

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 828	Date: September 28, 2018
	Change Request 10067

SUBJECT: Guidance Regarding the Use of Statistical Sampling for Overpayment Estimation

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update sections 8.4 through 8.4.9.2 in chapter 8 of Publication (Pub.) 100-08, which contain instructions for Unified Program Integrity Contractors (UPICs), Recovery Audit Contractors (RACs), the Supplemental Medical Review Contractor (SMRC), and Medicare Administrative Contractors (MAC) regarding the use of statistical sampling in their reviews and estimation of overpayments. This update will help ensure that a statistically representative sample of the claim universe is drawn that yields an unbiased estimate of an overpayment.

EFFECTIVE DATE: January 2, 2019

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

IMPLEMENTATION DATE: January 2, 2019

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-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	8/TOC/Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation
R	8/8.4/Use of Statistical Sampling for Overpayment Estimation
R	8/8.4/8.4.1.1/General Purpose
R	8/8.4/8.4.1.2/The Purpose of Statistical Sampling
R	8/8.4/8.4.1.3/Steps for Conducting Statistical Sampling
R	8/8.4/8.4.1.4/Reserved for Future Use
R	8/8.4/8.4.1.5/Consultation with a Statistical Expert
R	8/8.4/8.4.1.6/Use of Other Sampling Methodologies
R	8/8.4/8.4.2/Probability Sampling
R	8/8.4/8.4.3.1/Selection of Period for Review
R	8/8.4/8.4.3.2/Defining the Universe, the Sampling Unit, and the Sampling Frame
R	8/8.4/8.4.3.2.1/Composition of the Universe
R	8/8.4/8.4.3.2.2/The Sampling Unit
R	8/8.4/8.4.3.2.3/The Sample Frame
R	8/8.4/8.4.4.1/Sampling Methodology
D	8/8.4/8.4.4.1.1/Simple Random Sampling
D	8/8.4/8.4.4.1.2/Systematic Sampling
D	8/8.4/8.4.4.1.3/Stratified Sampling
D	8/8.4/8.4.4.1.4/Cluster Sampling
D	8/8.4/8.4.4.1.5/Design Combinations
R	8/8.4/8.4.4.2/Random Number Selection
R	8/8.4/8.4.4.3/Determining Sample Size
R	8/8.4/8.4.4.4.1/Documentation of Universe and Sample Frame
R	8/8.4/8.4.4.4.2/Reserved for Future Use
R	8/8.4/8.4.4.4.3/Worksheets
R	8/8.4/8.4.4.5/Maintenance of Documentation
R	8/8.4/8.4.5.1/The Point Estimate
R	8/8.4/8.4.5.2/Calculation of the Estimated Overpayment Amount
R	8/8.4/8.4.6/Actions to be Performed Following Selection of Provider or Supplier and Sample
R	8/8.4/8.4.6.1/Notification of Provider or Supplier of the Review and Selection of the Review Site

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	8/8.4/8.4.6.1.1/Written Notification of Review
R	8/8.4/8.4.6.1.2/Determining Review Site
R	8/8.4/8.4.6.2/Meetings to Start and End the Review
R	8/8.4/8.4.6.3/Conducting the Review
R	8/8.4/8.4.7.1/Recovery from Provider or Supplier
D	8/8.4/8.4.7.2/Informational Copy to Primary GTL, Associate GTL, SME or CMS RO
R	8/8.4/8.4.8/Corrective Actions
R	8/8.4/8.4.9/Changes Resulting From Appeals
R	8/8.4/8.4.9.1/Sampling Methodology Overturned
R	8/8.4/8.4.9.2/Revised Initial Determination
D	8/8.4/8.4.10/Resources (Non-Exhaustive List)
D	8/8.4/8.4.11/Additional Discussion of Stratified Sampling and Cluster Sampling
D	8/8.4/8.4.11.1/Stratified Sampling
D	8/8.4/8.4.11.2/Cluster Sampling

III. FUNDING:

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CFW	
10067.2.1	The contractors shall contact its business function lead, COR, or alternate COR prior to issuing the findings letter to the provider or supplier.									UPICs
10067.3	As stated in chapter 8, section 8.4.7.1 of Pub. 100-08, the contractors shall include, in the Final Review Results sent to the provider/supplier, information about the review and statistical sampling methodology that was utilized for estimation.	X	X		X					RAC, SMRC, UPICs

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Frank Whelan, 410-786-1302 or frank.whelan@cms.hhs.gov , Nadya Soto, 410-786-4153 or nadya.soto@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare Program Integrity Manual

Chapter 8 – Administrative Actions *and Sanctions* and Statistical Sampling for Overpayment *Estimation*

(Rev. 828, Issued: 09-28-18)

Transmittals for Chapter 8

- 8.4.3.2.3 – The *Sample* Frame
- 8.4.4.1 – *Sampling Methodology*
 - 8.4.4.4.1 – Documentation of Universe and *Sample* Frame
 - 8.4.4.4.2 – *Reserved for Future Use*
- 8.4.4.5 – *Maintenance of Documentation*

8.4 - Use of Statistical Sampling for Overpayment Estimation

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

This section applies to UPICs, RACs, the SMRC, and MACs (including DME MACs), hereinafter referred to as “contractors.” With regard to RACs and the SMRC, RACs and SMRC are required to receive CMS COR approval through each step of the statistical sampling process as certain steps/requirements may not be applicable or used in all instances.

8.4.1.1 – General Purpose

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The purpose of this section is to provide instructions for *contractors* on the use of statistical sampling in their reviews *and estimation of overpayments* to be recovered by recoupment, offset, or otherwise. *The intent of these instructions is to ensure that a probability sample drawn from the sampling frame of the target population yields an estimate of an overpayment in the target population. This means that every element in the sampling frame has a non-zero probability of being selected. It is important to note that this is consistent with methodologies such as stratification and cluster sampling as needed to warrant statistically sound inferences from the sample.* Reviews conducted by the *contractors* to assist law enforcement with the identification, case development, and/or investigation of suspected fraud or other unlawful activities may use sampling methodologies that differ from those prescribed herein. *However, in those cases, the methodologies used shall be well-accepted methodologies amongst statisticians, and complete explanation shall be provided for why the methodology used was the appropriate methodology in the situation.*

These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by a *contractor* 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 and must demonstrate actual error in the methodology that affects the overpayment amount.* Failure by the *contractor* to follow one or more of the requirements *contained herein* 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.*

8.4.1.2 - The Purpose of Statistical Sampling

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

A statistical sample is used to estimate the amount of overpayment(s) made on claims. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), mandates that before using extrapolation (*i.e., projection, extension, or expansion of known data*) to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error. By law, the determination that a sustained or high level of payment error exists is not subject to administrative or judicial review. *In this chapter, details are provided on the use of statistical estimation (sometimes, especially in legal contexts, referred to as “extrapolation”) to determine overpayment amounts.*

8.4.1.3 - Steps for Conducting Statistical Sampling

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The major steps in conducting statistical sampling are --

- (1) Identifying the provider/*supplier*;
- (2) *Identifying* the period to be reviewed;
- (3) Defining the universe (*target population*) and the sampling unit, and constructing the sampling frame;

- (4) *Assessing the distribution of the paid amounts in the sample frame to determine the sample design; it is very likely that the distribution of the overpayments will not be normal. However, there are many sampling methodologies (for example, use of the Central Limit Theorem) that may be used to accommodate non-normal distributions. The statistician should state the assumptions being made about the distribution and explain the sampling methodology selected as a result of that distribution.*
- (5) *Performing the appropriate assessment(s) to determine whether the sample size is appropriate for the statistical analyses used, and identifying, relative to the sample size used, the corresponding confidence interval;*
- (6) *Designing the sampling plan and selecting the sample from the sampling frame;*
- (7) *Examining each of the sampling units and determining if there was an overpayment or an underpayment; and*
- (8) *Estimating the overpayment. When an overpayment has been determined to exist, the contractor shall follow applicable instructions for notification and collection of the overpayment, unless otherwise directed by CMS.*

For each step, the contractor shall provide complete and clear documentation sufficient to explain the action(s) taken in the step and to replicate, if needed, the statistical sampling.

8.4.1.4 – Determining When Statistical Sampling May be Used

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The contractor shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error. For purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to:

- *high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review);*
- *provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices);*
- *CMS approval provided in connection to a payment suspension;*
- *information from law enforcement investigations;*
- *allegations of wrongdoing by current or former employees of a provider/supplier; and/or*
- *audits or evaluations conducted by the OIG.*

When an overpayment is identified by data analysis alone, the contractor shall consult with its Contracting Officer's Representative (COR)/Business Function Lead (BFL) as defined in PIM Chapter 4, §4.7 – Investigations. In addition, if CMS approves the data driven overpayment, the contractor shall also consult with its COR/BFL on whether statistical sampling and extrapolation are necessary to identify the overpayment.

If the contractor believes that statistical sampling and/or extrapolation should be used for purposes of estimation, and it does not meet any of the criteria listed above, it shall consult with its COR and BFL prior to creating a statistical sample and issuing a request for medical records from the provider/supplier. Examples of this may include, but are not limited to: billing for non-covered services, billing for services not rendered, etc. Extrapolation should not be used when the above criteria is not met unless prior approval is given by the COR and BFL.

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

8.4.1.5 - Consultation with a Statistical Expert

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The sampling methodology *used in estimations of* overpayments must be *reviewed and approved* by a statistician or by a person with equivalent expertise in probability sampling and estimation methods. This is done to ensure that a statistically appropriate sample is drawn, and that *appropriate* methods for *estimating the* overpayments *are* followed. The *contractor* shall obtain from the statistical expert a written approval of the methodology for the type of statistical sampling to be performed. *Regardless of whether* this sampling methodology is applied routinely and repeatedly, *each time a sample size calculation or estimation is performed, a detailed methodology (See Section 8.4.7.1.) should be submitted by the statistical expert to the corresponding contractor.*

Prior to releasing a findings letter or overpayment demand letter, the *contractor* shall have the statistical expert review the results of the sampling *and any other subsequent overpayment estimation or extrapolation. The contractor shall verify that the statistical findings have been reviewed and agreed to by the contractor.*

If questions or issues arise, the *contractor* shall also involve the statistical expert.

At a minimum, the statistical expert (either on-staff or consultant) *shall meet one of the following criteria:*

- *Have significant coursework in probability and estimation methodologies, and at least 10 years of experience applying methods of statistical sampling and interpreting the results.*
- *Possesses a Bachelor's degree (e.g., B.A., B.S.) in statistics or in some related field (e.g., psychometrics, biostatistics, econometrics, mathematics) with significant coursework in probability and estimation methodologies, and at least 6 years of experience applying methods of statistical sampling and interpreting the results.*
- *Possesses a Master's degree (e.g., M.A., M.S.) in statistics or in some related field with significant coursework in probability and estimation methodologies, and at least 4 years of experience applying methods of statistical sampling and interpreting the results.*
- *Possess a Doctoral degree in statistics or in some related field with significant coursework in probability and estimation methodologies, and at least 1 year of experience applying methods of statistical sampling and interpreting the results.*

If the *contractor* does not have staff with sufficient statistical experience as outlined here, it shall obtain such expert assistance prior to conducting statistical sampling.

8.4.1.6 - Use of Other Sampling Methodologies

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

Once it has been determined that statistical sampling may be used, nothing in these instructions precludes CMS *or its contractor* from relying on statistically *sound* sampling methodologies employed by other law enforcement agencies, including but not limited to the OIG, the DOJ, *and/or* the FBI. In these cases, a full explanation shall be provided explaining why the methodology was used and why it was statistically appropriate in the circumstances.

Where it is foreseen that the results of a *contractor's* review may be referred to law enforcement or another agency *to support* litigation or other law enforcement actions, the *contractor* shall discuss specific litigation and/or other requirements as they relate to statistical sampling with its statistical expert prior to undertaking the review to ensure that the review will meet their requirements and that such work will be funded accordingly.

8.4.2 - Probability Sampling

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

Regardless of the method of sample selection used, *the contractor* 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. *All that is required is* that one could, in *principle*, write down the samples, the sampling units contained therein, and the *relevant* probabilities; and
- Each sampling unit in each distinct possible sample must have a known probability of selection. *In the case of* 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.

Once a procedure *and design* that satisfies these *above* properties *has been selected, execution of the probability sampling may occur*. 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 *or that the* resulting estimates are “not statistically valid” cannot legitimately be made. In other words, a probability sample and its results are always “valid.” *However*, because of differences in the choice of a design, the level of available resources, and the method of estimation, some procedures lead to higher precision (smaller confidence intervals) than other methods. A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment as is discussed below.

8.4.3.1 - Selection of Period for Review

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

Following selection of the provider or supplier, *the contractor in conjunction with a statistical expert shall* determine the time period and the number of days, weeks, months, or years for which sampling units will be reviewed. *For RACs and SMRC, CMS will approve the time period*. The target universe shall be *selected based on these criteria*. The *scope of the* review is determined by considering several factors *that include, but are not limited to*:

- How long the pattern of sustained or high level of payment error is believed to have existed,
- The volume of claims that are involved,
- The length of time that a national coverage decision or local coverage *determination* has been in effect,
- The extent of prepayment review already conducted or currently being conducted,
- The dollar value of the claims that are involved relative to the cost of the sample,
- The applicable time periods for reopening claims (see *Pub. 100-04*, chapter 34, *section* 10.6),
- *A clear specification of the specific data elements to be used for defining the date (type of date, e.g., day, month, year).*

As examples: If dates of service are used, specify, as needed, whether the dates are line service dates or claim service dates, the first day of the billing statement or the ending date of service, etc. If a span of dates is used, clarify the criteria used when the span overlaps the boundary of one of

the other criterion date ranges. If paid dates or receipt dates are used, clarify the role of the adjusted claims.

All case documentation, including the overpayment demand letter and methodology, should consistently reflect the same date range and specify the same type of date.

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

8.4.3.2 - Defining the Universe, the Sampling Unit, and the Sampling Frame *(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)*

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

The universe includes all claim lines that meet the selection criteria. The sampling frame is the listing of sample units, derived from the universe, from which the sample is selected. However, in some cases, the universe may include items that are not utilized in the construction of the sample frame. This can happen for a number of reasons, including, but not limited to:

- 1. Some claims/claim lines are discovered to have been subject to a prior review,*
- 2. The definitions of the sample unit necessitates eliminating some claims/claim lines, or*
- 3. Some claims/claim lines are attributed to sample units for which there was no payment.*

All information needed to recreate the sample frame and sample shall be included in the case documentation.

The sample frame is normally constructed from the universe after the sample unit has been defined. The sampling frame includes all sample units which were paid (as appropriately interpreted for the type of reimbursement). When sample units are clusters, there may be lines or claims included which did not individually generate payment.

Other approaches to constructing the universe and sample frame are possible depending on the specific circumstances. One possibility is that the sample frame may be created first (for example, a list of beneficiaries) and then the universe corresponding to the sample frame may be constructed by querying claims history for the matching claims. Regardless of the process that is followed, the documentation in the case file must include a list of all sample units in the sample frame, all the universe elements that are incorporated into those sample units, and the elements in the universe. It must be possible to assemble the sample units from the universe during the replication process.

8.4.3.2.1 - Composition of the Universe *(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)*

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

For providers/*suppliers* reimbursed under PPS, the universe of claims from which the sample is selected will consist of all fully and partially paid claims submitted by the provider/*supplier* for the period under review. *Sample units with no final payment made at the time of sample selection should*

not be included in the sample frame. Claims with no payment may be included in the universe from which the sample frame is constructed and should be excluded when establishing the sample frame.

B. Part B Claims: The universe shall consist of all fully and partially paid claims submitted by the *provider/supplier* for the period selected for review and for the sampling units to be reviewed. For example, if the review is of Physician X for the period January 1, 2002 through March 31, 2002, and laboratory and other diagnostic tests have been selected for review, the universe would include all fully and partially paid claims for laboratory and diagnostic tests billed by that physician for the selected time period. For some reviews, the period of review may best be defined in terms of the date(s) of service because changes in coverage policy may have occurred. *Sample units with no final payment made at the time of sample selection should not be included in the sample frame. Claims with no payment may be included in the universe from which the same frame is constructed.*

8.4.3.2.2 - The Sampling Unit

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

Sampling units are the elements that are selected *based on* the chosen method of statistical sampling. They may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary). For example, possible sampling units may include specific beneficiaries seen by a physician during the time period under review, or claims for a specific item or service. In certain circumstances (e.g., multi-stage sample designs), other types of clusters of payments may be used.

Certain sampling theorems require an assumption that sampled items are “identically and independently distributed” (iid). In sampling from a finite universe without replacement, there is always a certain amount of dependence because the probability of selection changes with each unit that is selected. However, correlations of characteristics in the target population do not imply dependence in sampling. Sampling units may be correlated because they come from the same location, the same provider/supplier, the same time period, or any number of other reasons. In this context, independence means the selection of one sampling unit does not influence, or gives no information about, the outcome of another selection. Overpayments are not random variables. They are fixed values, though unknown prior to sampling. Therefore, regardless of any correlation that may exist between sample units, the outcome, or overpayment, of any particular unit does not change based on the outcomes of other units.

Unlike procedures for suppliers, *overpayment estimation* and recovery procedures for providers/suppliers and non-physician practitioners who bill *Part A MACs*, in a non-PPS environment, must be designed so that overpayment amounts can be accurately reflected on the provider’s cost report. Therefore, sampling units must coincide with an *estimation methodology* designed specifically for that type of provider/supplier to ensure that the results can be placed at the appropriate points on the cost report. The sample may be either claim-based or composed of specific line items. For example, home health cost reports are determined in units of “visits” for disciplines 1 through 6 and “lower of costs or charges” for drugs, supplies, etc. If claims are paid under cost report, the services reviewed and how those units link to the provider/supplier’s cost report must be known. *The contractor shall follow the instructions contained in section 8.4 et seq.*, but use the projection methodologies provided in *Pub. 100-08*, Exhibits 9 through 12, for the appropriate provider type. *Pub. 100-08*, Exhibits 9 through 12, are to be used only for claims not paid under PPS.

8.4.3.2.3 - The Sample Frame

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

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

8.4.4.1 - Sampling Methodology

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The contractor shall identify the sampling methodology to be followed. There are various ways a probability sample can be generated. The most appropriate method will depend on factors such as, the target universe and the resources available for sampling. (Refer to section 8.4.1.5 of this chapter regarding consultations with a statistical expert to determine the appropriate methodology.)

8.4.4.2 - Random Number Selection

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The *contractor* shall identify the source of the random numbers used to select the individual sampling units, *if used*. The *contractor* shall also document the program and its algorithm or table, when available, that is used; this documentation becomes part of the record of the sampling and must be available for review. The *contractor* shall document any starting point if using a random number table or drawing a systematic sample. In addition, the *contractor* shall document the known seed value if a computer algorithm is used. The *contractor* 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 through the *HHS-OIG* website. 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 *contractor's* statistician or systems programmer shall determine which package is best suited to the problem being reviewed.

8.4.4.3 - Determining Sample Size

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The size of the sample (i.e., the number of sampling units *constituting the sample*) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. It is neither possible nor desirable to specify a minimum sample size that applies to all situations.

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 *the entire* target population. In *determining* the sample size to be used, the *contractor* shall also consider *its* 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 *and overpayment estimation* have been followed. *Some challenges* to the validity of the sample that *are* sometimes made *include whether -- (1) The probability sample was chosen and drawn in a statistically appropriate way from the target population or (2) The particular sample size is too small to yield meaningful results. Such challenges are without merit when presented in isolation from any reference to the actual sample methodology used, and when presented without a complete account of the actual sample methodology used.*

8.4.4.4 - Documentation of Sampling Methodology

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The *contractor* shall maintain complete documentation of the sampling methodology that was followed.

8.4.4.4.1 - Documentation of Universe and *Sample* Frame

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

An explicit statement of how the universe is defined and elements included shall be made and maintained in writing. Further, the *sample* 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 *the contractor's* record of how the sampling was done. *If the sample frame does not contain the elements used to define the universe because the sampling unit does not permit it, then an electronic copy of the universe will be kept by the contractor.*

A record shall be kept of the random numbers used (*if used*) in the sample and how they were selected. Documentation shall be kept in sufficient detail so that the *sample* frame can be re-created should the methodology be challenged. The *contractor* shall keep *an electronic* copy of the *sample* frame.

8.4.4.4.2 – *Reserved for Future Use*

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

8.4.4.4.3 – Worksheets

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The *contractor* shall maintain *any formal* worksheets used by reviewers. *The worksheets* may include, *but are not limited to data and information, such as:*

- Name and identification number of the provider or supplier;
- Name and title of reviewer;
- The HICN/MBI, 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);
- *Other* information required by cost report worksheets in *Pub. 100-08*, Exhibits 9 through 12;
- The amount paid;
- The amount that should have been paid (either over or underpaid amount); *and*
- The date(s) of service.

8.4.4.5 – *Maintenance of Documentation*

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The *contractor* shall *maintain all documentation pertinent to the calculation of an estimated overpayment including but not limited to* the statistician-approved sampling methodology, *universe, sample frame and formal worksheets*. *The documentation must be sufficient to allow for any future replication and/or validation by an administrative or judicial body.*

8.4.5.1 - The Point Estimate

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

In most situations, the lower limit of a one-sided 90 percent confidence interval *should* be used as the amount of overpayment to be demanded for recovery from the provider/supplier. 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/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 *contractor* is not precluded from demanding the point estimate where high precision has been achieved, and when there are statistically sound reasons for the demand.

8.4.5.2 - Calculation of the Estimated Overpayment Amount

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

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

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

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

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

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

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The *contractor* shall first determine whether it will be giving advance notification to the provider or supplier of the review. Although in most cases the *contractor conducting the review* shall give prior notification, the provider/supplier is not always notified before the start of the review. When not giving advance notice, the *contractor* shall obtain the advance approval of the *BFL/COR*. When giving advance notice, *the contractor shall* provide written notification by certified mail with return receipt requested (retain all receipts).

Second, regardless of whether advance notice *is provided*, *the contractor* shall determine where to conduct the review of the medical and other records: either at the provider's/supplier's site(s) or at *the contractor's* office.

8.4.6.1.1 - Written Notification of Review

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The contractor 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 *the sampling* results *will be used to estimate the total overpayment* 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 *contractor* site reviews) or make available (for provider/supplier site reviews) the requested documentation. *The contractor shall* advise the provider or supplier that for requested documentation that is not submitted or made available by the end of 30 calendar days, *the contractor* will start the review and will deny those claims for which there is no documentation. The time limit for submission or production of requested documentation may be extended at *the contractor's* discretion.

NOTE: *The contractor need* not request all documentation at the time of notification of review; for example, *the contractor* may decide to request one-half of the documentation before *the contractor* arrives, and then request the other half following *the contractor's* arrival at the provider/supplier's site.

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

8.4.6.1.2 - Determining Review Site

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

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

B. Contractor Site Reviews

The *contractor* site reviews are performed at a location of the *contractor*.

8.4.6.2 - Meetings to Start and End the Review

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

In-person meetings to start and end the review are encouraged, but are not required or always feasible. If *the contractor* holds an in-person meeting at the start of the review, *the contractor shall* explain both the scope and purpose of the review as well as discuss what will happen once *the review is completed*. *The contractor shall* attempt to answer all questions of the provider/supplier related to the review.

During an exit meeting, *the contractor* may discuss the basic or preliminary findings of the review. *The contractor shall* give the provider/supplier an opportunity to discuss or comment on the claims decisions that were made. *The contractor shall also* advise the provider or supplier that a demand letter detailing the results of the review and the statistical sampling will be sent if an overpayment is determined to exist.

8.4.6.3 - Conducting the Review

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

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

The contractor shall document: (1) All findings made so that it is apparent from *the contractor's* written documentation if the initial determination has been reversed, and (2) The amount of all overpayments and underpayments and how they were determined.

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

The contractor's documentation of overpayment and underpayment determinations *must* be clear and concise. *The contractor shall* include copies of the local *coverage determination* and any applicable references needed to support individual case determinations. Compliance with these requirements facilitates adherence to the provider and supplier notification requirements.

8.4.7.1 - Recovery from Provider or Supplier

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

Once an overpayment has been determined to exist, *the contractor shall* proceed with recovery based on applicable instructions, *unless otherwise directed by CMS*. (See Pub. 100-6, chapter 3.) *The contractor shall obtain approval from CMS prior to issuing a findings letter to the provider/supplier when the estimated overpayment exceeds \$500,000 or is an amount that is greater than 25% of the provider's/supplier's Medicare revenue received within the previous 12 months. Accordingly, the contractor shall contact its BFL/COR prior to issuing the findings letter to the provider/supplier. The contractor shall provide the BFL/COR a summary of the investigation (if applicable), any prior history (if applicable), the medical review results (including denial reasons), and the extrapolated overpayment amount in a format agreed upon by the BFL/COR. Extrapolated overpayments meeting one of these criteria shall not be issued unless prior approval is supplied by the BFL/COR.*

The contractor shall include in the overpayment demand letter information about the review and statistical sampling methodology that was followed. Only MACs shall issue demand letters and recoup the overpayment. *In the Final Review Results sent to the provider/supplier, the contractor shall include information about the review and statistical sampling methodology that was utilized for estimation.*

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

- A description of the universe, the *sample* frame, and the *sampling methodology*,
- 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 overpayment estimation, the overpayment estimation methodology, and the calculated sampling error; and*
- *The amount of the actual overpayment/underpayment from each of the claims reviewed.*

The contractor shall also include a list of any problems/issues identified during the review and any recommended corrective actions.

8.4.8 - Corrective Actions

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

The contractor shall take or recommend other corrective actions *it deems* necessary *and consistent with the contractor's authority* (such as payment suspension, imposition of civil money penalties, institution of pre- or post-payment review, additional edits, etc.) based upon *its* findings during or after the review.

8.4.9 - Changes Resulting From Appeals

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

If the decision issued on appeal contains either a finding that the sampling methodology was *invalid* or reverses the revised initial claim determination, *the contractor* shall take appropriate action to adjust the *estimation* of overpayment *with the revised input of the statistical expert who created the initial methodology or the revised input of another statistical expert supplied by the contractor should the creator of the initial methodology no longer be available.*

8.4.9.1 - Sampling Methodology Overturned

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

If the decision issued on appeal contains a finding that the sampling methodology was *invalid*, there are several options for revising the estimated overpayment based upon the appellate decision:

- A. If the decision issued on appeal permits correction of errors in the sampling methodology, *the contractor* shall revise the overpayment determination after making the corrections. *The contractor shall* consult with *its BFL/COR* to confirm that this course of action is consistent with the decision of the *MAC, Qualified Independent Contractor (QIC), Administrative Law Judge (ALJ), Medicare Appeals Council (the Council) within the Departmental Appeals Board (DAB), or Federal District Court.*
- B. *The contractor* may elect to recover the actual overpayments related to the sampled claims and then initiate a new review of the provider or supplier. If the actual overpayments related to the sampling units in the original review have been recovered, these individual sampling units shall be eliminated from the *sample* frame used for any new review. *The contractor shall* consult with *its BFL/COR* to confirm that this course of action is consistent with the decision of the *MAC, QIC, ALJ, the Council or Federal District Court.*
- C. *The contractor* may conduct a new review (using a new, valid methodology) for the same time period covered by the previous review. If this option is chosen, *the contractor* shall not recover the actual overpayments on any of the sample claims found to be in error in the original sample. Before employing this option, *the contractor shall* consult with *its BFL/COR* to verify that this course of action is consistent with the decision of the *MAC, QIC, ALJ, Council, or the Federal District Court.*

8.4.9.2 - Revised Initial Determination

(Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19)

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