CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11797	**Date: January 19, 2023**
	Change Request 13066

SUBJECT: Updates of Chapters 4 and 8 in Publication (Pub.) 100-08, Including an Update to the Statistical Sampling Process, in Addition to Various Other Minor Updates

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update sections within Chapter 4 and 8 in Pub. 100-08. The updates in this CR include revising a section within Chapter 8 regarding the statistical sampling process for Program Integrity contractors. Various other sections within Chapter 4 in Pub. 100-08 are also being revised.

EFFECTIVE DATE: February 21, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: February 21, 2023

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	4/4.2/4.2.2/4.2.2.8.1.4/UPIC Coordination with Other Contractors Related to the RAC Data Warehouse
R	4/4.7/4.7.3/4.7.3.1/Supplier Proof of Delivery Documentation Requirements
R	4/4.7/4.7.4/4.7.4.1/Production of Medical Records and Documentation for an Appeals Case File
R	8/8.4/8.4.1/8.4.1.4/Determining When Statistical Sampling May Be Used
R	8/8.4/8.4.3/8.4.3.2/Defining the Universe, the Sampling Unit, and the Sampling Frame
R	8/8.4/8.4.5/Calculating the Estimated Overpayment
D	8/8.4/8.4.5/8.4.5.1/The Point Estimate
D	8/8.4/8.4.5/8.4.5.2/Calculation of the Estimated Overpayment Amount

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 11797	Date: January 19, 2023	Change Request: 13066

SUBJECT: Updates of Chapters 4 and 8 in Publication (Pub.) 100-08, Including an Update to the Statistical Sampling Process, in Addition to Various Other Minor Updates

EFFECTIVE DATE: February 21, 2023
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IMPLEMENTATION DATE: February 21, 2023

I. GENERAL INFORMATION

A. Background: Based on updates to the Unified Program Integrity Contractor (UPIC) and Investigations Medicare Drug Integrity Contractor processes, we will revise various sections in Chapter 4 and 8 of Pub. 100-08, Program Integrity Manual.

B. Policy: This CR does not involve any legislative or regulatory policies.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13066.1	The contractor shall be aware that states are not required for National Provider Identification numbers, National Provider Enrollment (NPE) numbers, alphanumeric or Provider Transaction Access Numbers that are other than six digits long.									UPICs
13066.2	The contractor shall be aware that suppliers that consistently do not provide documentation to support that their items were delivered may be referred to the Office of Inspector General or									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	NPE for investigation and/or imposition of sanction.									
13066.3	The contractor shall send medical records and/or documentation for an appeals case file on the next business day, if the 5th business day falls on an observed holiday where either the Unified Program Integrity Contractor or MAC is closed for business.									UPICs
13066.4	The contractor shall be aware that for purposes of extrapolation, a sustained or high level of payment error shall be determined to exist through a high error rate determination by the contractor or by other medical reviews compared to similar service providers.									UPICs
13066.5	The contractor shall consult with its Contracting Officer's Representative (COR) and Business Function Lead (BFL), as defined in Chapter 4, section 4.7 (Investigations) of Pub. 100-08, prior to creating a statistical sample and issuing a request for medical records from the provider/supplier									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	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 in Chapter 8, section 8.4.1.4 (Determining When Statistical Sampling May Be Used) of Pub. 100-08.									
13066.6	The contractor shall consult with its COR and BFL when an overpayment is identified by data analysis alone.									UPICs
13066.6.1	The contractor shall consult with its COR and BFL on whether statistical sampling and extrapolation are necessary to identify the overpayment, if CMS approves the data driven overpayment.									UPICs
13066.7	The contractor shall be aware that the universe is the target population that lists all claims/claim lines potentially under review and is used to construct the sampling frame.									UPICs
13066.8	The contractor shall be aware that the sampling frame lists all sampling units which may be selected by the statistical sampling									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	software.									
13066.8.1	The contractor shall be aware that the sampling frame further refines the review criteria from the claims/claim lines listed in the universe.									UPICs
13066.8.2	The contractor shall be aware that the sampling unit may be the claim line, or may be a higher-level unit such as: 1. The claim/claim number, or 2. A cluster of claims/claim lines associated with a patient, or 3. A cluster of claims/claim lines associated with a treatment "day," or 4. Any other sampling unit appropriate for the issue under review.									UPICs
13066.9	The contractor shall be aware that an auditor may refine the selection criteria during the construction of the sampling frame, for example: 1. Excluding claims/claim lines that									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	have been subject to a prior review, or 2. Excluding claims/claim lines for which there was no payment, or 3. Excluding claims/claim lines which cannot be assigned to a sample unit due to missing information.									
13066.10	The contractor shall be aware that the extrapolation estimate of total overpayments is an estimate of total overpayment for sampling units in the sampling frame.									UPICs
13066.11	The contractor shall be aware that the results of the sampling unit reviews are used to calculate an estimate of the overpayment amount.									UPICs
13066.11.1	The contractor shall be aware that 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.									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13066.11.2	The contractor shall be aware that this conservative procedure incorporates the uncertainty inherent in the sample design.									UPICs
13066.11.2.1	The contractor shall be aware that this conservative procedure works to the financial advantage of the provider/supplier.									UPICs
13066.11.2.2	The contractor shall be aware that it yields a demand amount for recovery that is very likely less than the true amount of overpayment.									UPICs
13066.11.2.3	The contractor shall be aware that it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate.									UPICs
13066.11.3	The contractor shall be aware that they not preclude from demanding the point estimate where high precision has been achieved.									UPICs
13066.11.4	The contractor shall be aware that they not preclude from demanding the point estimate when there are statistically sound reasons for the demand.									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13066.12	The contractor shall be aware that standard methods for calculating a one-sided 90 percent confidence interval, such as those based on the central limit theorem or others found in standard statistics texts and journals, are generally acceptable.									UPICs
13066.12.1	The contractor shall be aware that it may not be feasible to guarantee 90 percent coverage in all circumstances (i.e., that the lower bound of the 90 percent confidence interval is below the true overpayment in 90 percent of audits) due to the use of theoretical assumptions underlying standard statistical methods.									UPICs
13066.12.1.1	The contractor shall be aware that application of these methods is generally appropriate.									UPICs
13066.13	The contractor shall be aware that in some cases, the point estimate or the lower bound of the estimate for the total overpayment in the sampling frame may be greater than the total payment in the sampling frame.									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13066.13.1	The contractor shall be aware that this is expected to occur frequently when the true overpayment is high.									UPICs
13066.13.2	The contractor shall be aware that the use of the lower bound to calculate the demand amount continues to operate in accounting for uncertainty in the estimate and providing a methodology that is generally favorable toward the provider.									UPICs
13066.13.3	The contractor shall be aware that if the point estimate of overpayment is greater than the total payment in the sampling frame, but the lower bound is less than total payment, then the lower bound may be demanded.									UPICs
13066.13.4	The contractor shall be aware that if the lower bound of the estimated overpayment is greater than total payment, the demand amount shall be reduced from the lower bound to the total payment amount in the sampling frame to avoid demanding more than originally paid.									UPICs
13066.14	The contractor shall									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	record the result of each sampling unit review.									
13066.14.1	The contractor shall set a sampling unit's overpayment 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).									UPICs
13066.14.2	The contractor shall set a sampling unit's overpayment to zero if 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.									UPICs
13066.14.3	The contractor shall be aware that sampling units for which the requested records were not provided are to be treated as improper payments (i.e., as overpayments).									UPICs
13066.14.4	The contractor shall record sampling units that are found to be underpayments, in whole or in part, as negative overpayments and shall be used in calculating the									UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	estimated overpayment.									
13066.14.5	The contractor shall use sampling units that are found to be underpayments, in whole or in part, in calculating the estimated overpayment.									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): Jesse Havens, 410-786-6566 or jesse.havens@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 4 - Program Integrity

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(Rev. 11797; Issued: 01-19-23)

4.2.2.8.1.4 – UPIC Coordination with Other Contractors Related to the RAC Data Warehouse

(Rev. 11797; Issued: 01-19-23; Effective: 02-21-23; Implementation: 02-21-23)

This section applies to UPICs, RACs, MACs, CERT, and SMRC as indicated.

The CMS established the RAC Data Warehouse (RACDW) to track RAC activity and prevent conflicts between RAC reviews and other program integrity activities. The success of this mission depends on timely and accurate information reporting by the UPICs, as well as by claims processing contractors and by the RACs themselves. CMS has expanded the functionality of the RACDW to allow all contractors that perform medical review to collaborate so there is no duplication of effort.

To prevent other contractors from interference with active investigations or cases, UPICs shall enter suppressions in the RAC Data Warehouse to temporarily mark entire providers/suppliers or subsets of a provider's/supplier's claims as "off-limits" to the RACs, MACs, CERT, and SMRC. The suppression must be entered in the RACDW when the investigation is opened, but no later than 2 business days after the investigation is opened.

Individual claims that have been previously reviewed (or that are part of an extrapolated settlement universe) shall be excluded to permanently block them from repeat reviews by a RAC, MAC, CERT, or SMRC.

The RAC Data Warehouse allows users to enter suppressions on any combination of provider ID, Diagnostic Related Group (DRG), International Classification of Diseases-9/10 (ICD- 9/10) procedure code, Healthcare Common Procedure Coding System (HCPCS) code, State, or ZIP code although CMS requires that suppressions be tailored as narrowly as possible.

UPICs shall suppress targeted procedure codes from specific providers/suppliers associated with open investigations/cases. Suppressions of one or more procedure codes across an entire geographic area may be considered in egregious situations of widespread fraud, waste and/or abuse of specific codes or types of services (e.g., infusion therapy in South Florida).

The Data Warehouse can accept suppressions on a rendering provider, supplier, or institution ID. Suppressions on referring, ordering, billing (for professional DME claims) and attending providers (institutional claims) are not currently supported.

Whether suppressing an entire provider or only a portion of a provider's claims, the UPIC shall indicate the nature of the provider being suppressed (i.e., hospital, individual physician, physician group, home health agency, etc.) in the provider type field, using the codes specified in the Data Warehouse. The UPIC shall also indicate the name of the provider being suppressed in the comment field, which can accommodate up to 256 characters.

When entering a suppression on a six-digit provider/supplier ID, the UPIC shall also enter the provider's/supplier's practice State. States are not required for NPIs, *National Provider Enrollment (NPE)* numbers, alphanumeric or PTANs that are other than six digits long; but six-digit PTANs potentially overlap with six-digit CMS institutional provider numbers. Having the provider/supplier state will help CMS suppression reviewers to differentiate among multiple providers/suppliers with the same ID.

Specific suppression start and end dates are also mandatory. Suppressions can extend up to three (3) years into the past and one (1) year forward from date of entry (the start date is initially fixed at 10/1/2007, which is the earliest start date that RACs can select for their reviews). Users will be notified as their suppressions approach the expiration dates and can

renew them if necessary. CMS expects users to release them sooner if the underlying investigations/cases are closed.

Once a suppression is lifted or expires, UPICs are also responsible for entering any necessary exclusions. Any claims for which the UPIC has requested medical records shall be excluded to prevent re-review by a RAC.

In addition, the UPICs shall review the RACDW to determine if other contractors currently have a particular provider under review. If the provider is under review by another contractor (RAC, MAC, CERT, SMRC) the UPIC shall contact that respective contractor to determine which entity should continue to review that provider and how to handle the current medical review,
i.e. close it out or complete the medical review and then refer to the UPIC.

Below are examples of suppressions and exclusions in various circumstances: this list is not all-inclusive. The UPIC staff may need to consult with its respective CMS COR and BFLs and/or CMS RAC liaison to determine the appropriate level of suppression or exclusion.

4.7.3.1 – Supplier Proof of Delivery Documentation Requirements

(Rev. 11797; Issued: 01-19-23; Effective: 02-21-23; Implementation: 02-21-23)

This section applies to UPICs. This section is applicable to DME MACs, RACs, SMRC, and CERT MR contractors, as noted in Ch. 5, Section 5.8. Suppliers are required to maintain proof of delivery documentation in their files. Proof of delivery documentation must be maintained in the supplier's files for seven years (starting from the date of service).

Section 1833(e) grants Medicare contractors the authority to request any information necessary to determine the amounts due. This includes proof of delivery in order to verify that the beneficiary received the DMEPOS item and thus to determine the amounts due to the provider. Proof of delivery is also one of the supplier standards as noted in 42 CFR § 424.57(c)(12). If the UPIC has reason to be concerned that Medicare was billed for an item that was not received (such as a complaint from a beneficiary about non-receipt), the UPIC shall request proof of delivery from the supplier. Proof of delivery documentation must be made available, within the prescribed timeframes, to the UPIC upon request. For any items that do not have proof of delivery from the supplier, such claimed items shall be denied by the UPIC and overpayments recovered. Suppliers that consistently do not provide documentation to support that their items were delivered may be referred to the OIG or *NPE* for investigation and/or imposition of sanctions.

4.7.4.1 - Production of Medical Records and Documentation for an Appeals Case File

Rev. 11797; Issued: 01-19-23; Effective: 02-21-23; Implementation: 02-21-23)

When the UPIC denies a claim and the provider, supplier, physician or beneficiary appeals the denial, the MAC shall request the medical records and documentation that the UPIC used in making its determination. The UPIC shall assemble the case file and send it to the MAC within five (5) business days. If the MAC request is received outside of normal business hours or on an observed holiday that the UPIC is closed for business, the first business day will not be counted until the first business day after receipt of the request (i.e., if received on Saturday, the following Monday will be counted as the first business day). *If the 5th business day falls on an observed holiday where either the UPIC or MAC is closed for business, documentation shall be sent on the next business day.*

The UPIC shall include any position papers or rationale and support for its decision so that the appeals adjudicator can consider it during the appeals process. However, UPICs shall be

aware that an appeals case file is discoverable by the appellant. This means that the appellant can receive a complete copy of the case file. Since the provider may receive the case file, the UPIC shall consult with law enforcement before including any sensitive information relative to a case.

If the UPIC would like to be notified of an Administrative Law Judge (ALJ) hearing on a particular case, the UPIC shall put a cover sheet in the case file before sending it to the MAC. The cover sheet shall state that the UPIC would like to be notified of an ALJ hearing and list a contact name with a phone and fax number where the contact can be reached. The cover sheet shall also include language stating, "PLEASE DO NOT REMOVE" to ensure it stays on the case file should the file be sent to the Quality Improvement Contractor (QIC). If the UPIC receives a notice of hearing, the UPIC shall contact the QIC immediately.

The QICs are tasked with participating in ALJ hearings; therefore, they are the primary Medicare contractor responsible for this function. UPICs may participate in an ALJ hearing, but they shall work with the QIC to ensure that duplicative work is not being performed by both the UPIC and the QIC in preparation for the hearing. UPICs shall never invoke party status. If the UPIC participates in a hearing, it shall be as a non-party. An ALJ cannot require participation in a hearing, whether it is party or non-party. If a UPIC receives a notice that appears contrary to this instruction, the UPIC shall contact the QIC and their primary COR and BFL immediately.

Medicare Program Integrity Manual

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

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(Rev. 11797; Issued: 01-19-23)

8.4.1.4 - Determining When Statistical Sampling May Be Used

Rev. 11797; Issued: 01-19-23; Effective: 02-21-23; Implementation: 02-21-23)

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 *compared to similar service providers*;
- 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.

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*, as defined in PIM Chapter 4, §4.7 – Investigations,* 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.

When an overpayment is identified by data analysis alone, the contractor shall consult with its COR and BFL. 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.

Additionally, a UPIC shall consult with the appropriate MAC on whether an extrapolated overpayment is more efficient in processing a data-driven overpayment before requesting recoupment from the MAC.

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.

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

(Rev. 11797; Issued: 01-19-23; Effective: 02-21-23; Implementation: 02-21-23)

The universe is the target population that lists all claims/claim lines potentially under review and is used to construct the sampling frame.

The sampling frame lists all sampling units which may be selected by the statistical sampling software, and further refines the review criteria from the claims/claim lines listed in the universe. The sampling unit may be the claim line, or may be a higher-level unit such as:

1. *The claim/claim number, or*
2. *A cluster of claims/claim lines associated with a patient, or*
3. *A cluster of claims/claim lines associated with a treatment "day," or*

4. *Any other sampling unit appropriate for the issue under review.*

The auditor may refine the selection criteria during the construction of the sampling frame, for example:

1. *Excluding claims/claim lines that have been subject to a prior review, or*
2. *Excluding claims/claim lines for which there was no payment, or*
3. *Excluding claims/claim lines which cannot be assigned to a sample unit due to missing information.*

The extrapolation estimate of total overpayments is an estimate of total overpayment for sampling units in the sampling frame.

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

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.

8.4.5 - Calculating the Estimated Overpayment

Rev. 11797; Issued: 01-19-23; Effective: 02-21-23; Implementation: 02-21-23)

The results of the sampling unit reviews are used to calculate an estimate of the overpayment amount. 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 conservative procedure incorporates the uncertainty inherent in the sample design and 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.

Standard methods for calculating a one-sided 90 percent confidence interval, such as those based on the central limit theorem or others found in standard statistics texts and journals, are generally acceptable. It may not be feasible to guarantee 90 percent coverage in all circumstances (i.e., that the lower bound of the 90 percent confidence interval is below the true overpayment in 90 percent of audits) due to the use of theoretical assumptions underlying standard statistical methods. Nonetheless, application of these methods is generally appropriate.

In some cases, the point estimate or the lower bound of the estimate for the total overpayment in the sampling frame may be greater than the total payment in the sampling frame. This is expected to occur frequently when the true overpayment is high. Nonetheless, the use of the lower bound to calculate the demand amount continues to operate in accounting for uncertainty in the estimate and providing a methodology that is generally favorable toward the provider. If the point estimate of overpayment is greater than the total payment in the sampling frame, but the lower bound is less than total payment, then the lower bound may be demanded. If the lower bound of the estimated overpayment is greater than total payment, the

demand amount shall be reduced from the lower bound to the total payment amount in the sampling frame to avoid demanding more than originally paid.

The result of each sampling unit review 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.