Medicare Program Integrity Manual

Chapter 8 – Administrative Actions and Statistical Sampling for Overpayment Estimates

Table of Contents
(Rev. 377, 05-27-11)

Transmittals for Chapter 8

8.1 – Appeal of Denials

8.2 – Overpayment Procedures

- 8.2.1 – Overpayment Assessment Procedures
  - 8.2.1.1 – Definition of Overpayment Assessment Terms
- 8.2.2 – Assessing Overpayment When Review Was Based on Statistical Sampling for Overpayment Estimation
- 8.2.3 – Assessing Overpayment or Potential Overpayment When Review Was Based on Limited Sample or Limited Sub–sample
  - 8.2.3.1 – Contractor Activities to Support Assessing Overpayment
  - 8.2.3.2 – Conduct of Expanded Review Based on Statistical Sampling for Overpayment Estimation and Recoupment of Projected Overpayment by Contractors
  - 8.2.3.3 - Consent Settlement Instructions
    - 8.2.3.3.1 - Background on Consent Settlement
    - 8.2.3.3.2 - Opportunity to Submit Additional Information Before Consent Settlement Offer
    - 8.2.3.3.3 - Consent Settlement Offer
    - 8.2.3.3.4 - Option 1 - Election to Proceed to Statistical Sampling for Overpayment Estimation
    - 8.2.3.3.5 - Option 2 - Acceptance of Consent Settlement Offer
    - 8.2.3.3.6 - Consent Settlement Budget and Performance Requirements for ACs
- 8.2.4 – Coordination with Audit and Reimbursement Staff

8.3 – Suspension of Payment

- 8.3.1 – When Suspension of Payment May Be Used
  - 8.3.1.1 – Fraud or Willful Misrepresentation Exists – Fraud Suspensions
  - 8.3.1.2 – Overpayment Exists But the Amount is Not Determined – General Suspensions

8.3.1.3 – Payments to be Made May Not be Correct – General Suspensions
8.3.1.4 – Provider Fails to Furnish Records and Other Requested Information – General Suspensions
8.3.2 – Procedures for Implementing Suspension of Payment
8.3.2.1 – CMS Approval
8.3.2.2 – The Notice of Intent to Suspend
8.3.2.2.1 – Prior Notice Versus Concurrent Notice
8.3.2.2.2 – Content of Notice
8.3.2.2.3 – Shortening the Notice Period for Cause
8.3.2.2.4 – Mailing the Notice to the Provider
8.3.2.2.5 – Opportunity for Rebuttal
8.3.2.3 – Claims Review During the Suspension Period
8.3.2.3.1 – Claims Review
8.3.2.3.2 – Case Development - Benefit Integrity
8.3.2.4 – Duration of Suspension of Payment
8.3.2.5 – Removing the Suspension
8.3.2.6 – Disposition of the Suspension
8.3.2.7 – Contractor Suspects Additional Improper Claims
8.3.3 – Suspension Process for Multi–Region Issues
8.3.3.1 – DME MACs and DME PSCs and ZPICs
8.3.3.2 – Reserved for Future Use
8.4 – Use of Statistical Sampling for Overpayment Estimation
8.4.1 – Introduction
8.4.1.1 – General Purpose
8.4.1.2 - The Purpose of Statistical Sampling
8.4.1.3 – Steps for Conducting Statistical Sampling
8.4.1.4 - Determining When Statistical Sampling May be Used
8.4.1.5 – Consultation With a Statistical Expert
8.4.1.6 – Use of Other Sampling Methodologies
8.4.2 – Probability Sampling
8.4.3 – Selection of Period to be Reviewed and Composition of Universe
8.4.3.1 – Selection of Period for Review
8.4.3.2 – Defining the Universe, the Sampling Unit, and the Sampling Frame
8.4.3.2.1 – Composition of the Universe
8.4.3.2.2 – The Sampling Unit
8.4.3.2.3 – The Sampling Frame
8.4.4 – Sample Selection

8.4.4.1 – Sample Design
8.4.4.1.1 – Simple Random Sampling
8.4.4.1.2 – Systematic Sampling
8.4.4.1.3 – Stratified Sampling
8.4.4.1.4 – Cluster Sampling
8.4.4.1.5 – Design Combinations
8.4.4.2 – Random Number Selection
8.4.4.3 – Determining Sample Size
8.4.4.4 – Documentation of Sampling Methodology
8.4.4.4.1 – Documentation of Universe and Frame
8.4.4.4.2 – Arrangement and Control Totals
8.4.4.4.3 – Worksheets
8.4.4.4.4 – Overpayment/Underpayment Worksheets
8.4.4.5 – Informational Copies to Primary GTL, Associate GTL, SME or CMS RO
8.4.5 – Calculating the Estimated Overpayment
8.4.5.1 – The Point Estimate
8.4.5.2 – Calculation of the Estimated Overpayment Amount
8.4.6 – Actions to be Performed Following Selection of Provider or Supplier and Sample
8.4.6.1 – Notification of Provider or Supplier of the Review and Selection of the Review Site
8.4.6.1.1 – Written Notification of Review
8.4.6.1.2 – Determining Review Site
8.4.6.2 – Meetings to Start and End the Review
8.4.6.3 – Conducting the Review
8.4.7- Overpayment Recovery
8.4.7.1 – Recovery from Provider or Supplier
8.4.7.2 – Informational Copy to Primary GTL, Associate GTL, SME or CMS RO
8.4.8 – Corrective Actions
8.4.9 – Changes Resulting from Appeals
8.4.9.1 – Sampling Methodology Overturned
8.4.9.2 – Revised Initial Determination
8.4.10 – Resources
8.4.11 – Additional Discussion of Stratified Sampling and Cluster Sampling
8.4.11.1 – Stratified Sampling
8.4.11.2 – Cluster Sampling

8.1 - Appeal of Denials

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

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

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

A. Use of Medical Specialist

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

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

B. Documenting Reopening and Good Cause

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

8.2 – Overpayment Procedures

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

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

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

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

Contractors have the option to request the periodic production of records or supporting documentation for a limited sample of submitted claims from providers or suppliers to which amounts were previously overpaid to ensure that the practice leading to the overpayment is not continuing. The contractor may take any appropriate remedial action described in this chapter if a provider or supplier continues to have a high level of payment error.

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

8.2.1 – Overpayment Assessment Procedures

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

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

- Actual overpayment;

- Settlement based overpayment, or
- Statistically extrapolated overpayments.

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

Provider Name	
Provider UPIN or PIN:	
Reason for Review	
Type of Sample Reviewed: Statistical Sampling for Overpayment Estimation	
Explanation of Sampling Methodology:	
Number of Claims in Sample:	
Number of Claims in Universe:	
Amount of Overpayment (after allowance for deductible and coinsurance)	
Claims Reviewed	
Billed Amount	
Allowed Amount	
Rationale for Denial	
§1879 Determinations	
§1870 Determinations	
Total Actual Overpayment	
Overpayment extrapolated over the universe	

8.2.1.1 – Definition of Overpayment Assessment Terms

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

A. Actual Overpayment

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

B. Projected Overpayment

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

C. Limited Projected Overpayment

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

8.2.2 – Assessing Overpayment When Review Was Based on Statistical Sampling for Overpayment Estimation

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

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

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

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

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

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

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

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

8.2.3.1 – Contractor Activities to Support Assessing Overpayment

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

A. Step 1

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

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

B. Step 2

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

C. Step 3

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

D. Step 4

Calculate the final overpayment.

E. Step 5

Refer to the overpayment recoupment staff.

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

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

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

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

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

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

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

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

E. Calculate the final overpayment; and

F. Refer to the overpayment recoupment staff.

8.2.3.3 - Consent Settlement Instructions

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

8.2.3.3.1 - Background on Consent Settlement

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

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines consent settlement as an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based

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

A complete explanation of the review and the review findings

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

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

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

8.2.3.3.2 - Opportunity to Submit Additional Information Before Consent Settlement Offer

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

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

- The preliminary evaluation of the records indicates there would be an overpayment;

- The nature of the problems in the billing and practice patterns identified in the evaluation;

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

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

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

8.2.3.3.3 - Consent Settlement Offer

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

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

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

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

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

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

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

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

8.2.3.3.5 - Option 2 - Acceptance of Consent Settlement Offer

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

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

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

8.2.3.3.6 - Consent Settlement Budget and Performance Requirements for **ACs**

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

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

8.2.4 - Coordination With Audit and Reimbursement Staff

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

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

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

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

In most instances, the Audit/Reimbursement staff will:

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

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

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

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

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

8.3 – Suspension of Payment

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

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

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

8.3.1 – When Suspension of Payment May Be Used

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

Suspension may be used when there is reliable information that:

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

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

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

8.3.1.1 – Fraud or Willful Misrepresentation Exists - Fraud Suspensions

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

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

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

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

A. Complaints

There is considerable latitude with regard to complaints alleging fraud and abuse. The history, or newness of the provider, the volume and frequency of complaints concerning the provider, and the nature of the complaints all contribute to whether suspension of payment should be recommended. If there is a credible allegation(s) that a provider is submitting or may have submitted false claims, the contractor, MAC, PSC or ZPIC shall

recommend suspension of payment to the CMS Central Office (CO) Division of Benefit Integrity Management Operations Fraud and Abuse Suspensions and Sanctions (DBIMO FASS) team.

B. Provider Identified in CMS Fraud Alert

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

C. Requests from Outside Agencies

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

- CMS -- Initiate suspension as requested.
- OIG/FBI – Contractors, MACs, PSCs, and ZPICs shall forward the written request to the CO DBIMO FASS team for its review and determination. The CO DBIMO FASS team will decide.
- AUSA/DOJ – Contractors, MACs, PSCs, and ZPICs shall forward the written request to the CO DBIMO FASS team for review and determination.
- Other – Other situations the contractor, MAC, PSC or ZPIC may consider recommending suspension of payment to the CO DBIMO FASS team are:
    - Provider has pled guilty to, or been convicted of, Medicare, Medicaid, CHAMPUS, or private health care fraud and is still billing Medicare for services;
    - Federal/State law enforcement has subpoenaed the records of, or executed a search warrant at, a health care provider billing Medicare;
    - Provider has been indicted by a Federal Grand Jury for fraud, theft, embezzlement, breach of fiduciary responsibility, or other misconduct related to a health care program;
        - Provider presents a pattern of evidence of known false documentation or statements sent to the contractor or the MAC; e.g., false treatment plans, false statements on provider application forms.

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

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

Suspension of payment may be used when the contractor, MAC, PSC or ZPIC or CMS possesses reliable information that an overpayment exists but has not yet determined the amount of the overpayment. In this situation, the contractor, MAC, PSC, and ZPIC shall recommend suspension to the CO DBIMO FASS team. For the purposes of this section, these types of suspensions will be called "general suspensions."

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

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

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

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

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

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

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

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

8.3.2 – Procedures for Implementing Suspension of Payment

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

8.3.2.1 – CMS Approval

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

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

The contractor, MAC, PSC or ZPIC shall forward a draft of the proposed notice of suspension and a brief summary of the evidence upon which the recommendation is based to the CO DBIMO FASS team. The contractor, MAC, PSC, and ZPIC shall not take suspension action without the explicit approval of the CO DBIMO FASS team. In most cases, the PSC or ZPIC will notify OIG and other law enforcement partners of its decision and will keep law enforcement apprised of any future decisions to modify the suspension. However, if a contractor, MAC, PSC or ZPIC, or CMS has been working with law enforcement on the case, immediately notify them of the proposed recommendation being submitted to the CO DBIMO FASS team. Notice may consist of a telephone call or a fax. If law enforcement wants more time to study or discuss the suspension, contractors, MACs, PSCs, and ZPICs shall discuss their request with the CO DBIMO FASS team. If law enforcement requests that suspension action should, or should not, be taken, contractors, PSCs, and ZPICs shall contact the CO DBIMO FASS team. Contractors, MACs, PSCs and ZPICs shall also advise law enforcement that the request must be in writing and must provide a detailed rationale justifying why payment should, or should not, be suspended.

8.3.2.2 – The Notice of Intent to Suspend

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

8.3.2.2.1 – Prior Notice Versus Concurrent Notice

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

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

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

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

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

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

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

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

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

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

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

8.3.2.2.2 – Content of Notice

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

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

- That suspension action will be imposed;
- The extent of the suspension (i.e., all claims, certain types of claims, 100 percent suspension or partial suspension);
- That suspension action is not appealable;
- That CMS has approved implementation of the suspension;
- When suspension will begin;
- The items or services affected;
- How long the suspension is expected to be in effect;
- The reason for suspending payment;

- That the provider has the opportunity to submit a rebuttal statement within 15 days of notification; and

- Where to mail the rebuttal.

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

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

8.3.2.2.3 – Shortening the Notice Period for Cause

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

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

8.3.2.2.4 – Mailing the Notice to the Provider

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

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

8.3.2.2.5 – Opportunity for Rebuttal

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

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

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

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

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

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

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

8.3.2.3 – Claims Review During the Suspension Period

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

8.3.2.3.1 – Claims Review

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

A. Claims Review of Suspended Claims:

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

B. Review of Suspected Fraudulent or Overpaid Claims:

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

NOTE: Claims selected for postpayment review may be reopened within 1 year for any reason or within 4 years for good cause. Cost report determinations may be reopened within 3 years after the Notice of Program Reimbursement has been issued. Good cause is defined as new and material evidence, error on the face of the record, or clerical error. The regulations have open-ended potential for fraud or similar fault. The exception to the 1-year rule is for adjustments to DRG claims. A provider has 60 days to request a change in an assignment of a DRG. (See 42 CFR 412.60(d).)

8.3.2.3.2 – Case Development – Benefit Integrity

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

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

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

8.3.2.4 – Duration of Suspension of Payment

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

A. Time Limits

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

- Name and address of the provider under suspension;

- Amount of additional time needed (not to exceed the 180 days); and

- Rationale explaining why the additional time is necessary.

B. Exceptions to Time Limits

The following exceptions may apply:

- Department of Justice (including U.S. Attorneys). The CO DBIMO FASS team may grant an additional 180-day extension (beyond the first extension referred to in Section 3.9.2.4.A above) if an overpayment has not yet been determined and the Department of Justice submits a written request for an extension. Requests must include: 1) the identity of the person or entity under suspension, 2) the amount of time needed for continued suspension in order to implement an ongoing or anticipated criminal and/or civil proceeding, and 3) a statement of why and/or how criminal and/or civil actions may be affected if the suspension is not extended. This extension may be granted based on a request received by the CO DBIMO FASS team at any time before or during the period of suspension.

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

C. Provider Notice of the Extension

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

8.3.2.5 – Removing the Suspension

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

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

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

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

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

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

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

8.3.2.6 – Disposition of the Suspension

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

Payments for appropriate Medicare claims that are withheld during a suspension should not exceed the suspected amount of overpayment. Contractors, MACs, PSCs and ZPICs shall maintain an accurate, up-to-date record of the amount withheld and the claims that comprise the suspended amount. Contractors, MACs, PSCs and ZPICs shall keep a separate accounting of payment on all claims affected by the suspension. They shall keep track of how much money is uncontested and due the provider. The amount needs to be known as it represents assets that may be applied to reduce or eliminate any overpayment. (See PIM, chapter 8, §8.2.) Contractors, MACs, PSCs and ZPICs shall be able to provide, upon request, copies of the claims affected by the suspension. After the suspension has been removed, they shall apply the amount withheld first to the Medicare overpayment and then to reduce any other obligation to CMS or to DHHS. Contractors and MACs shall remit to the provider all monies held in excess of the amount the provider owes. If the provider owes more money than was held in suspension, the contractor or MAC shall initiate recoupment action.

8.3.2.7 – Contractor Suspects Additional Improper Claims

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

A. Present Time

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

B. Past Period of Time

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

C. Additional Services

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

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

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

8.3.3 – Suspension Process for Multi-Region Issues

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

8.3.3.1 – DME MACs and DME PSCs, and ZPICs

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

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

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

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

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

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

8.3.3.2 – Reserved for Future Use

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

8.4 - Use of Statistical Sampling for Overpayment Estimation

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

8.4.1 – Introduction

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

8.4.1.1 – General Purpose

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

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

These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC or the ZPIC BI unit or the contractor MR unit to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. Failure by the PSC or ZPIC BI units or the contractor MR units to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.

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

8.4.1.2 - The Purpose of Statistical Sampling

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

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

8.4.1.3 - Steps for Conducting Statistical Sampling

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

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

8.4.1.4 - Determining When Statistical Sampling May Be Used

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

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

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

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

8.4.1.5 - Consultation With a Statistical Expert

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

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

issues arise during the on-going review, the PSC or ZPIC BI unit or the contractor MR unit shall also involve the statistical expert.

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

8.4.1.6 - Use of Other Sampling Methodologies

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

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

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

8.4.2 - Probability Sampling

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

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

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

- Each sampling unit in each distinct possible sample must have a known probability of selection. For statistical sampling for overpayment estimation, one

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

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

8.4.3 - Selection of Period to be Reviewed and Composition of Universe

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

8.4.3.1 - Selection of Period for Review

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

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

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

- The applicable time periods for reopening claims (see the Medicare Claims Processing Manual, chapter 34 §10.6

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

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

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

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

8.4.3.2.1 - Composition of the Universe

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

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

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

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

8.4.3.2.2 - The Sampling Unit

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

Sampling units are the elements that are selected according to the design of the survey and the chosen method of statistical sampling. They may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary). For example,

possible sampling units may include specific beneficiaries seen by a physician during the time period under review; or, claims for a specific item or service. In certain circumstances, e.g., multi-stage sample designs, other types of clusters of payments may be used. In principle, any type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts.

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

8.4.3.2.3 - The Sampling Frame

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

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

The ideal frame is a list that covers the target universe completely. In some cases the frame must be constructed by combining lists from several sources and duplication of sampling units may result. Although duplicate listings can be handled in various ways that do not invalidate the sample, it is recommended that duplicates be eliminated before selecting the sample.

8.4.4 - Sample Selection

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

8.4.4.1 - Sample Design

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

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

8.4.4.1.1 - Simple Random Sampling

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

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

8.4.4.1.2 - Systematic Sampling

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

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

8.4.4.1.3 - Stratified Sampling

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

Stratified sampling involves classifying the sampling units in the frame into non-overlapping groups, or strata. The stratification scheme should try to ensure that a sampling unit from a particular stratum is more likely to be similar in overpayment amount to others in its stratum than to sampling units in other strata. Although the amount of an overpayment cannot be known prior to review, it may be possible to stratify on an observable variable that is correlated with the overpayment amount of the sampling unit. Given a sample in which the total frame is covered by non-overlapping strata, if independent probability samples are selected from each of the strata, the design is called stratified sampling. The independent random samples from the strata need not have the same selection rates. A common situation is one in which the overpayment amount in a frame of claims is thought to be significantly correlated with the amount of the original payment to the provider or supplier. The frame may then be stratified into a number of distinct groups by the level of the original payment and separate simple random samples are drawn from each stratum. Separate estimates of overpayment are made for each stratum and the results combined to yield an overall projected overpayment.

The main object of stratification is to define the strata in a way that will reduce the margin of error in the estimate below that which would be attained by other sampling

methods, as well as to obtain an unbiased estimate or an estimate with an acceptable bias. The standard literature, including that referenced in Section 3.10.10, contains a number of different plans; the suitability of a particular method of stratification depends on the particular problem being reviewed, and the resources allotted to reviewing the problem. Additional discussion of stratified sampling is provided in Section 8.4.11.1.

8.4.4.1.4 - Cluster Sampling

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

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

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

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

8.4.4.1.5 - Design Combinations

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

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

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

8.4.4.2 - Random Number Selection

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

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

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

8.4.4.3 - Determining Sample Size

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

The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.

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

8.4.4.4 - Documentation of Sampling Methodology

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

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

8.4.4.4.1 - Documentation of Universe and Frame

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

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

8.4.4.4.2 - Arrangement and Control Totals

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

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

8.4.4.4.3 - Worksheets

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

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

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

8.4.4.4.4 - Overpayment/Underpayment Worksheets

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

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

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

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

The PSC or ZPIC BI units or the contractor MR units shall send informational copies of the statistician-approved sampling methodology to their Primary GTL, Associate GTL, SME or CMS RO. The Primary GTL, Associate GTL, SME or CMS RO will keep the methodology on file and will forward to CO upon request. If this sampling methodology is applied routinely and repeatedly, the PSC or ZPIC BI units or the contractor MR units shall not repeatedly send the methodology to the Primary GTL, Associate GTL, SME or CMS RO.

8.4.5 - Calculating the Estimated Overpayment

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

8.4.5.1 - The Point Estimate

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

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

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

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

8.4.5.2 - Calculation of the Estimated Overpayment Amount

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

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

8.4.6 - Actions to be Performed Following Selection of Provider or Supplier and Sample

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

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

8.4.6.1 – Notification of Provider or Supplier of the Review and Selection of the Review Site

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

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

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

8.4.6.1.1 - Written Notification of Review

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

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

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

- the time period under review,

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

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

- information on appeal rights,

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

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

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

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

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

8.4.6.1.2 - Determining Review Site

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

A. Provider/Supplier Site Reviews

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

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

- the presence of multiple program integrity issues;

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

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

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

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

8.4.6.2 - Meetings to Start and End the Review

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

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

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

8.4.6.3 - Conducting the Review

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

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

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

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

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

8.4.7 - Overpayment Recovery

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

8.4.7.1 - Recovery From Provider or Supplier

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

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

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

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

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

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

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

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

8.4.8 - Corrective Actions

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

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

8.4.9 - Changes Resulting From Appeals

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

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

8.4.9.1 - Sampling Methodology Overturned

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

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

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

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

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

8.4.9.2 - Revised Initial Determination

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

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

8.4.10 - Resources

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

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

Arkin, H., Handbook of Sampling for Auditing and Accounting, 1984.

Cochran, W. G., Sampling Techniques, 3rd ed., New York: John Wiley and Sons, 1977.

Deming, W. E., Sample Design in Business Research, New York: John Wiley and Sons, 1960 (Paperback 1990).

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

Hedayat, A., Bekas, K. S., Design and Inference in Finite Population Sampling, John Wiley & Sons, New York, 1991.

Kish, L., Survey Sampling, New York: John Wiley and Sons, 1967, 2nd printing. (Paperback 1995).

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

Scheaffer, R. L., Mendenhall, W., and Ott, L., Elementary Survey Sampling, 5th ed., Duxbury Press, 1996.

Som, R. K., Practical Sampling Techniques, M. Dekker, New York, 1996, 2 nd ed.

8.4.11 - Additional Discussion of Stratified Sampling and Cluster Sampling

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

8.4.11.1 – Stratified Sampling

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

Generally, one defines strata to make them as internally homogeneous as possible with respect to overpayment amounts, which is equivalent to making the mean overpayments for different strata as different as possible. Typically, a proportionately stratified design with a given total sample size will yield an estimate that is more precise than a simple random sample of the same size without stratifying. The one highly unusual exception is one where the variability from stratum mean to stratum mean is small relative to the average variability within each stratum. In this case, the precision would likely be reduced, but the result would be valid. It is extremely unlikely, however, that such a situation would ever occur in practice. Stratifying on a variable that is a reasonable surrogate for an overpayment can do no harm, and may greatly improve the precision of the estimated overpayment over simple random sampling. While it is a good idea to stratify whenever there is a reasonable basis for grouping the sampling units, failure to stratify does not invalidate the sample, nor does it bias the results.

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

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

Given the definition of a set of strata, the designer of the sample must decide how to allocate a sample of a certain total size to the individual strata. In other words, how much of the sample should be selected from Stratum 1, how much from Stratum 2, etc.? As shown in the standard textbooks, there is a method of “optimal allocation,” i.e., one

designed to maximize the precision of the estimated potential overpayment, assuming that one has a good idea of the values of the variances within each of the strata. Absent that kind of prior knowledge, however, a safe approach is to allocate proportionately. That is, the total sample is divided up into individual stratum samples so that, as nearly as possible, the stratum sample sizes are in a fixed proportion to the sizes of the individual stratum frames. It is emphasized, however, that even if the allocation is not optimal, using stratification with simple random sampling within each stratum does not introduce bias, and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample.

8.4.11.2 - Cluster Sampling

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

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

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

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R377PI	05/27/2011	Program Integrity Manual Reorganization of Chapters 3 and 8	06/28/2011	6560
R71PI	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
R03PIM	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292
R01PIM	06/2000	Initial Release of Manual	NA	931

Back to top of chapter