

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 184	Date: JANUARY 26, 2007
	Change Request 5399

SUBJECT: Revisions for MACs and PSCs

I. SUMMARY OF CHANGES: Since the transition of all BI work to PSCs has been completed, all references to Medicare contractor BI unit were deleted. MAC responsibilities as they relate to BI and supporting PSCs have been added to chapter 3 of the PIM. The Consent Settlement section of chapter 3 was clarified to indicate that medical review units can use consent settlements as well as PSC BI units.

MANUALIZATION/CLARIFICATION

EFFECTIVE DATE: February 26, 2007

IMPLEMENTATION DATE: February 26, 2007

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/Table of Contents
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 Overpayment by Contractors
R	3/3.8.3.3.1/Background on Consent Settlement
R	3/3.8.3.3.3/Consent Settlement Offer
R	3/3.8.3.3.4/Option 1 - Election to Proceed to Statistical Sampling for Overpayment Estimation
R	3/3.8.3.3.6/Consent Settlement Budget and Performance Requirements for ACs
R	3/3.9/Suspension of Payment
R	3/3.9.3.1/DMEC, DME MACs and DME PSCs
R	3/3.10.1.1/General Purpose
R	3/3.10.1.4/Determining When Statistical Sampling May Be Used
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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:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 184	Date: January 26, 2007	Change Request: 5399
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SUBJECT: Revisions for MACs and PSCs

Effective Date: February 26, 2007

Implementation Date: February 26, 2007

I. GENERAL INFORMATION

A. Background: Since the transition of all BI work to PSCs has been completed, all references to Medicare contractor BI unit were deleted. MAC responsibilities as they relate to BI and supporting PSCs have been added to chapter 3 of the PIM. The Consent Settlement section of chapter 3 was clarified to indicate that medical review units can use consent settlements as well as PSC BI units.

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 M A C	D M M A C	F I I E R	C A R I E R	D M R C	R E R C	H I H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F			
5399.1	Affiliated contractors (ACs) and Medicare administrative contractors (MACs) shall follow the indicated sections in chapter 3 of the PIM.	X	X	X	X	X	X						
5399.2	Medical review may use consent settlements.	X	X	X	X	X	X						PSCs
5399.3	PSC BI units and contractor medical review units shall submit via secure e-mail the consent settlement to the primary and associate GTLs before offering a consent settlement to the provider or supplier. If the PSC BI units and contractor medical review units do not have secure e-mail, the consent settlement shall be sent to the Primary GTL and the Associate GTL via hard copy.	X	X	X	X	X	X						PSCs
5399.4	The PSC BI units and the contractor medical review units may contact the provider upon approval of the consent settlement.	X	X	X	X	X	X						PSCs

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B M A C	D M M A C	F I I E R	C A R I E R	D M R C	R E R C	H I H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F			
	None.												

IV. SUPPORTING INFORMATION

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:
	N/A

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

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

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

VI. FUNDING

A. For TITLE XVIII Contractors, use only one of the following statements: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. For Medicare Administrative Contractors (MAC), use only one of the following statements: The contractor is hereby advised that this constitutes technical direction as defined in your contract. We do not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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. 184, 01-26-07)

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

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

3.8 – Overpayment Procedures

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

The PSCs 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 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 *shall refer* such requests to the Primary GTL, Associate GTL, and SME. If delaying recoupment minimizes eventual recovery, delay may not be appropriate. PSCs *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.

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

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

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

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

- o The amount of the original claim;
- o The allowed amount;
- o The rationale for denial;
- o 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);
- o 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
- o 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. 184, Issued: 01-26-07; Effective/Implementation Dates: 02-26-07)

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

3.8.3.3.3 - Consent Settlement Offer

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

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 BI units *and the contractor medical review units* may choose to present the consent settlement letter to the provider or supplier in a face-to-face meeting. The consent settlement correspondence shall describe the two options available to the provider or supplier. The provider or supplier is given 60 days from the date of the correspondence to choose an option. If there is no response, Option 1 shall be selected by default.

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

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

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

- Notify the provider or supplier of the actual overpayment and refer to overpayment recoupment staff; and
- Initiate statistical sampling for overpayment estimation of the provider's or supplier's claims for the service under review following instructions in the Program Integrity Manual, chapter 3, §3.10

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

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

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

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

3.9 – Suspension of Payment

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

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

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

3.9.3.1 – DMERC, *DME MACs* and *DME PSCs*
(Rev. 184, Issued: 01-26-07; Effective/Implementation Dates: 02-26-07)

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

A. The initiating DMERC *or DME MAC* shall get the approval of its lead RO or for *DME PSCs*, the Primary GTL, Associate GTL and SME. CMS' ROs have agreed to support the decision of another RO.

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

C. The lead RO or for PSCs, the Primary GTL, Associate GTL, and SME shall issue one suspension letter on CMS letterhead advising that payments will be held by the DMERC and all *DME MACs* and *DME PSCs*. This letter shall advise the supplier to contact the initiating DMERC, *DME MAC* or *DME PSC* should the supplier have any questions.

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

3.10.1.1 – General Purpose

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

The purpose of this section is to provide instructions for PSC 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 BI units or *contractor MR units*. Reviews that are conducted by the PSC 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 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 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. 184, Issued: 01-26-07; Effective/Implementation Dates: 02-26-07)

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

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

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

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

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

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

For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper

randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are “not statistically valid” cannot legitimately be made. In other words, a probability sample and its results are always “valid.” Because of differences in the choice of a design, the level of available resources, and the method of estimation, however, some procedures lead to higher precision (smaller confidence intervals) than other methods. A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment as is discussed below.

3.10.4.2 - Random Number Selection

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

The PSC BI *unit* or *the contractor* MR unit shall identify the source of the random numbers used to select the individual sampling units. The PSC 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 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 BI *units* or *the contractor* MR units shall document the known seed value if a computer algorithm is used. The PSC 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 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. 184, Issued: 01-26-07; Effective/Implementation Dates: 02-26-07)

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

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

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 BI *units* or *the contractor* MR units shall keep a copy of the frame.

3.10.4.4.3 - Worksheets

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

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

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

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

NOTE: The instructions in this section dealing with notification and determination of location of the review do not supersede instructions for PSC 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. 184, Issued: 01-26-07; Effective/Implementation Dates: 02-26-07)

The PSC 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 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 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 *BI units* or contractor MR units).

3.10.6.1.1 - Written Notification of Review

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

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

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 BI *Unit* or *Contractor* MR Unit Site Reviews

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

3.10.7.1 - Recovery From Provider or Supplier

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

Once an overpayment has been determined to exist, proceed with recovery based on applicable instructions. (See Publication 100-6, Financial Management Manual, chapter 3.) Include in the overpayment demand letter information about the review and statistical sampling methodology that was followed. For PSCs, only ACs *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/issues identified during the review, and any recommended corrective actions.