as noted in 42 CFR, 424.57(12). Proof of delivery documentation must be made available to the DMERC upon request. For any services, which do not have proof of delivery from the supplier, such claimed items and services shall be denied and overpayments recovered. Suppliers who consistently do not provide documentation to support their services may be referred to the OIG for investigation and/or imposition of sanctions.

4.26.1 - Proof of Delivery and Delivery Methods

(Rev. 71, 04-09-04)

For the purpose of the delivery methods noted below, ***designee*** *is defined as:*

"Any person who can sign and accept the delivery of durable medical equipment on behalf of the beneficiary."

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The relationship of the designee to the beneficiary should be noted on the delivery slip obtained by the supplier (i.e., spouse, neighbor, etc.). The signature of the designee should be legible. If the signature of the designee is not legible, the supplier/shipping service should note the name of the designee on the delivery slip.

Suppliers may deliver directly to the beneficiary or the designee. An example of proof of delivery to a beneficiary is having a signed delivery slip, and it is recommended that the delivery slip include: 1) The patient's name; 2) The quantity delivered; 3) A detailed description of the item being delivered; 4) The brand name; and 5) The serial number. The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply shall be the date of service on the claim.

If the supplier utilizes a shipping service or mail order, an example of proof of delivery would include the service's tracking slip, and the supplier's own shipping invoice. If possible, the supplier's records should also include the delivery service's package identification number for that package sent to the beneficiary. The shipping service's

tracking slip should reference each individual package, the delivery address, the corresponding package identification number given by the shipping service, and if possible, the date delivered. If a supplier utilizes a shipping service or mail order, suppliers shall use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a form of proof of delivery. The descriptive information concerning the DMEPOS item (i.e., the patient's name, the quantity, detailed description, brand name, and serial number) as well as the required signatures from either the beneficiary or the beneficiary's designee should be included on this invoice as well.

For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill. This shall be done to ensure that the refilled item is necessary and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DMERCs shall allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.

For those patients that are residents of a nursing facility, upon request from the DMERC, suppliers should obtain copies of the necessary documentation from the nursing facility to document proof of delivery or usage by the beneficiary (e.g., nurse's notes).

4.26.2 – Exceptions

(Rev. 71, 04-09-04)

Exceptions to the preceding statements concerning the date(s) of service on the claim occur when the items are provided in anticipation of discharge from a hospital or nursing facility. A supplier may deliver a DMEPOS item to a patient in a hospital or nursing facility for the purpose of fitting or training the patient in the proper use of the item. This may be done up to 2 days prior to the patient's anticipated discharge to their home. The supplier shall bill the date of service on the claim as the date of discharge and shall use the Place of Service (POS) as 12 (Patient's Home). The item must be for subsequent use in the patient's home. No billing may be made for the item on those days the patient was receiving training or fitting in the hospital or nursing facility.

A supplier may not bill for drugs or other DMEPOS items used by the patient prior to the patient's discharge from the hospital or a Medicare Part A nursing facility stay. Billing the DMERC for surgical dressings, urological supplies, or ostomy supplies that are provided in the hospital or during a Medicare Part A nursing facility stay is not allowed. These items are payable to the facility under Part A of Medicare. This prohibition applies even if the item is worn home by the patient from the hospital or nursing facility. Any attempt by the supplier and/or facility to substitute an item that is payable to the

supplier for an item that, under statute, should be provided by the facility, may be considered to be fraudulent. These statements apply to durable medical equipment delivered to a patient in hospitals, skilled nursing facilities (Place of Service = 31), or nursing facilities providing skilled services (Place of Service = 32).

A supplier may deliver a DMEPOS item to a patient's home in anticipation of a discharge from a hospital or nursing facility. The supplier may arrange for actual delivery of the item approximately 2 days prior to the patient's anticipated discharge to their home. The supplier shall bill the date of service on the claim as the date of discharge and should use the Place of Service (POS) as 12 (Patient's Home).

4.27 - Annual Deceased-Beneficiary Postpayment Review

(Rev. 71, 04-09-04)

PSCs and Medicare contractor BI units shall identify and initiate actions to recover payments with a billed date of service that is after the beneficiary's date of death. The identification of improperly paid claims shall be performed at a minimum on an annual fiscal year basis, starting fiscal year 2003, for beneficiaries who died the previous fiscal year. In addition, the PSCs shall forward the identified overpayments to the AC for recoupment. The associated overpayment recoupment shall be initiated as soon as administratively possible.

> ***EXAMPLE**: Services rendered to beneficiaries who died during fiscal year 2002 - PSCs and Medicare contractor BI units must identify improperly paid services. Upon identification, PSCs and Medicare contractors will refer this information to their respective AC or appropriate area within the Medicare contractor for recoupment. ACs and Medicare contractors must issue associated overpayment demand letters as soon as administratively possible.*

PSCs, ACs, and Medicare contractors are not required to perform medical review for paid claims with dates of service after a beneficiary's date of death. PSCs and Medicare contractor BI units shall identify the service that has been rendered after the beneficiary's date of death, and refer it to their respective AC or appropriate area within the Medicare contractor. Subsequent notification to the provider that an improper payment has been made, for which recovery is being sought, shall be initiated by the AC or the Medicare contractor.

At a minimum, PSCs and Medicare contractor BI units shall identify deceased beneficiaries and associated improperly paid claims by using one of the following two options:

- *Utilize Internal Beneficiary Eligibility Records - This option involves performing a data extract against eligibility files for all beneficiaries within the PSC's or Medicare contractor BI unit's jurisdiction and identifying those beneficiaries who have died during the applicable fiscal year. Once the list of deceased*

beneficiaries has been identified, PSCs and Medicare contractor BI units utilize the claims processing history files to identify any services/claims containing a paid date of service that is after the CWF-posted date of death.

- *Utilize External Beneficiary Eligibility Records - This option allows PSCs and Medicare contractor BI units to utilize a CMS-created annual computer file of all deceased beneficiaries. On an annual calendar year basis, CMS creates a computer file of all Medicare beneficiaries who died in the preceding calendar year. This computer file should be available for PSCs and Medicare contractor BI units to download from the CMS Data Center by mid-February of each year. PSCs and Medicare contractor BI units then review the format for this file to determine if any changes have been made from the previous fiscal year file. In accordance with the Health Insurance Portability and Accountability Act of 1996, a security firewall has been installed to protect the privacy rights of deceased beneficiaries. This firewall prevents unauthorized users from gaining access to the files of deceased beneficiaries. Due to the confidential information within these files, PSCs and Medicare contractor BI units will not be able to access them without their secured authorized identification code being included in the CMS-allowed-access list associated with the files.*

To have access to these files, the PSC and Medicare contractor BI unit shall submit the name of the person(s) who will be accessing the files, their CMS mainframe user identification number, the PSC or Medicare contractor name and contractor number, the PSC Task Order number, and a telephone number. Only the person(s) identified will be allowed access to the files. Submit this information via email to the CMS CO Director of the Division of Benefit Integrity and Law Enforcement Liaison.

The annual computer files are located on CMS's mainframe computer and may be found using the dataset naming convention "c@pig.#dbpc.deceased.benes.dodyyyy", where "yyyy" is equal to the calendar year in which the beneficiaries died. The format for this file is a text file and may also be found using "c@pig.#dbpc.deceased.benes.format". For example, computer file "c@pig.#dbpc.deceased.benes.dod2001" contains information on all Medicare beneficiaries who died during calendar year 2001. Computer file "c@pig.#dbpc.deceased.benes.dod.2002" contains information on all Medicare beneficiaries who died during calendar year 2002. Download both computer files and manipulate the data to determine those beneficiaries who died during fiscal year 2002 (October 1, 2001 - September 30, 2002). Then utilize the claims processing history files to identify any services/claims containing a paid date of service that is after the posted date of death.

On an annual basis, PSCs and Medicare contractor BI units shall submit a report to the on the accounting of the improper payments identified by the PSC or Medicare contractor BI unit and respective overpayments recouped by the AC and Medicare contractor. This report shall be due on December 5th of each year and sent to the GTL, Co-GTL, and SME. The report shall also be sent to the following address:

Director of the Division of Benefit Integrity and Law Enforcement Liaison
Centers for Medicare & Medicaid Services
Re: Deceased Beneficiaries
Mail Stop C3-02-16
7500 Security Boulevard
Baltimore, Maryland 21244

4.28 - Joint Operating Agreement

(Rev. 71, 04-09-04)

A Joint Operating Agreement (JOA) is a document developed by the PSC and the AC that delineates the roles and responsibilities for each entity specific to a Task Order.

As it applies to the PSC's task order, the JOA shall, at a minimum:

- *Include a description and documentation of process/workflows that illustrate how the PSC and AC intend to interact with one another to complete each of the tasks outlined in the Task Order on a daily basis.*
- *Establish responsibility for who shall request medical records/documentation(s) not submitted with the claim.*
- *Ensure that the AC communicates to the PSC any interaction with law enforcement on requests for cost report information.*
- *Establish responsibility for how medical documentation that has been submitted without being requested shall be stored and tracked.*
- *Establish responsibility for how medical documentation that has been submitted without being requested shall be provided to the PSC if documentation becomes necessary in the review process.*
- *Mitigate risk of duplicate medical documentation requests.*
- *Ensure that there is no duplication of effort by the PSC and the AC (e.g., the AC must not re-review PSC work).*
- *Identify the JOA participants*
- *Describe the roles and responsibilities of the PSC and the AC*
- *Clearly define dispute resolution processes*
- *Describe communication regarding CMS changes*

- *Include systems information*
- *Include training and education*
- *Include complaint screening and processing (including the immediate referral by the AC second-level screening staff of provider complaints and immediate advisements to the PSC)*
- *Include data analysis*
- *Include suspension of payment*
- *Include overpayments processing*
- *Include excluded providers*
- *Include voluntary refunds*
- *Include incentive Reward Programs*
- *Include appeals*
- *Include provider enrollment*
- *Include system edits and audits*
- *Include requests for information*
- *Include FOIA and Privacy Act responsibilities*
- *Include interaction with law enforcement*
- *Include fraud investigations*
- *Include prepayment reviews*
- *Include postpayment reviews*
- *Include Harkin Grantees*
- *Include OIG Hotline referrals*
- *Include Self-Disclosures*
- *Include consent settlements*

- *Include securing email information*
- *Include JOA workgroup meetings*
- *Contain other items identified by CMS, the PSC, and/or AC*

4.29 - Medicare Contractor Benefit Integrity Unit Quarterly Status Report

(Rev. 71, 04-09-04)

This section only applies to Medicare contractors who have not transitioned their BI work to a PSC.

The Medicare contractor BI unit shall document the activities it performs and reports them to CMS using the Contractor Reporting of Operational & Workload Data *(CROWD) system. The BI unit shall maintain data on the following topics:*

- Complaints (volume, source, processing time, disposition)
- Volume and kinds of referrals to OI
- Networking activities
- Types of fraud and abuse identified and corrective actions taken, including administrative action

4.30 – Quality Improvement (QI) Program Reporting

(Rev. 71, 04-09-04)

This does not apply to PSCs.

Medicare contractor BI units shall assist in protecting the Medicare Trust Fund from those entities that would seek payment for items and services under false or fraudulent circumstances. This includes effectively developing potential fraud cases and referral of them to the Office of Inspector General (OIG) for determining if criminal and/or civil statutes have been violated.

In order to accomplish their responsibilities, CMS requires the *Medicare* contractor *BI units* to develop BI QI programs. The purpose of the QI program is to systematically improve the quality of the case referrals; enhance proactive approaches to identify potential fraud; and identify program vulnerabilities resulting from investigative

activities. The QI plan shall be submitted each fiscal year to the RO 30 days before the beginning of the fiscal year. The content of the BI QI program shall:

1. Ensure decisions made are effective in preventing, detecting, and deterring potential fraud in the Medicare program;

2. Ensure standard operational procedures are in place and are adhered to and monitored;

3. Improve the case development actions and documentation standards;

4. Ensure the proper handling of complaints;

5. Increase the potential acceptance of OIG case referrals by submitting quality referrals;

6. Improve the working relationship with law enforcement through enhanced networking and training;

7. Improve proactive use of data analysis;

8. Improve the quality of cases referred to law enforcement through partnering. Partnering is an informal meeting with law enforcement to discuss case details prior to referral.

9. Improve communication and coordination efforts with partners (OIG, FBI, other carriers, intermediaries, PSCs, etc.);

10. Implement and maintain a cross-functional data analysis team in each site. It will consist of representation from each functional unit and meet monthly to share data, observations of questionable billing practice patterns, voluntary refund information, and other concerns;

11. Improve and increase program safeguard actions including payment suspensions, prepayment review and referral to medical review, as appropriate.

12. Ensure proper maintenance and updating of the FID;

13. Ensure the accuracy of medical review decisions made in support of BI. The accuracy of these medical review determinations in support of BI whether made by BI or MR staff shall be a component of the BI QI program.

(Utilizing this tool will increase the number of cases accepted by law enforcement and ensure the efficiency and effectiveness of the program.)

The *Medicare contractor BI unit* shall submit the results of the QI program to the RO on a quarterly basis. This report shall include the following information:

- The date QI was performed and by whom;
- The program weakness or vulnerability;
- Source of the program weakness/vulnerability;
- How the program weakness/vulnerability was detected;
- The PIM chapter(s) and section(s) or Program Memorandum (PM) supporting the identification of the program weakness/vulnerability;
- Actions taken to correct the program weakness/vulnerability;
- Actions taken to avoid the same program weakness/vulnerability from recurring;
- How the weakness/vulnerability is being monitored for compliance;
- The results of individual and unit error rate percentages of quality reviews; and
- A synopsis of management practices within the context of the QI program.

4.31 – Vulnerability Report

(Rev. 71, 04-09-04)

Program vulnerabilities can be identified through a variety of sources such as the Chief Financial Officer's (CFO) Audit, Fraud Alerts, the General Accounting Office (GAO), the Office of Inspector General (OIG), and *PSC and Medicare contractor* operations, as examples. *PSCs and Medicare* contractor *BI units* shall submit any identified program vulnerabilities to CMS RO and CO on a quarterly basis. The identified vulnerabilities shall also include recommendations for resolving the vulnerability and *shall* describe the detection methodology.

The PSC and Medicare contractor BI unit shall send a copy of the identified vulnerabilities to the GTL and Co-GTL. The *PSC and Medicare* contractor *BI unit* shall *also* send the CMS CO a copy of the identified vulnerabilities to the following address:

Centers for Medicare & Medicaid Services (CMS)
Division of Benefit Integrity and Law Enforcement Liaison (DBILEL)
Re: Program Vulnerabilities
Mail Stop C3-02-16
7500 Security Boulevard
Baltimore, Maryland 21244