Medicare Program Integrity Manual
Chapter 8 – Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation

Table of Contents
(Rev. 13110, Issued: 04-11-25)

<u>**Transmittals for Chapter 8**</u>

8.1 - Appeal of Denials
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

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

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

A. Use of Medical Specialist

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

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

B. Documenting Reopening and Good Cause

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

8.2 – Overpayment Procedures
(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

This section applies to Medicare Administrative Contractors (MACs) and Unified Program Integrity Contractors (UPICs).

The UPIC shall refer all identified overpayments to the 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, contractors shall request recovery of the overpayment.

The UPIC shall refer such overpayments to the MAC only after the investigation has been vetted with CMS (see Pub. 100-08, chapter 4, section 4.6). In addition, if a UPIC is making a referral to law enforcement, it shall refrain from referring the overpayment determination to the MAC during specified times noted in Pub. 100-08, chapter 4, section 4.9.4. If a large number of claims are involved, contractors consider using statistical sampling for overpayment estimation to calculate the amount of the overpayment. (See section 8.4 of this chapter.)

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 MAC may take any appropriate remedial action described in this chapter if a provider or supplier continues to have a high level of payment error. Offer the provider a consent settlement based on the potential projected overpayment amount.

8.2.1 – Overpayment Assessment Procedures
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

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

- Actual overpayment;

- Settlement based overpayment, or

- Extrapolated overpayments.

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

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

8.2.1.1 – Definition of Overpayment Assessment Terms
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A. Actual Overpayment

An actual overpayment is, for those claims reviewed, the sum of payments (based on the amount paid to the provider/supplier and Medicare approved amounts) made to a

provider/supplier for services which were determined to be medically unnecessary or incorrectly billed.

B. Projected Overpayment

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

8.2.2 – Assessing Overpayment When Review Was Based on Statistical Sampling for Overpayment Estimation
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

If contractors use statistical sampling for overpayment estimation of claims, they follow instructions in section 8.4 of this chapter to calculate the valid projected overpayment. They document the sampling methodology when review is based on statistical sampling for overpayment estimation. They notify the provider/supplier of the overpayment and refer the case to overpayment staff to make payment arrangements with the provider/supplier to collect the overpayment.

8.2.3 – Assessing Overpayment or Potential Overpayment When Review Was Based on Limited Sample or Limited Sub-sample
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

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

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

- Conduct an expanded review based on statistical sampling for overpayment estimation instructions in section 8.4 of this chapter and recoup the projected overpayment.

8.2.3.1 – Contractor Activities to Support Assessing Overpayment
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A. Step 1

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

- The amount of the original claim;

- The allowed amount;

- The rationale for denial;

- The §1879 determination for each assigned claim in the sample denied because the service was not medically reasonable and necessary (or the §1842(1) provider/supplier refund determination on non-assigned provider/supplier claims denied on the basis of §1862 (a)(1)(A)) (refer to Exhibit 14.1 of this manual);

- The §1870 determination for the provider/supplier for each overpaid assigned claim in the sample (refer to Exhibit 14.2 of this manual); and

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

B. Step 2

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

C. Step 3

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

D. Step 4

Calculate the final overpayment.

E. Step 5

Refer to the overpayment recoupment staff.

8.2.3.2 – Conduct of Expanded Review Based on Statistical Sampling for Overpayment Estimation and Recoupment of Projected Overpayment by Contractors
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

The MACs shall perform the actual recoupment identified by the UPICs. When a UPIC or medical review audit determines an extrapolated overpayment the sample claims reviewed are adjusted for denial. For history purposes, contractors shall deny the sample claims individually in the shared system and shall suppress the sample claims from going to HIGLAS. Once the entire extrapolated amount is identified, contractors shall create one large account receivable (AR) for the extrapolated amount (including the adjusted sample claim amounts) to demand and recoup.

A.   If an expanded review of claims is conducted, contractors shall follow the sampling instructions found in section 8.4 of this chapter, 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/supplier refund determination on non-assigned provider/supplier claims denied on the basis of §1862(a)(1)(A)) (refer to Exhibit 14.1 of this manual);

o   The §1870 determination for the provider/supplier for each overpaid assigned claim in the sample (refer to Exhibit 14.2 of this manual); 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/supplier did not have knowledge that the service was not medically necessary;

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

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

E.   Calculate the final overpayment; and

F.   Refer to the overpayment recoupment staff.

8.2.3.3 - Reserved for Future Use
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

8.2.3.3.1 - Background on Consent Settlement
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

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 UPICs 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 UPICs 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 UPICs 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:

1. A complete explanation of the review and the review findings;

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

3. The consequences of deciding to accept or decline the consent settlement offer; and

4. It is rare that a UPIC will offer and develop a consent settlement.

However, when the UPIC offers and develops a consent settlement, the AC or MAC shall administer the settlement.

8.2.3.3.2 - Opportunity to Submit Additional Information Before Consent Settlement Offer
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

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

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

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

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

8.2.3.3.3 - Consent Settlement Offer
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

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

8.2.3.3.4 - Option 1 - Election to Proceed to Statistical Sampling for Overpayment Estimation
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

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, UPICs and the contractor medical review units shall:

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

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

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

8.2.3.3.5 - Option 2 - Acceptance of Consent Settlement Offer
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

8.2.3.3.6 - Consent Settlement Budget and Performance Requirements for ACs
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

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

8.2.4 - Coordination With Audit and Reimbursement Staff
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

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

- The sample documentation contained in Pub. 100-08, chapter 3, section 3.5.2;

- The identification of incorrectly paid or incorrectly denied services; and

- All other information required by the Cost Report Worksheets in Pub. 100-08, chapter 3, section 3.5.2 and applicable Exhibits.

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

In most instances, the Audit/Reimbursement staff will:

- Determine the overpayment to be recovered based on MR findings and pursue the recovery of the overpayment; and

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

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

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

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

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

8.3 – Suspension of Payment
(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

This section applies to Medicare Administrative Contractors (MACs) and Unified Program Integrity Contractors (UPICs).

Hereinafter, suspension of payment may be referenced as "payment suspension."

Requests for Suspension of Payment ("Payment Suspension") may be approved when there is reliable information that an overpayment exists, when payments to be made may not be correct, or when there is a credible allegation of fraud existing against a provider. The process by which the UPIC notifies and coordinates with the MAC to implement a CMS-approved suspension of payment shall be documented in the Joint Operating Agreement (JOA) between the MAC and the UPIC. The UPICs shall advise and coordinate the imposition of a payment suspension with the appropriate MAC when a payment suspension has been approved by CMS. The UPIC shall perform the necessary medical review and development of overpayments for payment suspensions that have received CMS approval, when appropriate.

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 §405.370-375, which provide for the suspension of payments.

All payment suspensions shall be referred to the CMS/Center for Program Integrity (CPI) via the Unified Case Management System (UCM) for approval. UPICs shall notify their appropriate CPI Business Function Lead (BFL), with a copy to the Contracting Officer's Representative (COR), of the submission by providing the UCM number via email.

8.3.1 – When Suspension of Payment May Be Used
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

A payment suspension may be used when there is:

Reliable information that an overpayment exists, but the amount of the overpayment is not yet determined;

Reliable information that the payments to be made may not be correct;

Reliable information that the provider fails to furnish records and other essential information necessary to determine the amounts due to the provider;

In cases of suspected fraud, a payment suspension may be used when there is a credible allegation of fraud.

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

NOTE: If a payment suspension is approved, this edit of withholding of Medicare funds takes precedent over any other edits withholding money in the MAC systems. When it is time to terminate the payment suspension, the withheld funds must first be applied to the Medicare overpayment(s) and any excess is then applied to any other outstanding overpayments or debts owed to CMS or HHS in accordance with 42 CFR §405.372(e), unless otherwise directed by CMS.

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

NOTE: If a payment suspension is approved for a home health agency, <u>all</u> Requests for Anticipated Payments (RAPs) are to be suppressed (disapproved) in accordance with 42 C.F.R. §409.43(c)(2). The UPIC shall make this request to CPI as part of its request for a payment suspension.

In addition, CMS may suppress RAP payments for program integrity concerns absent a payment suspension. If the UPIC determines that a RAP suppression is appropriate they shall submit the following information to CMS:

- Are final bills being submitted by the HHA? Yes or No
- Indicate the volume (dollar and number of claims) of RAPs for the past 12 months.

- A brief summary supporting the request for RAP suppression.

8.3.1.1 – Credible Allegation of Fraud Exists Against a Provider - Fraud Suspensions
(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

A payment suspension may be used when the UPIC, law enforcement, or CMS determines that a credible allegation of fraud exists against a provider or supplier (hereinafter referred to as provider). For purposes of section 8.3 et seq., these types of payment suspensions will be called "fraud suspensions."

Fraud suspensions may also be imposed for reasons not typically viewed within the context of false claims. For example:

- The Quality Improvement Organization (QIO) has reviewed inpatient claims and determined that the diagnosis related groups (DRGs) have been upcoded.

- The UPIC or MAC may suspect a violation of the physician self-referral ban. For this reason, the violation may be considered the cause for a payment suspension since claims submitted in violation of this statutory provision must be denied and any payments made would constitute an overpayment.

- Even though services are rendered and may be determined as medically necessary and reasonable by the Medicare contractor, law enforcement has credible allegations of kickbacks.

- Forged signatures on medical record documentation (e.g., Certificates of Medical Necessity (CMN), treatment plans, etc.) and/or other misrepresentations on Medicare claims or associated forms to obtain payment that would result in an overpayment determination.

Whether or not the UPIC recommends a payment suspension to CMS, the final determination is determined on a case-by-case basis and requires review and analysis of the allegation and facts. The following information is provided to assist the UPIC in deciding when to recommend a payment suspension to CPI.

A. Complaints

There is considerable latitude with regard to complaints alleging fraud, waste, and abuse. The provider's Medicare history, including the volume and frequency of complaints concerning the provider, and the nature of the complaints all contribute to whether a payment suspension should be referred to CPI. If there is a credible allegation(s) that a provider is submitting or may have submitted false claims, the UPIC may recommend a fraud suspension to CPI only after the UPIC has vetted the provider in accordance with Pub. 100-08, chapter 4, section 4.6. (If the MAC identifies the potential fraud issue from

a complaint, the MAC shall refer its information to the respective UPIC for development).

B. Requests for Suspension of Payment

For initial UPIC requests to suspend payments, the UPIC shall inform its assigned BFL of the potential suspension. The BFL will discuss all findings with the UPIC. After informing the BFL about the suspension, the contractor shall submit the payment suspension request via the UCM if the contractor determines such action is warranted. The Payment Suspension Administrative Action Request (AAR), draft suspension notice, and all other relevant documentation that supports the suspension request shall be uploaded by the contractor as part of the UCM submission.

The UPIC shall also prepare and submit, if appropriate, a payment suspension referral package to CPI via the UCM for all requests received from (but not limited to):

- CMS

- Office of Inspector General (OIG)

- Federal Bureau of Investigation (FBI)

- Assistant United States Attorney (AUSA)

- Other law enforcement agencies

C. Other Situations

Other situations that may be considered when recommending a fraud suspension to CPI include, but are not limited to:

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

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

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

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

D. Good Cause Exceptions

Reference is made in 42 CFR §405.371(b)(1) that allows for good cause exceptions to not suspend payments or continue a payment suspension when there are credible allegations of fraud. These exceptions may be considered for approval by CMS if any apply:

- Law enforcement has requested that a payment suspension not be imposed because such action may compromise or jeopardize its investigation;

- CMS/CPI has determined that a beneficiary access to care issue may exist and potentially cause a danger to life or health in whole or part;

- CMS/CPI has been determined that other administrative remedies may be implemented that would be more effective in protecting Medicare funds (such as revocation, prepayment review); or

- CMS determines that the imposition or the continuation of a payment suspension is not in the best interest of the Medicare program.

Every 180 calendar days after the initiation of a payment suspension based on credible allegations of fraud, CMS is required to evaluate whether there is good cause to terminate the payment suspension. Good cause to terminate a payment suspension is deemed to exist if the payment suspension has been in effect for 18 months. However, there are two exceptions. The first exception is that the case has been referred to and is being considered by the OIG for an administrative action such as a civil monetary penalty or permissive exclusion, or such administrative action is pending, and the OIG has made its request to not terminate the payment suspension in writing. The second exception is that the Department of Justice has submitted a written request to extend the payment suspension based on the ongoing investigation and its anticipation of filing a criminal or civil action or both, or based on a pending criminal or civil action or both. (See 42 CFR §405.371(b)(2) and §405.371(b)(3).)

CMS/CPI makes the final decision on whether good cause to terminate exists, based on the totality of the circumstances. For all fraud suspensions, the UPICs shall submit requests to CPI via the UCM within 14 calendar days before the suspension expires. CPI will evaluate the request to consider whether good cause to terminate the payment suspension exists.

8.3.1.2 – Reliable Information that an Overpayment Exists - General Suspensions
(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

A payment suspension may be implemented when the MAC, UPIC, or CMS possesses reliable information that an overpayment exists. In this situation, the MAC shall refer its

information to the respective UPIC for development of a potential suspension. The UPIC shall refer a payment suspension to CPI via the UCM for consideration. For the purposes of this section, these types of payment suspensions will be called "general suspensions."

EXAMPLE (including but not limited to): Several claimed services identified from either a prepayment or post-payment review were determined to be non-covered or miscoded. It has been determined that there is a pattern of noncompliant billings (the provider has billed this service many times before) and it is suspected that there may be a substantial number of additional non-covered or miscoded claims paid in the past.

8.3.1.3 – Reliable Information that the Payments to Be Made May Not Be Correct - General Suspensions
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

A payment suspension may be implemented when the MAC or UPIC or CMS possesses reliable information that the payments to be made may not be correct. In this situation, the MAC shall refer its information to the respective UPIC for development of a potential suspension. The UPIC shall refer a payment suspension to CPI for consideration. For the purposes of this section, these types of payment suspensions will be called "general suspensions."

EXAMPLE (including but not limited to): Several claimed services identified from a post-payment review were determined to be non-covered or miscoded. It has been determined that the provider has not changed its billing behavior and it is suspected that there may be a continuance of non-covered or miscoded claimed services to be billed in the future.

8.3.1.4 – Provider Fails to Furnish Records and Other Requested Information - General Suspensions
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

A payment suspension may be used when the MAC, UPIC, or CMS possesses reliable information that the provider has failed to furnish records and other information requested or that is due, and which is needed to determine the amounts due the provider. In this situation, the MAC shall refer its information to the respective UPIC for development of a potential suspension. The UPIC shall refer a payment suspension to the CPI for consideration. For the purposes of this section, these types of payment suspensions will be called "general suspensions."

EXAMPLE (including but not limited to): During a post-payment review, medical records and other supporting documentation are solicited from the provider to support payment. The provider fails to submit the requested records after two attempts. The UPIC may request a payment suspension due to non-response from the provider.

In lieu of imposing a payment suspension, the MAC or UPIC may deny the paid claims because the provider failed to provide the requested documentation after two attempts. In either case, the MAC or UPIC should determine if the provider is continuing to submit claims for the services in question and take appropriate action(s) to correct the behavior.

NOTE: In the above example, if the only reason for the payment suspension is the failure by the provider to furnish the requested records, and if the provider does eventually provide the requested information, the UPIC shall discuss this matter with CPI for guidance.

EXAMPLE (including but not limited to): The provider fails to timely file an acceptable cost report. Refer to 42 CFR §405.371(d). (NOTE: Such requests regarding the timely filing of an acceptable cost report shall be submitted only to and approved by the CMS, Office of Financial Management and not CPI.)

8.3.2 – Procedures for Implementing a Payment Suspension
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

8.3.2.1 – CMS Approval
(Rev. 12515; Issued:02-22-24; Effective: 03-25-24; Implementation:03-25-24)

If the UPIC believes that a UPIC-initiated Payment Suspension is a viable option for an investigation, they shall update UCM appropriately to ensure the case is included on the next case coordination meeting agenda for discussion. For national or multi-regional suspensions, only the lead UPIC shall discuss the suspension at the case coordination meeting.

During the case coordination meeting, if CMS agrees that the criteria for Payment Suspension is met, CMS will instruct the UPIC to submit the Payment Suspension request(s) with the completed Administrative Action Review (AAR) form to CPI through the UCM. The Payment Suspension team member will review the submissions and make a formal determination as to whether a Payment Suspension is a viable option.

During the case coordination meeting, the UPIC may receive additional guidance from CMS related to subsequent actions related to these investigations. If the UPIC has questions following the case coordination meeting, the UPIC shall coordinate with its COR, BFL, and/or suspension team member, as needed.

When a payment suspension is approved by CPI, the UPIC shall inform the respective MAC of this action and the MAC shall effectuate the suspension of payments to the provider unless prior notice of the payment suspension is necessary. When prior notice is necessary, the MAC shall effectuate the suspension of payment in concert with the established date from the payment suspension notice.

For all payment suspensions, the UPIC shall request the MAC implement a "payment suspension" or "partial payment suspension" when applicable. For all payment

suspensions and emergency payment suspensions, the MAC shall no longer use "F_Fraud and Abuse", "F_CMS Request" or "P_CMS Request" HIGLAS hold reason codes for UPIC requested payment suspension activities. MACs shall only use "F_PSC Request" (Full Hold) or "P_PSC Request"(Partial Hold) HIGLAS hold reason codes going forward for all UPIC requested payment suspension and emergency payment suspension activities.

UPICs shall not request that MACs create placeholder debts or "escrow amounts" based on anticipated provider settlements. The MAC shall no longer create these debts in HIGLAS. If a UPIC requests a MAC to create a placeholder debt, the MAC shall reach out to OFM for guidance before any action is taken.

The MACs shall ensure that all money on the payment floor is not released to the provider after the effective date of the suspension and the money is withheld in accordance with the payment suspension rules and regulations. MACs shall provide an accounting of the money withheld on day one of the payment suspension to the UPIC. The UPIC shall enter this amount in the UCM as the first monetary entry.

Unless otherwise specified, when a payment suspension is imposed, no payments are to be released to the provider as of the effective date of the payment suspension. This includes payments for new claims processed, payments for adjustments to claims previously paid, interim PIPs. If it is discovered that money is released to the provider after the effective date of the payment suspension, the MAC or UPIC shall contact CPI for guidance.

8.3.2.2 – The Notices Involving Payment Suspensions
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

The UPICs shall use the following exhibits in this manual as the model notices when preparing the draft notices for CMS approval:

- The Notice to Suspend Payments (Refer to Exhibits 16A to 16D)
- The Notice to Extend the Payment Suspension (Refer to Exhibit 16E) The Notice to
Terminate the Payment Suspension (Refer to Exhibit 16F)

8.3.2.2.1 – Issuing a Prior Notice versus Issuing a Concurrent Notice
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

UPICs shall inform the provider of the payment suspension action being taken. When prior notice is appropriate, the UPIC shall, in most instances, give at least 15 calendar days' prior notice before effectuating the payment suspension. Day one begins the calendar day after the notice is mailed.

A. If the Medicare Trust Fund would be harmed by giving prior notice: the UPIC shall recommend to CPI not to give prior notice if, in the UPIC's opinion, any of the

following apply:

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

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

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

4. A delay may impact law enforcement's investigation.

If CPI approves waiver of the prior notice requirement, the UPIC shall send the provider notice concurrent with implementation of the payment suspension, but no later than 5 calendar days after the payment suspension is imposed. If additional time is needed to release the notice, the UPIC shall confer with CPI for guidance.

B. If the reason for the payment suspension request is because the provider failed to furnish requested information, the UPIC shall recommend that CPI waive the prior notice. If CPI concurs to waive the prior notice requirement, the UPIC shall send the provider notice concurrent with implementation of the payment suspension, but no later than 5 calendar days after the payment suspension is imposed. If additional time is needed to release the notice, the UPIC shall confer with CPI for guidance.

C. If the payment suspension request is a fraud suspension, the UPIC shall recommend to CPI that prior notice not be given. If CPI concurs to waive the prior notice requirement, the UPIC shall send the provider notice concurrent with implementation of the payment suspension, but no later than five calendar days after the payment suspension is imposed. If additional time is needed to release the notice, the UPIC shall confer with CPI for guidance.

8.3.2.2.2 – Content of Payment Suspension Notice
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

The UPIC shall prepare a "draft notice" (in accordance with section 8.3.2.2 of this chapter) and send it, along with the recommendation and any other supportive information, to CPI for approval. The draft notice shall include, at a minimum:

• The date the payment suspension action will be or has been imposed;

• How long the suspension is expected to be in effect (**NOTE**: All payment suspensions shall be established in 180 calendar day increments.);

• The reason for suspending payment. (For fraud suspensions, the UPIC shall include

the rationale to justify the action being taken.);

• In most notices, the UPIC shall identify and describe at least five example claims that are associated with the reason for the payment suspension, if available. The claim examples are to be the most current claims available unless otherwise directed by CMS. The notice shall only reference the example claim control number, the amount of payment, and the date of service;

• The extent of the payment suspension (i.e., 100 percent payment suspension or partial payment suspension, where less than 100 percent of payments are withheld);

• The payment suspension action is not appealable;

• CMS/CPI has approved implementation of the payment suspension;

• Documentation that the provider has been given the opportunity to submit a rebuttal statement within 15 calendar days of notification; and

• An address for the provider to mail the rebuttal.

8.3.2.2.3 – Shortening the Notice Period for Cause
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

At any time, the UPIC may recommend to CPI that the prior notice be shortened during a previously approved notice period. Such a recommendation would be appropriate if the MAC or UPIC believes that the provider will intentionally submit additional claims prior to the effective date of the payment suspension. If CPI approves that the payment suspension is to be imposed earlier than indicated in the issued notice, the UPIC shall notify the provider in writing of the change and the reason. The UPIC shall draft a notice for CPI's approval before releasing the notice to the provider.

8.3.2.2.4 – Mailing the Notice to the Provider
(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

After consultation with and approval from CPI, the UPIC shall send the approved payment suspension notice (initial, responses to rebuttals, extensions, and terminations) to the provider. All such notices shall be sent via USPS certified mail or utilizing other commercial mail carriers that allow the tracking of the correspondence to ensure receipt by the provider. In the case of fraud suspensions, the UPIC shall send an informational copy to the OIG, FBI, or the AUSA for its file, if law enforcement has been previously involved and/or has an active investigation/case on the provider. The UPIC shall also upload the signed copies of all notices released to the provider into the UCM.

8.3.2.2.5 – Opportunity for Rebuttal
(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

If the payment suspension is approved with prior notice, the provider is afforded an opportunity to submit to the UPIC a statement within 15 calendar days indicating why the payment suspension action should not be imposed. However, this time may be shortened or lengthened for cause. (See 42 CFR §405.374(b).)

If the payment suspension is approved without prior notice, the provider is also afforded an opportunity to submit to the UPIC a statement as to why the payment suspension action should not be imposed. (See 42 CFR §405.372(b)(2).) For purposes of consistency for both prior notice and no prior notice, CMS/CPI suggests that a 15 calendar day response time be established for the provider.

If a provider submits a rebuttal timely, a timely determination and written response by the UPIC is required in accordance with 42 CFR §405.375. If a provider does not respond in a timely manner, the UPIC shall submit a written response to the provider within 30 calendar days from the receipt date of the rebuttal.

UPICs shall ensure the following:

- CMS Review – UPICs shall forward the provider's rebuttal statement and any pertinent information to CPI via the UCM within 1 business day of receipt. The UPIC shall evaluate the information presented and then draft a response addressing each item mentioned in the rebuttal and submit it to CPI for approval via the UCM no later than 10 calendar days from receipt. The UPIC may contact CPI for guidance before drafting a response.

- Timing –The payment suspension shall go into effect as indicated in the notice.

- Review of Rebuttal – Because payment suspension actions are not appealable, the rebuttal is the provider's only opportunity to present information as to why suspension action should not be initiated or should be terminated. UPICs shall carefully review the provider's rebuttal statement and pertinent information, and shall consider all facts and issues raised by the provider. If the UPIC is convinced that the payment suspension action should not be initiated or should be terminated, it shall consult with the CPI for guidance.

- Response – CMS is obligated to consider the initial rebuttal and supportive information received from the provider and to make a determination within 15 calendar days from receipt of the rebuttal. (See 42 CFR §405.375(a).) If a full response cannot be drafted in the required timeframe, the UPIC shall draft an interim response for release that is approved by CPI.

8.3.2.3 – Claims Review During the Payment Suspension Period
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A payment suspension does not stop submitted claims from processing. A payment suspension only stops the claim payments from being released to the provider. These claim payments will be withheld in an account (which does not accrue any interest) for the purpose of applying the withheld funds to any potential overpayment(s) or other debts owed to CMS or HHS in accordance with 42 CFR §405.372(e). (This withholding of Medicare payments is for everything payable and releasable to the provider. It also includes adjustments to claims that would result in payments being released to the provider, RAPs, etc.) If a claim is submitted for payment and is partially or fully denied, the provider is afforded appeal rights to those denials.

8.3.2.3.1 – Claims Review
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

While a payment suspension does not stop claims processing, CMS prefers that all claims being processed during the payment suspension period be reviewed on a prepayment basis for reasonableness and necessity. If fraud-related, the review of claims should also address whether services were actually rendered as billed. This will ensure that the withheld payments only include payable claims to be used in the disposition of the funds when the final overpayment(s) are determined.

A. Claims Review

Once a payment suspension has been imposed, the MACs and UPICs shall follow the claims processing and review procedures in accordance with Pub. 100-08, chapter 3. MACs and UPICs shall ensure that the provider is not substituting a new category of improper billings to counteract the effect of the payment suspension. (If such a situation arises, the UPIC shall modify the payment suspension accordingly with CPI's approval.) If the claim is determined to not be payable, it shall be denied and the provider afforded its appeal rights. For claims that are not denied, the MAC shall send a remittance advice to the provider showing that payment was approved but the actual funds not sent.

UPICs are not required to perform 100 percent prepayment review of claims processed during the payment suspension period. If prepayment review is not conducted, a post-payment review shall be performed on the universe of claims adjudicated for payment during the payment suspension, prior to the issuance of the overpayment determination. In order to reduce the burden of resources, if only specific claim types (or certain codes) are the subject of noncompliance, the UPIC may elect to only place such claims types on prepayment or post-payment review. UPICs shall consult with CPI for guidance when resources may be better utilized employing statistical sampling for overpayment determination(s). UPICs shall use the principles of statistical sampling for overpayment estimation found in section 8.4 of this chapter to determine what percentage of claims in a given universe of withheld claims payments are payable. In all cases involving a post-payment review, the UPIC shall follow the rules of reopening as defined in 42 C.F.R. §405.980 and inform the provider that the claims are reopened in accordance with the regulations when requesting records and supportive information.

B. Review of Suspected Fraudulent or Overpaid Claims:

The UPIC shall follow procedures in Pub. 100-08, chapter 3, section 3.6 in establishing an overpayment. The overpayment consists of all claims in a specific time period(s) determined to have been paid incorrectly. The UPIC shall make all reasonable efforts to expedite the determination of the overpayment amount. The UPIC shall account for binding revised determinations or binding reconsiderations in its overpayment determination in accordance with 42 CFR §405.984.

NOTE: Claims selected for post-payment review may be reopened within one year for any reason or within four years for good cause. (See 42 CFR §405.980.) Cost report determinations may be reopened within three years after the Notice of Program Reimbursement has been issued. Good cause is defined as new and material evidence, error on the face of the record, or clerical error. The regulations have open-ended potential for fraud or similar fault. The exception to the one-year rule is for adjustments to DRG claims. A provider has 60 calendar days to request a change in an assignment of a DRG. (See 42 C.F.R. §412.60(d).)

8.3.2.3.2 – Case Development – Program Integrity
(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

The UPIC shall enter all payment suspensions into the UCM. In the Suspension Narrative field, the UPIC shall include the items/services affected (i.e., type of item/service and applicable HCPCS/CPT codes). The first monetary entry of money withheld in the UCM shall reflect the money withheld on Day One of the payment suspension.

8.3.2.4 – Duration of the Payment Suspension
(Rev.13110; Issued:04-11-2025; Effective: 05-12-2025; Implementation:05-12-2025)

A. Time Limits for General Suspensions

If CPI approves a general suspension, it will be for a 180 calendar day period. The UPIC shall complete its medical review and any subsequent activities (i.e., statistical sampling extrapolation, draft overpayment determination notice, etc.) during the initial 180 days of a general suspension. CMS expects the medical reviews to be completed and the calculation of any potential overpayments to be determined before the end of the initial suspension period. Only in rare instances will an extension be granted.

If an extension is required, the UPIC shall request an extension of an additional 180 calendar days if time is needed to complete the overpayment determination. Only CPI may approve the request to extend the period of the payment suspension for up to an additional 180 calendar days upon the written request of the UPIC. The request to CPI to extend the payment suspension shall provide the following:

- The AAR – Payment Suspension form
- A draft of the proposed payment suspension extension notice following the

format noted in section 8.3.2.2 of this chapter (in a word document format);
- A timeline of the completion of the medical review; and
- Any other supporting documentation.

If approved for an extension, the period of time shall not exceed 180 calendar days. General suspensions shall not continue beyond 360 calendar days. However, there may be an occasion when the information gathered by the UPIC during its review supports a change from a general suspension to a fraud suspension. Only with CPI approval may the category of the type of payment suspension be transitioned from a general payment suspension to a fraud suspension. If the transition from a general payment suspension to a fraud payment suspension is approved, the provider must be informed of the new development by the UPIC with a CPI-approved notice. Additionally, the provider must be afforded the opportunity for rebuttal.

B. Exceptions to Time Limits for Fraud Suspensions

If a payment suspension is based on credible allegations of fraud, the payment suspension may continue beyond 360 days with a written request for an extension from law enforcement. An extension may be warranted if there has not been a resolution of law enforcement's investigation of the potential fraud. After 18 months, good cause not to continue a payment suspension is deemed to exist unless certain criteria are satisfied. (See 42 C.F.R. §405.371(b)(3).) To extend a fraud suspension beyond 18 months:

- The Department of Justice must submit a written request for an extension. Requests must include: 1) the identity of the person or entity under the payment suspension, 2) the amount of time needed for continuation of the payment suspension in order to conclude the criminal or civil proceeding or both, and 3) a statement of why and/or how criminal and/or civil actions may be affected if the payment suspension is not granted.

- The OIG must submit a written request to extend the payment suspension because the case is being considered by the OIG for an administrative action (e.g., permissive exclusions, CMPs) or such action is pending. However, this exception does not apply to pending criminal investigations by OIG.\

C. Provider Notice of the Extension

The UPIC shall obtain CPI approval for the extension request and draft notice, and shall notify the provider if the suspension action has been extended. The UPIC shall prepare a "draft extension notice" (in accordance with section 8.3.2.2 of this chapter) and submit it via the UCM, along with any other supportive information, to CPI for approval *30 calendar days prior to the suspension's expiration date (limited early submissions are acceptable based on operational realities). If the 30th day falls on a non-business day, the UPIC shall submit the request on the next business day*. The draft notice shall follow the model language provided in the exhibits and shall include, at a minimum:

- The date the payment suspension will be extended (**NOTE**: The date is to be the same date the payment suspension was to expire);

- The reason for extending the payment suspension; and

- That CMS has approved the extension of the payment suspension.

Upon approval of the notice from CPI, the UPIC shall provide a copy of the signed notice to CPI via the UCM.

8.3.2.5 – Terminating the Payment Suspension
(Rev. 12515; Issued:02-22-24; Effective: 03-25-24; Implementation:03-25-24)

The UPIC shall recommend to CPI that the payment suspension be terminated prior to the payment suspension expiring. The UPIC shall provide this request via the UCM at least 14 calendar days prior to the anticipated payment suspension expiration date. No action associated with the termination shall be taken without the explicit approval of CPI. The UPIC shall prepare a "draft termination notice" (in accordance with section 8.3.2.2 of this chapter) and send it, along with a draft overpayment notice(s) and any other supportive information, to CPI for approval.

The UPIC shall recommend to CPI that a suspension be terminated when any of the following occur:

- The basis for the payment suspension action was that an overpayment may exist or money to be paid may be incorrect, and the UPIC has determined the amount of the overpayment, if any.

- The basis for the payment suspension action was that a credible allegation of fraud exists against the provider, and the amount of the overpayment has been determined.

- The basis for the payment suspension action was that payments to be made may not be correct, and the UPIC has determined that current payments to be made are now correct, and any associated overpayments have been determined.

- The basis for the payment suspension action was that the provider failed to furnish records, and the provider has now submitted all appropriate requested records.

When the payment suspension is terminated, the disposition of the withheld funds shall be achieved in accordance with 42 CFR §405.372(e) and the payment suspension edit withholding the provider's funds is removed in the MAC system accordingly, within 60

days. Upon approval of the termination notice by CPI, the UPIC shall provide a copy of the signed notice via the UCM to CPI.

8.3.2.6 – Disposition of the Withheld Funds
(Rev. 10228; Issued: 07-27-20; Effective: 08-27-20; Implementation: 08-27-20)

The MAC and UPIC shall maintain an accurate, up-to-date record of the dollar amount withheld and the claims that comprise the withheld amount. The MAC and UPIC shall keep a separate accounting of payment on all claims affected by the payment suspension. They shall keep track of how much money is uncontested and due the provider. The amount needs to be known as it represents assets that may be applied to reduce or eliminate any overpayment. (See section 8.2 of this chapter.) The MAC and UPIC shall be able to provide, upon request, copies of the claims affected by the payment suspension. The MAC shall coordinate the issuance of the demand for the overpayment(s) and termination of the payment suspension with respect to approved action by CPI. The MAC shall apply the amount withheld first to the Medicare overpayment(s) and then apply any excess money to reduce any other obligation to CMS or to DHHS, unless otherwise directed by CMS. The MAC shall remit to the provider all monies held in excess of the amount the provider owes. If the provider owes more money than what was withheld as a result of the payment suspension, the MAC shall initiate recoupment action, unless otherwise directed by CMS. See 42 CFR §405.372(e).

8.3.2.7 – Contractor Suspects Additional Improper Claims
(Rev. 11529; Issued: 07-28-2022; Effective: 08-30-2022; Implementation: 08-2022)

If the payment suspension is in the process of being terminated or has been terminated, and the UPIC believes that the provider will continue to submit noncovered, misrepresented, or potentially fraudulent claims, the UPIC shall consider implementing or recommending other actions as appropriate (e.g., education, prepayment review, revocation, a new suspension of payment).

8.3.3 – Suspension Process for Multi-Region Issues (National Payment Suspensions)
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

8.3.3.1 – DME Payment Suspensions (MACs and UPICs)
(Rev. 12515; Issued:02-22-24; Effective: 03-25-24; Implementation:03-25-24)

For national payment suspensions involving durable medical equipment (DME) suppliers that are enrolled in multiple jurisdictions, the following is applicable for DME MACs and UPICs:

- When CMS suspends payments to a DME supplier, all payments to the supplier are suspended in all DME jurisdictions if the same Tax Identification

Number is used. The information (whether based on fraud or non-fraud) that payments should be suspended in one DME jurisdiction is sufficient reason for payment suspension decisions to apply to the other locations.

- The UPIC that requests the national payment suspension to CPI shall become the "Lead" UPIC for the payment suspension if the payment suspension is approved. The Lead UPIC is responsible for informing the other UPICs (non-lead UPICs) of the payment suspension being initiated and for the coordination of the payment suspension activities. CMS suggests that monthly contractor calls be held to communicate the current activities of the national suspension by each of the contractors.

- The Lead UPIC is responsible for coordinating and reporting to its BFL, with a copy to their COR, whether the non-lead UPICs are compliant with the payment suspension timeframe and activities.

- All non-lead UPICs are responsible for determining an overpayment(s) for its jurisdiction. Non-lead UPICs shall take into account the findings of the Lead UPIC and take appropriate measures (prepayment review, etc.) to protect and safeguard Medicare Trust Fund dollars from being inappropriately paid.

For UPIC-initiated DME payment suspensions:

- Each UPIC shall be responsible for ensuring that the payment suspension edit has been initiated in its respective DME MAC jurisdiction and has communicated this to the lead UPIC. If non-lead UPIC determines that medical review would not be appropriate in their jurisdiction for subject provider, non-lead UPIC shall notify and request permission from their BFL to opt out of the medical review.

- The Lead UPIC shall create both a CSE record, if not already created, to track the investigative activities and a PSP record to track the activities specific to the payment suspension in UCM. The lead UPIC shall check the "lead" checkbox. Non-lead UPICs shall not create a separate PSP and is responsible for timely updating the lead UPIC's PSP with monthly suspended amounts within their jurisdictions, as well as adding any pertinent comments and/or documentation.

  Non-lead UPICs shall create a CSE and the appropriate administrative action records to track their activities.

8.3.3.2 – Non-DME National Payment Suspensions (MACs and UPICs)
(Rev. 12515; Issued:02-22-24; Effective: 03-25-24; Implementation:03-25-24)

For national payment suspensions involving national providers (such as chain hospitals, chain Skilled Nursing Facilities, franchised clinics, laboratories, etc.) that are enrolled in

multiple jurisdictions, the following may be applicable for MACs and UPICs:

- When CMS suspends payments to a national provider, all payments to the national provider are suspended in all jurisdictions if they share the same Tax Identification Number. The information (whether based on fraud or non-fraud) that payments should be suspended in one jurisdiction is sufficient reason for payment suspension decisions to apply to the other locations.

- The UPIC that requests the national payment suspension to CPI shall become the "Lead" UPIC for the payment suspension. The Lead UPIC is responsible for informing the other UPICs (non-lead UPICs) of the payment suspension being initiated and for the coordination regarding the payment suspension activities. CMS suggests that monthly contractor calls be held to communicate the current activities by each of the contractors.

- The Lead UPIC is responsible for coordinating and reporting to its BFL, with a copy to the COR, whether the non-lead UPICs are compliant with the payment suspension timeframe and activities.

- All non-lead UPICs are responsible for determining an overpayment(s) for its jurisdiction. Non-lead UPICs shall take into account the findings of the Lead UPIC and take appropriate measures (prepayment review, etc.) to protect and safeguard Medicare Trust Fund dollars from being inappropriately paid.

For UPIC-initiated non-DME national payment suspensions:

- Each UPIC shall be responsible for ensuring that the payment suspension edit has been initiated in its respective MAC jurisdiction and has communicated this to the Lead UPIC. If non-lead UPIC determines that medical review would not be appropriate in their jurisdiction for subject provider, non-lead UPIC shall notify and request permission from their BFL to opt out of the medical review.

- The Lead UPIC shall create both a CSE record to track the investigative activities and a PSP record to track the activities specific to the payment suspension in UCM. The lead UPIC shall check the "lead" checkbox. Non-lead UPICs shall not create a separate PSP and is responsible for timely updating the lead UPIC's PSP with monthly suspended amounts within their jurisdictions, as well as adding any pertinent comments and/or documentation.

  Non-lead UPICs shall create a CSE and the appropriate administrative action records to track their activities.

8.4 - Use of Statistical Sampling for Overpayment Estimation
(Rev. 906, Issued: 09-26-19; 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 – Introduction
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

8.4.1.1 – General Purpose
(Rev. 906, Issued: 09-26-19; 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 a valid 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. 906; Issued: 09-26-19; 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. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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 sampling frame to determine the sampling 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. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

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 BFL, with a copy to the COR, 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 BFL, with a copy to the COR. In addition, if CMS approves the data driven overpayment, the contractor shall also consult with its BFL, with a copy to the COR, 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.

8.4.1.5 - Consultation With a Statistical Expert
(Rev. 906; Issued: 09-26-19; 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. 906; Issued: 09-26-19; Effective: 01-02-19; Implementation: 01-02-19)

Once it is 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. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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 sampling design is properly executed, i.e., defining the universe, the sampling 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 - Selection of Period to be Reviewed and Composition of Universe
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

8.4.3.1 - Selection of Period for Review
(Rev. 906; Issued: 09-26-19; 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. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The universe is the target population that contains 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 sampling 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 sampling frame and sample shall be included in the case documentation.

Other approaches to constructing the universe and sampling frame are possible depending on the specific circumstances. One possibility is that the sampling frame may be created first (for example, a list of beneficiaries) and then the universe corresponding to the sampling 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 sampling units in the sampling frame, all the universe elements that are incorporated into those sampling units, and the elements in the universe. It must be possible to assemble the sampling units from the universe during the replication process.

8.4.3.2.1 - Composition of the Universe
(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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. Sampling units with no final payment made at the time of sample selection should not be included in the sampling frame. Claims with no payment may be included in the universe from which the sampling frame is constructed and should be excluded when establishing the sampling 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. Sampling units with no final payment made at the time of sample selection should not be included in the sampling 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. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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 sampling 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 sampling 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 Sampling Frame
(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

The sampling 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.
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8.4.4 - Sample Selection
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

8.4.4.1 - Sampling Methodology
(Rev. 906; Issued: 09-26-19; 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. 906; Issued: 09-26-19; 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. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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 sampling methodology used, and when presented without a complete account of the actual sampling methodology used.

8.4.4.4 - Documentation of Sampling Methodology
(Rev. 906; Issued: 09-26-19; 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 Sampling Frame
(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

An explicit statement of how the universe is defined and elements included shall be made and maintained in writing. Further, the sampling 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 sampling 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 sampling frame can be re-created should the methodology be challenged. The contractor shall keep an electronic copy of the sampling frame.

8.4.4.4.2 - Reserved for Future Use
(Rev. 906; Issued: 09-26-19; Effective: 01-02-19; Implementation: 01-02-19)

8.4.4.4.3 - Worksheets
(Rev. 906; Issued: 09-26-19; 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.

8.4.4.4.4 - Overpayment/Underpayment Worksheets
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Worksheets shall be used in calculating the net overpayment. The worksheet shall include data on the claim number, line item, amount paid, audited value, amount

overpaid, reason for disallowance, etc., so that each step in the overpayment calculation is clearly shown. Underpayments identified during reviews shall be similarly documented.

8.4.4.5 - Maintenance of Documentation
(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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, sampling 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 - Calculating the Estimated Overpayment
(Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

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 sampling 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 error rate 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.

8.4.6 - Actions to be Performed Following Selection of Provider or Supplier and Sample
(Rev. 906; Issued: 09-26-19; 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. 906; Issued: 09-26-19; 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. 906; Issued: 09-26-19; 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. 906; Issued: 09-26-19; 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. 906; Issued: 09-26-19; 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. 906; Issued: 09-26-19; 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 - Overpayment Recovery
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

8.4.7.1 - Recovery From Provider or Supplier
(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

Once an overpayment has been determined to exist, the UPIC shall provide its BFL, with a copy to the COR, a summary of the investigation, any prior history (if applicable), the medical review results (including denial reasons), and the extrapolated overpayment amount in a format agreed upon by CPI for all extrapolation requests not associated with a Payment Suspension.

If the CPI agree that an extrapolated overpayment is appropriate, the UPIC shall include the case on the next case coordination meeting agenda for discussion and final approval. During the case coordination meeting, the UPIC may receive additional guidance from CMS related to subsequent actions associated with the investigations. If the UPIC has subsequent questions following the case coordination meeting, the UPIC shall coordinate with its COR and/or BFL, as needed.

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 sampling 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. 906; Issued: 09-26-19; 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. 906; Issued: 09-26-19; 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. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

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, with a copy to the 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 sampling frame used for any new review. The contractor shall consult with its BFL, with a copy to the 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, with a copy to the 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. 906; Issued: 09-26-19; 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.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R13110PI.	04/11/2025	Updates of Chapter 8 and Exhibit 16 in Publication (Pub.) 100-08, Including Unified Program Integrity Contractor (UPIC) Payment Suspension Protocols	05/12/2025	13930
R12515PI	02/22/2024	Updates of Chapter 4, Chapter 8, and Exhibits in Publication (Pub.) 100-08, Including Prioritization and Payment Suspension Language Guidance	03/25/2024	13508
R12333PI	10/26/2023	Updates of Chapter 4 and Chapter 8 in Publication (Pub.) 100-08, Including Adding Guidance Regarding Handling of Freedom Information Act (FOIA) Requests	11/28/2023	13404
R12127PI	07/21/2023	Updates of Chapters 4, Chapter 8, and Exhibits in Publication (Pub.) 100-08, Including Adding Additional Clarification to Ongoing Direction	08/21/2023	13281
R11962PI	04/21/2023	Updates of Chapters 4 and 8 in Publication (Pub.) 100-08, Including Point of Contact Clarification and Update to Statistical Sampling Terminology	05/22/2023	13173
R11797PI	01/19/2023	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	02/21/2023	13066
R11529PI	07/28/2022	Update of Chapter 3 in Publication (Pub.) 100-08, Including Update to Medicare Program Integrity Contractor Post-Payment Review Process, and Update of Chapter 8 Pub. 100-08, Including Revision to When Contractor Suspects Additional Improper Claims	08/30/2022	12827
R11032PI	09/30/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08	11/10/2021	12375
R10984PI	09/09/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08 – Rescinded and replaced by transmittal 11032	11/10/2021	12375
R10383PI	10/09/2020	Updates to Chapters 4, 5, 8, 15, and Exhibits of Publication (Pub.) 100-08	11/10/2020	11999

Rev #	Issue Date	Subject	Impl Date	CR#
R10228PI	07/27/2020	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08	08/27/2020	11884
R10184PI	06/19/2020	Updates to Chapters 4, 6, and 8 of Publication (Pub.) 100-08	07/21/2020	11812
R902PI	09/27/2019	Updates to Chapters 3, 4, 8, 15, and Exhibits of Publication (Pub.) 100-08	10/28/2019	11425
R906PI	09/26/2019	Guidance Regarding the Use of Statistical Sampling for Overpayment Estimation	01/02/2019	10067
R828PI	09/28/2018	Guidance Regarding the Use of Statistical Sampling for Overpayment Estimation – Rescinded and Replaced by Transmittal 906	01/02/2019	10067
R778PI	03/16/2018	Updates to Payment Suspension Notice	05/16/2018	10475
R687PI	11/10/2016	Extrapolated Overpayments	12/12/2016	9713
R670PI	08/19/2016	Update of Payment Suspension Instructions	11/23/2016	9396
R377PI	05/27/2011	Program Integrity Manual Reorganization of Chapters 3 and 8	06/28/2011	6560
R71PI	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
R03PIM	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292
R01PIM	06/2000	Initial Release of Manual	NA	931