CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 282	Date: January 8, 2009
	Change Request 6170

NOTE: Transmittal 278, dated December 19, 2008 is being rescinded and replaced by Transmittal 282, dated January 8, 2009. A partial sentence in section 3.8.3.3 has been deleted and a bullet point and paragraph that was erroneously left out has been added to section 3.10.7.1. All other material remains the same.

SUBJECT: Zone Program Integrity Contractor (ZPIC) Updates

I. SUMMARY OF CHANGES: Benefit integrity work will transition from PSCs to ZPICs and the ZPICs will be located in 7 zones. Therefore, the instructions have been updated to include ZPICs.

NEW / REVISED MATERIAL
EFFECTIVE DATE: January 26, 2009
IMPLEMENTATION DATE: January 26, 2009

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3/3.8/Overpayment Procedures
R	3/3.8.3.2/Conduct of Expanded Review Based on Statistical Sampling for Overpayment Estimation and Recoupment of Projected Overpayments by Contractors
R	3/3.8.3.3.1/Background on Consent Settlement
R	3/3.8.3.3.3/Consent Settlement Offer
R	3/3.8.3.3.6/Consent Settlement Budget and Performance Requirements for ACs
R	3/3.9/Suspension of Payment
R	3/3.9.1.1/Fraud or Willful Misrepresentation Exists - Fraud Suspensions
R	3/3.9.1.2/Overpayment Exists But the Amount is Not Determined - General Suspensions
R	3/3.9.1.3/Payments to be Made May Not be Correct - General

	Suspensions
R	3/3.9.1.4/Provider Fails to Furnish Records and Other Requested Information - General Suspensions
R	3/3.9.2.1/CMS Approval
R	3/3.9.2.2.1/Prior Notice Versus Concurrent Notice
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R	3/3.9.2.3.2/Case Development - Benefit Integrity
R	3/3.9.2.4/Duration of Suspension of Payment
R	3/3.9.2.5/Removing the Suspension
R	3/3.9.2.6/Disposition of the Suspension
R	3/3.9.2.7/Contractor Suspects Additional Improper Claims
R	3/3.9.3.1/DME MACs, DME PSCs, and ZPICs
R	3/3.9.3.2/Reserved for Future Use
R	3/3.10.1.1/General Purpose
R	3/3.10.1.4/Determining When Statistical Sampling May Be Used
R	3/3.10.1.5/Consultation With a Statistical Expert
R	3/3.10.1.6/Use of Other Sampling Methodologies
R	3/3.10.2/Probability Sampling
R	3/3.10.4.2/Random Numbers Selection
R	3/3.10.4.3/Determining Sample Size
R	3/3.10.4.4/Documentation of Sampling Methodology
R	3/3.10.4.4.1/Documentation of Universe and Frame
R	3/3.10.4.4.3/Worksheets
R	3/3.10.4.5/Informational Copies to Primary GTL, Associate GTL, SME or CMS RO
R	3/3.10.5.1/The Point Estimate
R	3/3.10.6/Actions to be Performed Following Selection of Provider or Supplier and Sample
R	3/3.10.6.1/Notification of Provider or Supplier of the Review and Selection of the Review Site

R	3/3.10.6.1.1/Written Notification of Review
R	3/3.10.6.1.2/Determining Review Site
R	3/3.10.7.1/Recovery From Provider or Supplier

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 282	Date: January 8, 2009	Change Request: 6170

NOTE: Transmittal 278, dated December 19, 2008 is being rescinded and replaced by Transmittal 282, dated January 8, 2009. A partial sentence in section 3.8.3.3 has been deleted and a bullet point and paragraph that was erroneously left out has been added to section 3.10.7.1. All other material remains the same.

SUBJECT: Zone Program Integrity Contractor (ZPIC) Updates

Effective Date: January 26, 2009
Implementation Date: January 26, 2009

I. GENERAL INFORMATION

A. Background: Benefit integrity work will transition from PSCs to ZPICs and the ZPICs will be located in 7 zones. Therefore, the instructions in chapter 3, of the PIM, have been updated to include ZPICs.

B. Policy: N/A

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6170.1	The ZPICs shall follow the requirements in PIM chapter 3.										ZPICs
6170.2	Contractors, MACs, PSCs and ZPICs shall recommend suspension of payment to the Division of Benefit Integrity Management Operations Fraud and Abuse Suspensions and Sanctions (DBIMO FASS) Team.	X	X	X	X	X					PSCs, ZPICs

III. PROVIDER EDUCATION TABLE

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

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Kimberly Downin, Kimberly.Downin@cms.hhs.gov, 410-786-0188
Post-Implementation Contact(s): Kimberly Downin, Kimberly.Downin@cms.hhs.gov, 410-786-0188

VI. FUNDING

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

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

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

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

Medicare Program Integrity Manual

Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

Table of Contents
(Rev.282, 01-08-09)

3.9.3.1 – DME MACs, DME PSCs, *and ZPICS*

3.9.3.2 – *Reserved for Future Use*

3.8 – Overpayment Procedures

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

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

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

If a large number of claims are involved, contractors consider using statistical sampling for overpayment estimation to calculate the amount of the overpayment. (See PIM, chapter 3, §3.10.)

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

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

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

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

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

A. If an expanded review of claims is conducted, contractors shall follow the sampling instructions found in PIM chapter 3, §3.10, obtain and review claims and medical records, and document for each claim reviewed:

- The amount of the original claim;

- The allowed amount;

- The rationale for denial;

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

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

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

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

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

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

E. Calculate the final overpayment; and

F. Refer to the overpayment recoupment staff.

3.8.3.3.1 - Background on Consent Settlement

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

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines consent settlement as an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved. The PSC *and ZPIC* BI units and the contractor medical review units shall submit via secure email the consent settlement to the Primary and Associate GTLs before offering a consent settlement to the provider or supplier. If the PSC *or the ZPIC* BI units or the contractor medical review units do not have secure email, the consent settlement shall be sent to the Primary GTL and the Associate GTL via hard copy. Upon receipt, GTLs will forward the consent settlement to the Director of the Division of Benefit Integrity Management Operations. The PSC *or the ZPIC* BI units and the contractor medical review units may contact the provider upon approval of the consent settlement. Consent settlement documents carefully explain, in a neutral tone,

what rights a provider waives by accepting a consent settlement. The documents shall also explain in a neutral tone the consequences of not accepting a consent settlement. A key feature of a consent settlement is a binding statement that the provider agrees to waive any rights to appeal the decision regarding the potential overpayment. The consent settlement agreement shall carefully explain this, to ensure that the provider is knowingly and intentionally agreeing to a waiver of rights. Consent settlement correspondence shall contain:

A complete explanation of the review and the review findings

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

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

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

3.8.3.3.3. - Consent Settlement Offer

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

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

3.8.3.3.6 - Consent Settlement Budget and Performance Requirements for ACs

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

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

3.9 – Suspension of Payment

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

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

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

3.9.1.1 – Fraud or Willful Misrepresentation Exists - Fraud Suspensions

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

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

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

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

A. Complaints

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

B. Provider Identified in CMS Fraud Alert

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

C. Requests from Outside Agencies

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

- CMS -- Initiate suspension as requested.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.9.2.1 – CMS Approval

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

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

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

should not, be taken, contractors, PSCs, *and ZPICs* shall contact the *CO DBIMO FASS team*. Contractors, *MACs,* PSCs *and ZPICs* shall also advise law enforcement that the request must be in writing and must provide a detailed rationale justifying why payment should, or should not, be suspended.

3.9.2.2.1 – Prior Notice Versus Concurrent Notice

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

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

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

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

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

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

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

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

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

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

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

3.9.2.2.2 – Content of Notice

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

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

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

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

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

3.9.2.2.3 – Shortening the Notice Period for Cause

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

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

3.9.2.2.4 – Mailing the Notice to the Provider

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

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

3.9.2.2.5 – Opportunity for Rebuttal

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

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

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

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

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

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

action should be non-initiated or terminated, they shall consult immediately with the *CO DBIMO FASS team*.

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

3.9.2.3.1 – Claims Review

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

A. Claims Review of Suspended Claims:

Once suspension has been imposed, contractors*, MACs,* PSCs *and ZPICs* shall follow normal claims processing and MR procedures. Contractors *and MACs* shall make every attempt within the MR budget to determine if suspended claims are payable. Contractors*, MACs,* PSCs *and ZPICs* shall ensure that the provider is not substituting a new category of improper billing to counteract the effect of the payment suspension. If the claim is determined to be not payable, it shall be denied. For claims that are not denied, the contractor *or MAC* shall send a remittance advice to the provider showing that payment was approved but not sent. Contractors*, MACs,* PSCs *and ZPICs* are not required to perform 100% pre-pay medical review of suspended claims. *If 100% prepayment review is not conducted, a 100% postpayment review shall be performed on all claims adjudicated during the suspension, prior to the issuance of the overpayment determination.* Contractors*, MACs,* PSCs *and ZPICs* shall consult with the *CO DBIMO FASS team* when resources *may* be better utilized *employing* statistical sampling procedures. Contractors*, MACs,* PSCs *and ZPICs* shall use the principles of statistical sampling found in the PIM, Chapter 3, §3.10, to determine what percentage of claims in a given universe of suspended claims are payable.

B. Review of Suspected Fraudulent or Overpaid Claims:

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

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

3.9.2.3.2 – Case Development – Benefit Integrity

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

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

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

3.9.2.4 – Duration of Suspension of Payment

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

A. Time Limits

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

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

B. Exceptions to Time Limits

The following exceptions may apply:

- Department of Justice (including U.S. Attorneys). The *CO DBIMO FASS team* may grant an additional *180-day* extension *(beyond the first extension referred to in Section 3.9.2.4.A above) if an overpayment has not yet been determined and* the Department of Justice submits a written request *for an extension*. Requests must include: 1) the identity of the person or entity under suspension, 2) the amount of time needed for

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

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

C. Provider Notice of the Extension

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

3.9.2.5 – Removing the Suspension

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

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

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

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

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

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

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

3.9.2.6 – Disposition of the Suspension

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

Payments for appropriate Medicare claims that are withheld during a suspension should not exceed the suspected amount of overpayment. Contractors, *MACs,* PSCs *and ZPICs* shall maintain an accurate, up-to-date record of the amount withheld and the claims that comprise the suspended amount. Contractors, *MACs,* PSCs *and ZPICs* shall keep a separate accounting of payment on all claims affected by the suspension. They shall keep track of how much money is uncontested and due the provider. The amount needs to be known as it represents assets that may be applied to reduce or eliminate any overpayment. (See PIM, chapter 3, §3.8.) Contractors, *MACs,* PSCs *and ZPICs* shall be able to provide, upon request, copies of the claims affected by the suspension. After the suspension has been removed, they shall apply the amount withheld first to the Medicare overpayment and then to reduce any other obligation to CMS or to DHHS. Contractors *and MACs* shall remit to the provider all monies held in excess of the amount the provider owes. If the provider owes more money than was held in suspension, the contractor *or MAC* shall initiate recoupment action.

3.9.2.7 – Contractor Suspects Additional Improper Claims

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

A. Present Time

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

B. Past Period of Time

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

C. Additional Services

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

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

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

3.9.3.1 – DME MACs, DME PSCs*, and ZPICs*

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

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

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

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

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

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

3.9.3.2 - *Reserved for Future Use*

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

3.10.1.1 – General Purpose

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

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

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

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

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

3.10.1.4 - Determining When Statistical Sampling May Be Used

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

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

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

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

3.10.1.5 - Consultation With a Statistical Expert

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

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

results of the sampling prior to releasing the overpayment demand letter. If questions or issues arise during the on-going review, the PSC *or ZPIC* BI unit or the contractor MR unit shall also involve the statistical expert.

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

3.10.1.6 - Use of Other Sampling Methodologies

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

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

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

3.10.2 - Probability Sampling

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

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

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

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

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

3.10.4.2 - Random Number Selection

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

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

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

3.10.4.3 - Determining Sample Size

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

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

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

3.10.4.4 - Documentation of Sampling Methodology

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

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

3.10.4.4.1 - Documentation of Universe and Frame

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

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

3.10.4.4.3 - Worksheets

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

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

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

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

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

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

3.10.5.1 - The Point Estimate

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

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

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

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

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

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

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

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

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

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

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

3.10.6.1.1 - Written Notification of Review

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

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

- an explanation of why the review is being conducted (i.e., why the provider or supplier was selected),
- the time period under review,
- a list of claims that require medical records or other supporting documentation,
- a statement of where the review will take place (provider/supplier office or contractor site),
- information on appeal rights,
- an explanation of how results will be projected to the universe if claims are denied upon review and an overpayment is determined to exist, and

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

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

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

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

3.10.6.1.2 - Determining Review Site

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

A. Provider/Supplier Site Reviews

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

- the extent of aberrant billing or utilization patterns that have been identified;
- the presence of multiple program integrity issues;
- evidence or likelihood of fraud or abuse; and/or,
- past failure(s) of the provider or supplier to submit requested medical records in a timely manner or as requested.

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

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

3.10.7.1 - Recovery From Provider or Supplier

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

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

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

- a description of the universe, the frame, and the sample design;
- a definition of the sampling unit,

- the sample selection procedure followed, and the numbers and definitions of the strata and size of the sample, including allocations, if stratified;

- the time period under review;

- the sample results, including the overpayment estimation methodology and the calculated sampling error as estimated from the sample results; and

- the amount of the actual overpayment/underpayment from each of the claims reviewed.

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