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Medicare and Medicaid Audits Using Statistical Sampling and Extrapolation: Challenging Methods and Results

THURSDAY, JUNE 14, 2018

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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The audio portion of the conference may be accessed via the telephone or by using your computer's speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact **Customer Service at 1-800-926-7926 ext. 1**.

TERMS Used in the "MEDICARE & MEDICAID AUDITS USING STATISTICAL SAMPLING & EXTRAPOLATION" Webinar June 2018

These are a list of terms and definitions to explain some of the statistical concepts in this webinar. They are working definitions to aid in understanding the statistics used in CMS audits. There is no attempt to provide the most statistically authoritative or mathematically precise definition.

MPIM CMS Medicare Program Integrity Manual Chapter 8 is 19 page of verbal guidance for using statistical sampling and extrapolation.

RAT-STATS – free DHHS provided statistical package to calculate sample size, random number tables, and extrapolations

Numbers can readily be manipulated and outcomes understood through the use of simple math: addition, subtraction, multiplication and division, e.g., percentages, differences, sums, averages and back of the envelope estimation.
Statistics is a branch of applied math concerned with the collection and interpretation of quantitative data and the use of probability theory to estimate universe parameters, e.g. correlations, *t*-tests and point estimates

INFERENTIAL STATISTICS is a branch of applied statistics drawing conclusions about a universe/frame from a random sample drawn from it. These mathematical analyses move beyond mere description of research data to make inferences about the larger population from which the sample was drawn.

Probability statistics Statistical analysis that uses probability theory to generate and properly interpret inferences. Probability theory is the mathematical basis of those distributions tested repeatedly and compared to random outcomes.

Parameter refers to a DISTRIBUTIONAL characteristic of a frame

- **Parametric Statistics** are probability estimates based on the parameters of a normal distribution. Parametric tests make specific assumptions about the population parameters that characterize the underlying distributions for that test
- **Non Parametric Statistics** tests make few or no assumptions about the underlying distribution of the and parameters of the population
- **Parametric tests** make specific assumptions about the population parameters that characterize the underlying distributions for that test
- **Non parametric** statistics make few or no assumptions about the underlying distribution of the parameters of the population

Samples
Sampling unit – the unit of measurement for the study: claim, beneficiary, specific payment codes. The auditor must stick with the chosen unit and not switch back and forth

Universe – claims paid to a Provider in a specific timeframe

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Sampling Frame – subset of the universe defined as variables of interest from which the sample will be randomly selected and over which the sample will be extrapolated

Sample – purportedly a randomly selected subset of sampling frame to be audited for overpayments
Unit of Analysis (Sampling Unit) – what is measured in the audit: claim line, claim, beneficiary, provider (must be invariant throughout the audit)

Random sample In mathematics and statistics random means: having a value which cannot be determined but only described probabilistically as a random variable, chosen without regard to any characteristics of the individual members of the population so that each has an equal chance and known probability of being selected randomly. It is not the lay meaning of "haphazard".

Representative – an unbiased sample that accurately reflects the numerical membership of the entire universe and its distribution. It must cover all salient features of the universe (without overlapping segments) to be a true picture of the universe from which it was selected and over which projections will be made. The distribution of the sample should represent the distribution of the frame.

SVRS Statistically Valid Random Sample selected from a frame of paid Medicare or Medicaid claims guards against cherry picking or any bias by the audit and will be an accurate estimator it (and only if): it meet the requirements the methodology – especially assumptions about distribution; proper statistics are used to measure it; it meets chosen sampling error; it is of sufficient size to accurately measure the variable;
is random; representative (without bias); and address the impact of non-sampling errors

Extrapolation
Extrapolation takes the results of an audited sample and projects the dollar amount of the claims in the universe of claims paid.

Null Hypothesis a statistical hypothesis that is tested then accepted or rejected; *specifically* **:** the hypothesis that an observed overpayment amount is due to chance alone and not due to a systematic or biasing cause

Distribution the measurement yardstick of statistics. It is a description of the relative numbers of times each possible outcome will occur in a number of trials. The frequency outcome forms a frequency distribution that is compared to a theoretical distribution. A mathematical function describing the probability that a given value will occur is called the probability function

Normal Distribution is the bell-shaped distribution necessary for use of parametric statistics. It is continuous probability distribution (a function that tells the probability of a number in some context falling between any two real numbers). The normal distribution is symmetric around the mean. The mean, median and mode are the same number. Its use allows two key theories of probability to be used (the theory of large numbers and the Central Limit Theorem).

Measures of central tendency In a normal distribution these three are the dame number

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- **Mean** (average) the arithmetic sum of all scores divided by the number of cases
- **Median** – the middle most real score in the data set
- **Mode** the score that occurs most frequently in the data set (does not have to be unique – sometimes more than one value is equally likely)

Independence Two events are independent if the occurrence of one event makes it neither more nor less probable that the other occurs.

Point Estimate uses sample data to calculate a single point (mean) which serves as the best estimate of a universe parameter

Confidence level – upper and lower probability level around a mean
Point Estimate +/- Precision amount = Confidence Level

Error

Precision - measurement of variability
Precision amount ½ the confidence level
Precision % =Precision amount/Point estimate
Variance - distance between each set of data points and their mean
Standard deviation – square root of the variance
Error rate – number of claims in error or dollars in error
Error rate – can measure number of dollars in error or dollars in error
Prior history of error requirement to determine sample size
Sampling error – getting a poor sample yielding poor estimate The difference the sample and the frame being extrapolated over **Non sampling error** – claims not in error labeled as in error, mistakes in coding, reporting, stratification, inaccurate documentation.

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Medicare Program Integrity Manual

Chapter 8 – Administrative Actions and Statistical Sampling for Overpayment Estimates

Table of Contents
(Rev. 687, 11-10-16)

Transmittals for Chapter 8

8.4.11.2 – Cluster Sampling

8.1 - Appeal of Denials
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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 PSC, then the PSC 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, PSCs 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 PSC 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 PSC does not need to establish good cause. However, the PSC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

This section applies to Medicare Administrative Contractors (MACs) and Zone Program Integrity Contractors (ZPICs). Hereinafter, Program Safeguard Contractors (PSCs) shall be included in the term ZPICs.

The ZPIC 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 ZPIC shall refer such overpayments to the MAC only after the investigation has been vetted with CMS (see Pub. 100-08, chapter 4, section 4.6.4). In addition, if a ZPIC 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 4.18. 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. 687; Issued: 11-10-16; Effective: 12-12-16; Implementation: 12-12-16)

The MACs shall perform the actual recoupment identified by the ZPICs. *When a ZPIC 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:

- The amount of the original claim;8
- 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. 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines consent settlement as an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved. The PSC and ZPIC BI units and the contractor medical review units shall submit via secure email the consent settlement to the Primary and Associate GTLs before offering a consent settlement to the provider or supplier. If the PSC or the ZPIC BI units or the contractor medical review units do not have secure email, the consent settlement shall be sent to the Primary GTL and the Associate GTL via

hard copy. Upon receipt, GTLs will forward the consent settlement to the Director of the Division of Benefit Integrity Management Operations. The PSC or the ZPIC BI units and the contractor medical review units may contact the provider upon approval of the consent settlement. Consent settlement documents carefully explain, in a neutral tone, what rights a provider waives by accepting a consent settlement. The documents shall also explain in a neutral tone the consequences of not accepting a consent settlement. A key feature of a consent settlement is a binding statement that the provider agrees to waive any rights to appeal the decision regarding the potential overpayment. The consent settlement agreement shall carefully explain this, to ensure that the provider is knowingly and intentionally agreeing to a waiver of rights. Consent settlement correspondence shall contain:

A complete explanation of the review and the review findings

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

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

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

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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

8.2.3.3.4 - Option 1 - Election to Proceed to Statistical Sampling for Overpayment Estimation
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

- Initiate statistical sampling for overpayment estimation of the provider's or supplier’s claims for the service under review following instructions in the Program Integrity Manual, chapter 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

When supporting PSCs or ZPICs in consent settlements, the ACs shall report these costs in the PSC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

This section applies to Medicare Administrative Contractors (MACs) and Zone Program Integrity Contractors (ZPICs). Hereinafter, Program Safeguard Contractors (PSCs) shall be included in the term ZPICs.

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 ZPIC 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 ZPIC. The ZPICs shall advise and coordinate the imposition of a payment suspension with the appropriate MAC when a payment suspension has been approved by CMS. The ZPIC 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 Fraud Investigation Database (FID) for approval. ZPICs shall notify their appropriate CPI Contracting Officer's Representative (COR)/Business Function Lead (BFL) of the submission by providing the FID number via email.

8.3.1 – When Suspension of Payment May Be Used

(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

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 ZPIC 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 ZPIC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A payment suspension may be used when the ZPIC, 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 ZPIC 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 ZPIC 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 ZPIC 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 ZPIC may recommend a

fraud suspension to CPI only after the ZPIC has vetted the provider in accordance with Pub. 100-08, chapter 4, section 4.6.4. (If the MAC identifies the potential fraud issue from a complaint, the MAC shall refer its information to the respective ZPIC for development).

B. Requests for Suspension of Payment

For initial ZPIC requests to suspend payments, the ZPIC shall inform its assigned BFL of the potential suspension. The BFL will discuss all findings with the ZPIC. After informing the BFL about the suspension, the contractor shall submit the payment suspension request via the FID 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 FID submission.

The ZPIC shall also prepare and submit, if appropriate, a payment suspension referral package to CPI via the FID 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 ZPIC 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 ZPICs shall submit requests to CPI via the FID 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A payment suspension may be implemented when the MAC, ZPIC, or CMS possesses reliable information that an overpayment exists. In this situation, the MAC shall refer its information to the respective ZPIC for development of a potential suspension. The ZPIC

shall refer a payment suspension to CPI via the FID 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A payment suspension may be implemented when the MAC or ZPIC 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 ZPIC for development of a potential suspension. The ZPIC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A payment suspension may be used when the MAC, ZPIC, or CMS possesses reliable information that the provider has failed to furnish records and other information requested or that is due, and which is needed to determine the amounts due the provider. In this situation, the MAC shall refer its information to the respective ZPIC for development of a potential suspension. The ZPIC 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 ZPIC may request a payment suspension due to non-response from the provider.

In lieu of imposing a payment suspension, the MAC or ZPIC may deny the paid claims because the provider failed to provide the requested documentation after two attempts. In

either case, the MAC or ZPIC 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 ZPIC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

The initiation (including whether or not to give advance notice), modification, extension, or removal of any type of suspension requires the explicit prior approval of CPI. The ZPIC will discuss requests for payment suspension and other proposed administrative actions with CPI. Where applicable, MACs should consult with the respective ZPIC about any potential payment suspension it believes should be considered. At which point, the MAC shall refer its information to the respective ZPIC for development of a potential suspension.

A meeting may be held between the ZPIC and CPI prior to the approval of a payment suspension action involving an initial request, rebuttal, extension or termination.

The ZPIC shall request all initial payment suspensions via FID and provide all required information in the respective fields and upload all required attachments. Information uploaded to the FID shall include:

1. The AAR – Payment Suspension form

2. A draft of the proposed payment suspension initial notice following the format noted in section 8.3.2.2 of this chapter (in a word document format);

3. Any other supporting documentation.

For general suspensions, the ZPIC shall complete its statistical sampling and have its medical records request letter prepared prior to the submission of the suspension request into the FID. A copy of the medical record request letter shall be included as supporting documentation when the suspension request is submitted into the FID.

The ZPIC shall request all extensions to payment suspensions via the FID and provide all required information in the respective fields and upload all required attachments. The ZPIC shall make the request for an extension at least 14 calendar days before the anticipated expiration of the payment suspension. Information uploaded to the FID shall include:

1. An updated AAR – Payment Suspension form

2. 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);

3. Any other supporting documentation.

The ZPIC shall request all terminations to payment suspensions via the FID and provide all required information in the respective fields and upload all required attachments. The ZPIC shall make the request for a termination at least 14 calendar days before the anticipated expiration of the payment suspension. Information uploaded to the FID shall include:

1. A draft of the proposed payment suspension termination notice following the format noted in section 8.3.2.2 (in a word document format);

2. A draft of the associated overpayment determination notice(s) (in a word document format).

NOTE: All law enforcement-requested payment suspensions must be sent directly to CPI by law enforcement for consideration. If a ZPIC receives a law enforcement-requested payment suspension request, the ZPIC shall contact CPI for guidance.

The ZPIC shall not take steps to implement any of the above suspension actions without the explicit approval of CPI. If approved, CPI shall make appropriate changes to the draft notice before approving the payment suspension notice and upload the approval and documents via the FID.

When a payment suspension is approved by CPI, the ZPIC 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. 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 ZPIC. The ZPIC shall enter this amount in the FID 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, and RAPs. If it is discovered that money is released to the provider after the effective date of the payment suspension, the MAC or ZPIC shall contact CPI for guidance.

8.3.2.2 – The Notices Involving Payment Suspensions
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

The ZPICs 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

ZPICs shall inform the provider of the payment suspension action being taken. When prior notice is appropriate, the ZPIC 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 ZPIC shall recommend to CPI not to give prior notice if, in the ZPIC'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 ZPIC has first-hand knowledge of a risk that the provider will cease or severely curtail operations or otherwise seriously jeopardize its ability to repay its debts; or

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

If CPI approves waiver of the prior notice requirement, the ZPIC 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 ZPIC 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 ZPIC shall recommend that CPI waive the prior notice. If CPI concurs to waive the prior notice requirement, the ZPIC 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 ZPIC shall confer with CPI for guidance.

C. If the payment suspension request is a fraud suspension, the ZPIC shall recommend to CPI that prior notice not be given. If CPI concurs to waive the prior notice requirement, the ZPIC 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 ZPIC shall confer with CPI for guidance.

8.3.2.2.2 – Content of Payment Suspension Notice

(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

The ZPIC 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 ZPIC shall include the rationale to justify the action being taken.);
- In most notices, the ZPIC shall identify and describe at least five example claims that are associated with the reason for the payment suspension, if available. The example claims are to be current claims not more than 1 year old from the paid date. 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

At any time, the ZPIC 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 ZPIC 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 ZPIC shall notify the provider in writing of the change and the reason. The ZPIC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

After consultation with and approval from CPI, the ZPIC 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 ZPIC 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 ZPIC shall also upload the signed copies of all notices released to the provider into the FID.

8.3.2.2.5 – Opportunity for Rebuttal
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

If the payment suspension is approved with prior notice, the provider is afforded an opportunity to submit to the ZPIC 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 ZPIC 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 ZPIC is required in accordance with 42 CFR §405.375. If a provider does not respond in a timely manner, the ZPIC shall submit a written response to the provider within 30 calendar days from the receipt date of the rebuttal.

ZPICs shall ensure the following:

- CMS Review – ZPICs shall forward the provider's rebuttal statement and any pertinent information to CPI via the FID within 1 business day of receipt. The ZPIC 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 FID no later than 10 calendar days from receipt. The ZPIC 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. ZPICs shall carefully review the provider's rebuttal statement and pertinent information, and shall consider all facts and issues raised by the provider. If the ZPIC 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 ZPIC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

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 ZPICs shall follow the claims processing and review procedures in accordance with Pub. 100-08, chapter 3. MACs and ZPICs 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 ZPIC 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.

ZPICs 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 ZPIC may elect to only place such claims types on prepayment or post-payment review. ZPICs shall consult with CPI for guidance when resources may be better utilized employing statistical sampling for overpayment determination(s). ZPICs 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 ZPIC 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 ZPIC 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 ZPIC shall make all reasonable efforts to expedite the determination of the overpayment amount. The ZPIC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

The ZPIC shall enter all payment suspensions into the FID. In the Suspension Narrative field, the ZPIC 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 FID shall reflect the money withheld on Day One of the payment suspension.

8.3.2.4 – Duration of the Payment Suspension

(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A. Time Limits for General Suspensions

If CPI approves a general suspension, it will be for a 180 calendar day period. The ZPIC 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 ZPIC 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 ZPIC. 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 ZPIC 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 ZPIC 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 ZPIC shall obtain CPI approval for the extension request and draft notice, and shall notify the provider if the suspension action has been extended. The ZPIC shall prepare a "draft extension notice" (in accordance with section 8.3.2.2 of this chapter) and submit it via the FID, along with any other supportive information, to CPI for approval at least 14 calendar days before the payment suspension is set to expire. 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 ZPIC shall provide a copy of the signed notice to CPI via the FID.

8.3.2.5 – Terminating the Payment Suspension

(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

The ZPIC shall recommend to CPI that the payment suspension be terminated prior to the payment suspension expiring. The ZPIC shall provide this request via the FID 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 ZPIC 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 ZPIC 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 ZPIC 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 ZPIC 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. Upon approval of the termination notice by CPI, the ZPIC shall provide a copy of the signed notice via the FID to CPI.

8.3.2.6 – Disposition of the Withheld Funds

(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

The MAC and ZPIC shall maintain an accurate, up-to-date record of the dollar amount withheld and the claims that comprise the withheld amount. The MAC and ZPIC 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 ZPIC 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. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

A. Present Time

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

B. Past Period of Time

If the payment suspension is in the process of being terminated or has been terminated, and the ZPIC believes there are past periods of claims submissions that may contain possible overpayments, the ZPIC shall consider recommending a new payment suspension covering those dates.

C. Additional Services

If, during the time that a provider is under a partial payment suspension for a particular service(s), the ZPIC determines there is reason to initiate a payment suspension action for a different service, a new payment suspension shall be initiated or the new service(s) shall be incorporated into the existing payment suspension depending on the circumstances. The ZPIC shall discuss this action with CPI for a decision.

Any time a new suspension action is initiated on a provider who is already under one or more partial payment suspension actions, the ZPIC shall, if appropriate: (1) obtain separate CMS approval, (2) issue an additional notice to the provider, and (3) offer a new rebuttal period to the provider.

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 ZPICs)

(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

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

- When CMS suspends payments to a DME supplier, all payments to the supplier are suspended in <u>all</u> 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 ZPIC that requests the national payment suspension to CPI shall become the "lead" contractor for the payment suspension if the payment suspension is approved. The lead contractor is responsible for informing the other respective contractors 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 is responsible for coordinating and reporting to its CORs and BFLs whether the other contractors are compliant with the payment suspension timeframe and activities.

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

For ZPIC-initiated DME payment suspensions:

- Each ZPIC 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 ZPIC.

  Each ZPIC shall be responsible for providing timely updates on the withheld money in its corresponding DME MAC jurisdiction to the lead ZPIC for input in the FID payment suspension module, and in accordance with the FID requirements.

8.3.3.2 – Non-DME National Payment Suspensions (MACs and ZPICs)
(Rev. 670, Issued: 08-19-16, Effective: 11-23-16, Implementation: 11-23-16)

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 ZPICs:

- 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 ZPIC that requests the national payment suspension to CPI shall become the "lead" contractor for the payment suspension. The lead contractor is responsible for informing the other respective contractors 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 is responsible for coordinating and reporting to its CORs and BFLs whether the other contractors are compliant with the payment suspension timeframe and activities.

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

For ZPIC-initiated non-DME national payment suspensions:

- Each ZPIC 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 ZPIC.

  Each ZPIC shall be responsible for providing timely updates on the withheld money in its respective zone to the Lead ZPIC, so it can update the FID payment suspension module in accordance with the FID requirements.

8.4 - Use of Statistical Sampling for Overpayment Estimation
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC or the ZPIC BI unit or

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

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

8.4.1.2 - The Purpose of Statistical Sampling

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Statistical sampling is used to calculate and project (i.e., extrapolate) the amount of overpayment(s) made on claims. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), mandates that before using extrapolation 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.

8.4.1.3 - Steps for Conducting Statistical Sampling

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The major steps in conducting statistical sampling are: (1) Selecting the provider or supplier; (2) Selecting the period to be reviewed; (3) Defining the universe, the sampling unit, and the sampling frame; (4) Designing the sampling plan and selecting the sample; (5) Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable, (6) Estimating the overpayment. Where an overpayment has been determined to exist, follow applicable instructions for notification and collection of the overpayment.

8.4.1.4 - Determining When Statistical Sampling May Be Used

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

- error rate determinations by MR unit, PSC, ZPIC or other area
- probe samples

- data analysis
- provider/supplier history
- information from law enforcement investigations
- allegations of wrongdoing by current or former employees of a provider or supplier
- audits or evaluations conducted by the OIG

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

8.4.1.5 - Consultation With a Statistical Expert

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

8.4.1.6 - Use of Other Sampling Methodologies

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

8.4.2 - Probability Sampling

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

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

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

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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Following selection of the provider or supplier, determine the time period and the number of days, weeks, months, or years, for which sampling units will be reviewed. The target universe shall be defined according to this period. The period of review is determined by considering several factors, including (but 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 regional or local coverage policy has been in effect (i.e., should the provider or supplier have succeeded in adjusting their billing/utilization practices by now);
- The extent of prepayment review already conducted or currently being conducted;
- The dollar value of the claims that are involved relative to the cost effectiveness of the sample; and/or,
- The applicable time periods for reopening claims (see the Medicare Claims Processing Manual, chapter 34 §10.6

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 defined cost reporting year. **If the period under review is greater than one year, select a separate sample for each cost-reporting year.**

8.4.3.2 - Defining the Universe, the Sampling Unit, and the Sampling Frame
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

8.4.3.2.1 - Composition of the Universe
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

A. Part A Claims: For providers 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. For such claims, use the service date to match findings to the cost report.

For providers 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 for the period under review.

B. Part B Claims: The universe shall consist of all fully and partially paid claims submitted by the 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.

8.4.3.2.2 - The Sampling Unit
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Sampling units are the elements that are selected according to the design of the survey and the chosen method of statistical sampling. They may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary). For example, possible sampling units may include specific beneficiaries seen by a physician during the time period under review; or, claims for a specific item or service. In certain circumstances, e.g., multi-stage sample designs, other types of clusters of payments may be used. In principle, any type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts.

Unlike procedures for suppliers, overpayment projection and recovery procedures for providers and non-physician practitioners who bill intermediaries, 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 a projection methodology designed specifically for that type of provider to ensure that the results can be placed at the appropriate points on the provider's 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's cost report must be known. Follow the instructions contained in section 3.10, but use the projection methodologies provided

in PIM, Exhibits 9 through 12, for the appropriate provider type. PIM, Exhibits 9 through 12, are to be used only for claims not paid under PPS.

8.4.3.2.3 - The Sampling Frame
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The sampling frame is the "listing" of all the possible sampling units from which the sample is selected. The frame may be, for example, 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.

The ideal frame is a list that covers the target universe completely. In some cases the frame must be constructed by combining lists from several sources and duplication of sampling units may result. Although duplicate listings can be handled in various ways that do not invalidate the sample, it is recommended that duplicates be eliminated before selecting the sample.

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

8.4.4.1 - Sample Design
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Identify the sample design to be followed. The most common designs used are simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these.

8.4.4.1.1 - Simple Random Sampling
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Simple random sampling involves using a random selection method to draw a fixed number of sampling units from the frame without replacement, i.e., not allowing the same sampling unit to be selected more than once. The random selection method must ensure that, given the desired sample size, each distinguishable set of sampling units has the same probability of selection as any other set - thus the method is a case of "equal probability sampling." An example of simple random sampling is that of shuffling a deck of playing cards and dealing out a certain number of cards (although for such a design to qualify as probability sampling a randomization method that is more precise than hand shuffling and dealing would be required.)

8.4.4.1.2 - Systematic Sampling
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Systematic sampling requires that the frame of sampling units be numbered, in order, starting with the number one (1) and ending with a number equal to the size of the frame. Using a random start, the first sampling unit is selected according to that random number, and the remaining sampling units that comprise the sample are selected using a fixed interval thereafter. For example, if a systematic sample with size one-tenth of the frame size is desired, select a random number between one and ten, say that it is "6", and then select every tenth unit thereafter, i.e., "16, 26, 36, …etc." until the maximum unit number in the frame has been exceeded.

8.4.4.1.3 - Stratified Sampling

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Stratified sampling involves classifying the sampling units in the frame into non-overlapping groups, or strata. The stratification scheme should try to ensure that a sampling unit from a particular stratum is more likely to be similar in overpayment amount to others in its stratum than to sampling units in other strata. Although the amount of an overpayment cannot be known prior to review, it may be possible to stratify on an observable variable that is correlated with the overpayment amount of the sampling unit. Given a sample in which the total frame is covered by non-overlapping strata, if independent probability samples are selected from each of the strata, the design is called stratified sampling. The independent random samples from the strata need not have the same selection rates. A common situation is one in which the overpayment amount in a frame of claims is thought to be significantly correlated with the amount of the original payment to the provider or supplier. The frame may then be stratified into a number of distinct groups by the level of the original payment and separate simple random samples are drawn from each stratum. Separate estimates of overpayment are made for each stratum and the results combined to yield an overall projected overpayment.

The main object of stratification is to define the strata in a way that will reduce the margin of error in the estimate below that which would be attained by other sampling methods, as well as to obtain an unbiased estimate or an estimate with an acceptable bias. The standard literature, including that referenced in Section 3.10.10, contains a number of different plans; the suitability of a particular method of stratification depends on the particular problem being reviewed, and the resources allotted to reviewing the problem. Additional discussion of stratified sampling is provided in Section 8.4.11.1.

8.4.4.1.4 - Cluster Sampling

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Cluster sampling involves drawing a random sample of clusters and reviewing either all units or a sample of units selected from each of the sampled clusters. Unlike strata, clusters are groups of units that do not necessarily have strong similarities, but for which their selection and review as clusters is more efficient economically than, for example, simple random sampling. For example, if the sampling unit is a beneficiary and the plan is to review each of the set of payments for each selected beneficiary, then the design is an example of cluster sampling with each beneficiary constituting a cluster of payments.

The main point to remember (when sampling all the units in the cluster) is that the sample size for purposes of estimating the sampling error of the estimate is the number of clusters, not the total number of individual payments that are reviewed.

A challenge to the validity of a cluster sample that is sometimes made is that the number of sampling units in a cluster is too small. (A similar challenge to stratified sampling is also raised – i.e., that the number of sampling units in a stratum is too small). Such a challenge is usually misguided since the estimate of the total overpayment is a combination of the individual cluster (or, in the case of stratified sampling, stratum) estimates; therefore the overall sample size is important, but the individual cluster (or stratum) sample sizes are usually not critical. Additional discussion of cluster sampling is provided in Section 8.4.11.2.

Both stratification and cluster sampling involve the grouping of more elementary units. The former is frequently recommended when there is sufficient prior knowledge to group units that are similar in some aspect and potentially different from other units. The latter is frequently recommended when there are natural groupings that make a study more cost effective. When carried out according to the rules of probability sampling both of the methods, or a combination, are valid. The use of any of the methods described in this section will produce valid results when done properly.

8.4.4.1.5 - Design Combinations

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

A sample design may combine two or more of the methods discussed above. For example, clusters may be stratified before selection; systematic selection rather than simple random sampling may be used for selecting units within strata; or clusters may be subsampled using either simple random sampling or systematic sampling, to cite some of the possible combinations of techniques.

The benefits of stratification by claim amount may be achieved without actually stratifying if the frame is arranged in ascending order by the original payment amount and systematic sampling applied with a random start. That is because the systematic selection "balances out" the sample over the different levels of original payment in a manner similar to the effect of formal stratification. Thus systematic selection is often used in the hope that it will result in increased precision through "implicit stratification."

8.4.4.2 - Random Number Selection

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The PSC or ZPIC BI unit or the contractor MR unit shall identify the source of the random numbers used to select the individual sampling units. The PSC or ZPIC BI unit or the contractor MR unit shall also document the program and its algorithm or table that is used; this documentation becomes part of the record of the sampling and must be available for review. The PSC or ZPIC BI unit or the contractor MR unit shall document any starting point if using a random number table or drawing a systematic sample. In

addition, the PSC or ZPIC BI units or the contractor MR units shall document the known seed value if a computer algorithm is used. The PSC or ZPIC BI units or the contractor MR units shall document all steps taken in the random selection process exactly as done to ensure that the necessary information is available for anyone attempting to replicate the sample selection.

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

8.4.4.3 - Determining Sample Size

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

8.4.4.4 - Documentation of Sampling Methodology

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

8.4.4.4.1 - Documentation of Universe and Frame

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

8.4.4.4.2 - Arrangement and Control Totals

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

It is often convenient in frame preparation to array the universe elements by payment amount, e.g., low to high values, especially when stratification is used. At the same time, tabulate control totals for the numbers of elements and payment amounts.

8.4.4.4.3 - Worksheets

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

- Name and identification number of the provider or supplier;
- Name and title of reviewer;
- The Health Insurance Claim Number (HICN), the unique claim identifier (e.g., the claim control number), and the line item identifier;
- Identification of each sampling unit and its components (e.g., UB-92 or attached medical information)
- Stratum and cluster identifiers, if applicable;
- The amount of the original submitted charges (in column format);

- Any other information required by the cost report worksheets in PIM Exhibits 9 through 12;

- The amount paid;

- The amount that should have been paid (either over or underpaid amount); and,

- The date(s) of service.

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 - Informational Copies to Primary GTL, Associate GTL, SME or CMS RO
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

8.4.5 - Calculating the Estimated Overpayment
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

8.4.5.1 - The Point Estimate
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

and the weighted stratum estimates are added together to produce an overall point estimate.

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

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

8.4.5.2 - Calculation of the Estimated Overpayment Amount

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

The results of the sampling unit reviews are used to project an estimate of the overpayment amount. Each result shall be recorded except that a sampling unit's overpayment shall be set to zero if there is a limitation on liability determination made to waive provider or supplier liability for that sampling unit (per provisions found in §1879 of the Social Security Act (the Act)) and/or there is a determination that the provider or supplier is without fault as to that sampling unit overpayment (per provisions found in §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 also be used in calculating the estimated overpayment.

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

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

8.4.6.1.1 - Written Notification of Review

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

- an explanation of why the review is being conducted (i.e., why the provider or supplier was selected),
- the time period under review,
- a list of claims that require medical records or other supporting documentation,
- a statement of where the review will take place (provider/supplier office or contractor site),
- information on appeal rights,

- an explanation of how results will be projected to the universe if claims are denied upon review and an overpayment is determined to exist, and

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

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

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

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

8.4.6.1.2 - Determining Review Site

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

A. Provider/Supplier Site Reviews

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

- the extent of aberrant billing or utilization patterns that have been identified;

- the presence of multiple program integrity issues;

- evidence or likelihood of fraud or abuse; and/or,

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

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

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

8.4.6.2 - Meetings to Start and End the Review

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

In-person meetings to start and end the review are encouraged, but are not required or always feasible. If you hold an in-person meeting at the start of the review, explain both the scope and purpose of the review as well as discuss what will happen once you have completed the review. Attempt to answer all questions of the provider or supplier related to the review.

During an exit meeting, you may discuss the basic or preliminary findings of the review. Give the provider or supplier an opportunity to discuss or comment on the claims decisions that were made. 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Following your receipt of the requested documentation (or the end of the period to submit or make available the requested documentation, whichever comes first), start your review of the claims. You may ask for additional documentation as necessary for an objective and thorough evaluation of the payments that have been made, but you do not have to hold up conducting the review if the documents are not provided within a reasonable time frame. 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 the Medicare law, HCFA/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.

Document all findings made so that it is apparent from your written documentation if the initial determination has been reversed. Document the amount of all overpayments and underpayments and how they were determined.

You are encouraged to complete your review and calculate the net overpayment within 90 calendar days of the start of the review (i.e., within 90 calendar days after you have 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 your control where you may not be able to complete the review within this time period (e.g., you have made a fraud referral to the OIG and are awaiting their response before pursuing an overpayment).

Your documentation of overpayment and underpayment determinations shall be clear and concise. Include copies of the local medical review policy 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. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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

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

- a description of the universe, the frame, and the sample design;
- a definition of the sampling unit,
- the sample selection procedure followed, and the numbers and definitions of the strata and size of the sample, including allocations, if stratified;
- the time period under review;
- the sample results, including the overpayment estimation methodology and the calculated sampling error as estimated from the sample results; and
- the amount of the actual overpayment/underpayment from each of the claims reviewed.

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

8.4.7.2 - Informational Copy to Primary GTL, Associate GTL, SME or CMS RO
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Send an informational copy of the demand letter to the Primary GTL, Associate GTL, SME or CMS RO. They will maintain copies of demand letters and will forward to CO upon request. If the demand letter is used routinely and repeatedly, you shall not repeatedly send it to the Primary GTL, Associate GTL, SME or CMS RO.

8.4.8 - Corrective Actions
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Take or recommend other corrective actions you deem necessary (such as payment suspension, imposition of civil money penalties, institution of pre- or post-payment review, additional edits, etc.) based upon your findings during or after the review.

8.4.9 - Changes Resulting From Appeals
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

If the decision issued on appeal contains either a finding that the sampling methodology was not valid, and/or reverses the revised initial claim determination, you shall take appropriate action to adjust the extrapolation of overpayment.

8.4.9.1 - Sampling Methodology Overturned
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

If the decision issued on appeal contains a finding that the sampling methodology was not valid, 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, you shall revise the overpayment determination after making the corrections. Consult with your Primary GTL, Associate GTL, SME or CMS RO to confirm that this course of action is consistent with the decision of the hearing officer (HO), administrative law judge (ALJ) or Departmental Appeals Board (DAB), or with the court order.

B. You 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, then these individual sampling units shall be eliminated from the sampling frame used for any new review. Consult with your Primary GTL, Associate GTL, SME or CMS RO to confirm that this course of action is consistent with the decision of the HO, ALJ or DAB, or with the court order.

C. You may conduct a new review (using a new, valid methodology) for the same time period as was covered by the previous review. If this option is chosen, you 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, consult with your Primary GTL, Associate GTL, SME or CMS RO to verify that this course of action is consistent with the decision of the HO, ALJ or DAB, or with the court order.

8.4.9.2 - Revised Initial Determination
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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 projection of overpayment issued.

8.4.10 - Resources
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

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Kish, L., Survey Sampling, New York: John Wiley and Sons, 1967, 2nd printing. (Paperback 1995).

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8.4.11 - Additional Discussion of Stratified Sampling and Cluster Sampling
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

8.4.11.1 – Stratified Sampling
(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Generally, one defines strata to make them as internally homogeneous as possible with respect to overpayment amounts, which is equivalent to making the mean overpayments for different strata as different as possible. Typically, a proportionately stratified design with a given total sample size will yield an estimate that is more precise than a simple random sample of the same size without stratifying. The one highly unusual exception is one where the variability from stratum mean to stratum mean is small relative to the average variability within each stratum. In this case, the precision would likely be

reduced, but the result would be valid. It is extremely unlikely, however, that such a situation would ever occur in practice. Stratifying on a variable that is a reasonable surrogate for an overpayment can do no harm, and may greatly improve the precision of the estimated overpayment over simple random sampling. While it is a good idea to stratify whenever there is a reasonable basis for grouping the sampling units, failure to stratify does not invalidate the sample, nor does it bias the results.

If it is believed that the amount of overpayment is correlated with the amount of the original payment and the universe distribution of paid amounts is skewed to the right, i.e., with a set of extremely high values, it may be advantageous to define a "certainty stratum", selecting all of the sampling units starting with the largest value and working backward to the left of the distribution. When a stratum is sampled with certainty, i.e., auditing all of the sample units contained therein, the contribution of that stratum to the overall sampling error is zero. In that manner, extremely large overpayments in the sample are prevented from causing poor precision in estimation. In practice, the decision of whether or not to sample the right tail with certainty depends on fairly accurate prior knowledge of the distribution of overpayments, and also on the ability to totally audit one stratum while having sufficient resources left over to sample from each of the remaining strata.

Stratification works best if one has sufficient information on particular subgroups in the population to form reasonable strata. In addition to improving precision there are a number of reasons to stratify, e.g., ensuring that particular types of claims, line items or coding types are sampled, gaining information about overpayments for a particular type of service as well as an overall estimate, and assuring that certain rarely occurring types of services are represented. Not all stratifications will improve precision, but such stratifications may be advantageous and are valid.

Given the definition of a set of strata, the designer of the sample must decide how to allocate a sample of a certain total size to the individual strata. In other words, how much of the sample should be selected from Stratum 1, how much from Stratum 2, etc.? As shown in the standard textbooks, there is a method of "optimal allocation," i.e., one designed to maximize the precision of the estimated potential overpayment, assuming that one has a good idea of the values of the variances within each of the strata. Absent that kind of prior knowledge, however, a safe approach is to allocate proportionately. That is, the total sample is divided up into individual stratum samples so that, as nearly as possible, the stratum sample sizes are in a fixed proportion to the sizes of the individual stratum frames. It is emphasized, however, that even if the allocation is not optimal, using stratification with simple random sampling within each stratum does not introduce bias, and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample.

8.4.11.2 - Cluster Sampling

(Rev. 377, Issued: 05-27-11, Effective: 06-28-11, Implementation: 06-28-11)

Selecting payments in clusters rather than individually usually leads to a reduction in the precision of estimation. However, your reasons for using cluster sampling instead of simple random sampling may be driven by necessity and/or cost-savings related to the location of records or the nature of a record. For example, for medical review to determine the appropriateness of certain charges for a beneficiary it may be necessary to examine the complete medical record of the patient. This then may allow for review of claims for several services falling within the selected review period. In another instance, the medical records that you must review may be physically located in a cluster (e.g., the same warehouse, the same file drawer, the same folder) with the medical records for other similar claims and it is cost effective to select units from the same location. Whenever the cost in time and other resources of selecting and auditing clusters is the same as the cost of simple random sampling the same number of payments, it is better to use simple random sampling because greater precision will be attained.

When reviewing all the units in each cluster, the sample size is the number of clusters, not the number of units reviewed. This is single-stage cluster sampling, a method frequently used when sampling beneficiaries. One may choose to review a sample of units within each cluster rather than all units. Textbooks that cover the topic of multi-stage sampling provide formulas for estimating the precision of such sample designs. One example for which multi-stage sampling might be an appropriate choice of design is the case of reviewing a supplier chain where records are spread out among many locations. The first-stage selection would be a sample of locations. At the second stage a subsample of records would be selected from each sampled location.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-10-230

In the case of	**Claim for**
Podiatric Medical Associates (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiaries)	**** (HIC Numbers)
Cahaba, GBA (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated October 1, 2009, which concerned a post-payment statistical sample of claims for Medicare coverage of podiatric and related medical services provided to various beneficiaries between September 1, 2004, and February 9, 2007. The ALJ found that the statistical sample and extrapolation of the sampled results upon which the overpayment was based were valid; that the appellant was liable for the cost of the non-covered services; and that the appellant's liability could not be waived. The appellant has asked the Medicare Appeals Council (Council) to review this action. The appellant's request for review has been entered into the record as Exhibit (Exh.) MAC-1.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c). As set forth below, the Council modifies the ALJ's decision. The Council finds that the statistical sampling cannot be upheld, and that the overpayment

is limited to the actual sample results on the twenty-six claims which remained at issue before the ALJ.

BACKGROUND

The appellant, in the person of Rondrick Williamson, DPM, operates a podiatric practice. On March 19, 2007, Cahaba Safeguard Administrators (Cahaba Safeguard), a Medicare Program Safeguard Contractor (PSC), notified Dr. Williamson that it would visit the appellant's facility, the next day, to review (*i.e.*, audit) claim files for seventy-four beneficiaries to ensure the propriety of the corresponding Medicare payments. Exh. 24 at Tab A. The appellant subsequently testified at the ALJ hearing, and the PSC did not dispute, that the PSC investigators copied complete medical files for seventy-four beneficiaries during this review. By letter dated May 5, 2008, the PSC notified the appellant of its preliminary audit results. Based upon a general finding of inadequately documented claims, the PSC determined that, during the period September 1, 2004, through February 9, 2007, the appellant had received a Medicare overpayment, totaling at least $625,258.84. The PSC indicated that the overpayment was projected from a sample of thirty claims, the documentation of which, "did not meet various Medicare coverage requirements." Exh. 1 at 346.

By letter dated May 27, 2008, Cahaba GBA, the appellant's Medicare carrier, formally notified the appellant of the overpayment. Exh. 1 at 99. Having retained counsel, the appellant requested a redetermination. Cahaba GBA issued a redetermination which "partially covered" some of the claims in issue. *Id.* at 321. Cahaba GBA subsequently recalculated the extrapolation based on the partially covered claims, and reduced the overpayment (including principal and interest) to $407,912.91. *Id.* at 317. The appellant requested reconsideration by a Qualified Independent Contractor (QIC).

The QIC issued a partially favorable reconsideration. Exh. 1 at 4. The QIC reconsideration found the actual overpayment on the sampled claims to be $1,481.29 and reduced the extrapolated overpayment to $362,094.63. Exh. MAC-1 at Tab G. Following the appellant's identification of errors in the post-reconsideration recalculation, the extrapolated overpayment was again recalculated and reduced to $334,428.57. *See* Exh. MAC-1 at 2 and Exh. 24 at Tab F-2.

The appellant requested a hearing before an ALJ.

The ALJ conducted a hearing by telephone on May 27, 2009. The appellant was represented by counsel and offered testimony from Dr. Williamson; Robert Weatherford, a compliance coding expert and John T. Sennetti, PhD., an expert in auditing and statistical sampling. The PSC, represented by counsel, appeared at the hearing and provided argument and testimony from a statistical expert (Mr. Casselman), an individual who participated in the medical review of the claims (Ms. Kelly), and an investigator (Mr. Carter). Cahaba GBA, offered argument/testimony from a senior statistician (Ms. Binns). Cahaba GBA's Medical Director (Dr. McKinney) also participated in the hearing. Dec. at 2-3. At this point, the overpayment was based on an extrapolation from a finding of actual overpayments in twenty-six claims for twenty-five beneficiaries. *See* Appendix to ALJ Decision.

The ALJ heard testimony on both the sampling process and the coverage aspects of the sampled claims. Throughout the hearing, the appellant maintained that the PSC had not provided it with information sufficient to assess the validity of the sample. The appellant also asserted that it was denied due process because it was not allowed to cross-examine the witnesses from either the PSC or Cahaba GBA.

Following the hearing, the ALJ issued an Order providing an opportunity for post-hearing briefs and responses. *See* Exh. 17 at 9. The PSC's post-hearing brief included a CD[1] with information pertinent to the sample in the case and addressed in its post-hearing brief. Upon consideration of the appellant's response to the PSC's submission, the ALJ determined that the PSC had not provided this CD to the appellant. *Sua sponte*, the ALJ provided a copy of the CD to the appellant. The ALJ gave the appellant an opportunity to respond, in writing, to its contents, as well as an opportunity for a supplementary hearing. Dec. at 3.

The appellant responded by letter dated August 28, 2009. There, the appellant recounted that it received the CD pursuant to notice from the ALJ's office that the PSC had not, of its own volition, provided the CD to the appellant. The appellant characterized this development as -

[1] Throughout the decision, the ALJ identified this disc as a DVD.

> once again a clear confirmation of what the Appellant has argued throughout this case: that Cahaba GBA and Cahaba GSA [the PSC] have both failed, despite formal requests by the Appellant, to provide the statistical documentation which they are required to maintain and produce to appellants. The Cahaba entities' lack of concern for fundamental due process continues unabated, and the Appellant wonders who will remedy this obvious breach of law and regulation.

Exh. 25 at 1.

The appellant continued, reasoning that – "[a]t this point it little matters what is on the CD-ROM." The appellant questioned the origin of the data on the CD, the time and manner of (as well as the reason for) the CD's creation, and its author. The appellant indicated that its skepticism was founded in its belief that documents "previously produced by Cahaba have been altered, modified and withheld, as discussed in prior briefing. The appellant maintained that it was not timely provided with all of the pertinent sampling information and now has "no ability to challenge it or respond to it in a meaningful way." Exh. 25 at 2.

Upon the advice of its expert, the appellant concluded, arguing that -

> the "new" documentation does <u>not</u> correct the flaws in the statistical study which were discussed at the hearing and in the Appellant's briefing:
>
> 1. The universe (sampling frame) is missing;
>
> 2. The random numbers are not connected to the universe of claims;
>
> 3. The sample size is far too small;
>
> 4. The co-efficient of variation (precision) is unacceptably high;
>
> 5. There are no working papers, as required by the Program Integrity Manual; and

> 6. Cahaba failed to comply with the Medicare Modernization Act in assessing and extrapolating the overpayment.

Exh. 25 at 2 (emphasis in original).

The ALJ's decision followed.

The ALJ first addressed the question of medical necessity for the underlying "podiatric treatments, evaluation and management services, and other physician services" present in the sampled claims. The ALJ found that "the medical record for the claims at issue is clearly deficient. Some of the files do not even contain medical records at all." Dec. at 11.

Addressing the evaluation and management (E/M) services, the ALJ found the medical records to be "clearly inadequate and insufficient to support billing with a HCPCS -25 modifier.[2] Many of these records do not even indicate that any E/M services were performed." Dec. at 11. Further, "treatment notes for the podiatric services rendered are extremely sparse" either failing to indicate the need for the particular service or indicating that the service in issue was routine foot care. Thus, the ALJ concluded that "the claims for uncovered services must also remain denied." *Id.*

Turning to statistical sampling, the ALJ noted that a provider bears the burden to demonstrate the invalidity of a sample. Based on consideration of the written and testimonial evidence, the ALJ rejected the appellant's contention that the PCS "cherry-picked" the claims which compromised the sample. Dec. at 13.

The ALJ recognized that the appellant had not received "the entire file in a timely manner." However, the ALJ reasoned that "the appellant's attempts in requesting all the necessary

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[2] Providers and suppliers utilize the Healthcare Common Procedure Coding System (HCPCS) in filing claims for Medicare reimbursement. HCPCS is comprised of two coding levels. HCPCS Level I consists of the American Medical Association's *Current Procedural Terminology* (CPT). CPT codes identify medical services and procedures furnished by physicians and other health care professionals. HCPCS Level II is an alphanumeric standardized coding system used primarily to identify products, supplies and services not included in the CPT codes. The HCPCS "-25" modifier identifies a "significant, separately identifiable evaluation and management service by the same physician on the day of a procedure."

documentation were fairly minimal" having been made to "the Medicare carrier [Cahaba GBA] and to the ALJ's office, neither of which are directly connected to the PSC." Dec. at 14. Further, the ALJ noted that once the PSC "finally submitted" the requested information to the ALJ, the appellant elected not to respond to it "even though the fact that [the] information was missing was fairly obvious from the PSC's brief itself and even noted by the appellant in its response." *Id.* (citation omitted). The ALJ found no merit in the appellant's position, as framed in its August 28, 2009, letter (Exhibit 25), that there was no point in responding to the late-supplied sampling information because the hearing was long-passed and it had been precluded from cross-examining the PSC's witnesses. The ALJ recounted that he had provided the appellant an opportunity for a supplementary hearing and questioned how the appellant could elect to not avail itself of every opportunity to make its case given the concerns it had expressed throughout the history of the case before the ALJ. While noting that he "sympathizes with the appellant's situation" the ALJ nevertheless found that -

> the late submission of part of the PSC's overpayment calculation file does not invalidate the overpayment itself. Given the extent to which the ALJ provided the appellant with an opportunity to challenge and voice any concern with any and all contents of the study . . . the appellant's due process rights were not violated.

Dec. at 14-15.

The ALJ rejected the appellant's argument that the lack of a probe study and/or validation review invalidated the sample, finding that as neither of those techniques was required by the guidance enunciated in the Medicare Program Integrity Manual (MPIM) (Pub. No. 100-08). Dec. at 15. Further, the ALJ did not accept the appellant's argument that the extrapolation was invalid because the coefficient of variation was too high and the sample size too small. The ALJ noted the PSC's argument that "the lack of precision rendered by the study is incorporated in the extrapolation, actually working to the financial advantage of the appellant." The ALJ distinguished between precision and accuracy pointing out that a greater coefficient of variation "without a larger sample size will necessarily increase the confidence interval." The ALJ reasoned that this method actually works in the appellant's favor because CMS, routinely, "only charges an overpayment of the *lower bound*

of the confidence interval." *Id.* at 15-16 (emphasis in original).

Responding to another facet of the appellant's "due process" argument, the ALJ then found that use of a one-sided 90% confidence interval was appropriate. The ALJ noted that while a 95% interval is generally "used for such extrapolations," the 90% methodology reflects the guidance in the MPIM and is supported by case law. Dec. at 16.

The ALJ also found no merit in the appellant's argument that the sample design was flawed because PSC was required to produce separate samples for each claim year under review. Again relying upon the MPIM, the ALJ noted that separate claim year samples are required for claims paid under "the Medicare cost report," that is Medicare Part A claims. The claims under review in the appellant's case involved Medicare Part B. Thus, the ALJ determined, the sample design was correct. Dec. at 16-17.

Regarding liability, the ALJ found no evidence in the record that the beneficiaries had received Advance Beneficiary Notices explaining possible non-coverage for the services provided. Thus, the ALJ determined, under section 1879 of the Act, the appellants could not be held liable for any of the resulting non-covered costs. However, as a provider whose knowledge of possible non-coverage was presumed, the appellant could be held liable for such non-covered costs. Further, the ALJ determined that the appellant's liability for the overpayment could not be waived under section 1870 of the Act. Dec. 11-12.

With modification to encompass issues arising during the ALJ hearing and subsequent decision, the appellant's arguments in its request for review otherwise consistently reflect those raised during the hearing as well as in its pre- and post-hearing briefs. Summarized here, the appellant argues that its due process rights were violated at the ALJ hearing because the ALJ denied it the opportunity to cross-examine witnesses afforded to parties to ALJ hearings by 42 C.F.R. §§ 405.1000(b) and 405.1036(g). Exh. MAC-1 at 4. The appellant asserts that it performed podiatric, as well as related E/M or physician services authorized for Medicare reimbursement under applicable federal law, regulations and program guidance. Exh. MAC-1 at 5-22. The appellant reiterates that - the PSC failed to follow the applicable laws and CMS program memoranda prior to

issuing an extrapolated overpayment; the extrapolated overpayment should be overturned because the PSC failed to follow basic due process requirements; the lack of documentation renders the extrapolation invalid; the PSC statistical study was flawed in design; and the ALJ accepted "inadmissible and improper evidence" from the PSC. Exh. MAC-1 at 22-38. For these reasons, the appellant maintains that if an overpayment is appropriate, it should be limited in amount to those Medicare funds associated with the claims actually review by the PSC, rather than to an extrapolated overpayment. Exh. MAC-1 at 38.

APPLICABLE LEGAL STANDARDS

Statistical Sampling

CMS (formerly HCFA) Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers. The Ruling also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation by CMS in calculating overpayments. We incorporate that discussion by reference here. The Ruling provides, in part:

> Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

CMS Ruling 86-1 at 9 and 10.

CMS's sampling guidelines are found in chapter 3, section 3.10 of the MPIM. Those guidelines reflect the perspective that the time and expense of drawing and reviewing the claims from large sample sizes and finding point estimates which accurately reflect the estimated overpayment with relative precision may not be administratively or economically feasible for contractors performing audits. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the carriers to assess the overpayment at the lower level of a confidence interval – generally, the lower level of a ninety-percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety-percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. As a result of the above policy decision, the question becomes whether the sample size and design were sufficiently adequate to provide a meaningful measure of the overpayment, and whether the provider/supplier is treated fairly despite any imprecision in the estimation.

The MPIM provides guidance to contractors in conducting statistical sampling for use in estimating overpayment amounts. The instructions are intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments where review of claims indicates that overpayments have been made. The MPIM describes the purpose of its guidance as follows:

> These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC or the ZPIC BI unit or the contractor MR unit to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. **Failure by the PSC or ZPIC BI units or the contractor MR units to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical**

sampling and/or the projection of the overpayment.

MPIM, ch. 3, § 3.10.1.1 (emphasis added).

The MPIM further provides that a contractor may employ any sampling methodology that results in a "probability sample." The MPIM explains:

> [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, especially if the number of possible distinct samples is large - possibly billions. It is merely meant that one could, in theory, write down the samples, the sampling units contained therein, and the probabilities if one had unlimited time; and
>
> - Each sampling unit in each distinct possible sample must have a known probability of selection. For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.
>
> For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost)

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

MPIM, ch. 3, § 3.10.2 (emphasis added). The MPIM recognizes that a number of sampling designs are acceptable, including: simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these. MPIM, ch. 3, at § 3.10.4.1. Stratified sampling is a design that "involves classifying the sampling units in the frame into non-overlapping groups or strata." The objectives are to "define the strata in a way that will reduce the margin of error in the estimate below that which would be attained by other sampling methods, as well as to obtain an unbiased estimate or an estimate with an acceptable bias." MPIM, ch. 3, § 3.10.4.1.3. This section continues providing that "the independent random samples from the strata need not have the same selection rates." *Id.*

The MPIM provides the following guidance with respect to selecting the sample size:

> The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by

> the selection rate, or more complicated methods such as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.
>
> **In addition to the above considerations, real-world economic constraints shall be taken into account.** As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC or ZPIC BI unit or the contractor MR unit shall also consider their available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. **A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design**.

MPIM, ch. 3, § 3.10.4.3 (emphasis added).

The MPIM further provides that:

> 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 projection of overpayment issued.**

MPIM, ch. 3, at § 3.10.9.2 (emphasis added).

Medically Reasonable and Necessary

Medicare covers “medical and other health services” under Part B, which is defined in the Social Security Act (Act) to include physician services. Act § 1861(s); *see also* 42 C.F.R.

§ 410.10(a). Physician services "are the professional services performed by a physician or physicians for a patient including diagnosis, therapy, surgery, consultation and care plan oversight." Medicare Benefit Policy Manual (MBPM), Pub. 100-02, ch. 15, § 30.A. Section 1862(a)(1)(A) of the Act provides that only items and services that are "reasonable and necessary" for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member are covered under the Medicare program. *See, also,* 42 C.F.R. § 411.15(k).

Section 1833(e) of the Act prohibits payment "to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due." It is the responsibility of the provider or supplier to furnish sufficient information to enable the contractor to determine whether payment is due and the amount of the payment. 42 C.F.R. § 424.5(a)(6).

The Medicare Claims Processing Manual (MCPM), Pub. 100-04, chapter 12, section 30.6 addresses the use of E/M service codes. Section 30.6.1.A provides, in part, that medical necessity is the overarching criterion for payment, in addition to the individual requirements necessary to support the level of service represented by the CPT code(s) billed.

DISCUSSION

Due Process

Contrary to its arguments during the hearing and in its post-hearing submissions, the appellant's due process rights were not compromised by its inability to cross-examine the Cahaba GBA or Cahaba Safeguard witnesses in the ALJ hearing.

The appellant contends that its right to cross-examine those witnesses is preserved by regulation. Specifically, the appellant relies upon 42 C.F.R. § 405.1000(b) which provides that parties to an ALJ hearing may "present and/or question witnesses," and 42 C.F.R. § 405.1036(g) which provides that an ALJ "may" allow a party or its representative to question witnesses. However, the appellant's right to cross-examine only extends to a "party" to an ALJ hearing.

The program regulations, addressing ALJ hearings provide, in pertinent part,

> (c) In some circumstances, a representative of CMS or its contractor, including the QIC, QIO, fiscal intermediary or carrier, may participate in or join the hearing as a party. (*see* § 405.1010 and § 405.1012).

42 C.F.R. § 405.1000.

The regulation at 42 C.F.R. § 405.1010 addresses CMS's role in an ALJ hearing as a **participant**, providing:

> (b) If CMS or one of its contractors elects to participate, it advises the ALJ, the appellant and all other parties identified in the notice of hearing of its intent to participate no later than 10 days after receiving the notice of hearing.
>
> (c) Participation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but does not include calling witnesses or cross-examining the witnesses of a party to the hearing.
>
> (d) When CMS or its contractor participates in an ALJ hearing, the agency or its contractor may not be called as a witness during the hearing.

The regulation at 42 C.F.R. § 405.1012 address CMS's role in an ALJ hearing as a **party**, providing:

> (b) CMS and/or its contractor(s) advise the ALJ, appellant and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 days after receiving the notice of hearing.
>
> (c) When CMS or one or more of its contractors participate in a hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or one or more of its contractor(s), when acting as parties, may also submit

> evidence to the ALJ within the timeframe designated by the ALJ.

The preamble to the Final Rule, implementing the regulations governing the Medicare Claims Appeal Procedures (42 C.F.R. Part 405), clarifies that participation by CMS or its contractor(s) at the ALJ hearing level, while optional, is consistent with the statute and intended to serve to develop information for both ALJs and beneficiaries. In response to comments raising concerns about the possible adversarial nature of an ALJ hearing in which CMS or its contractors participate, the regulatory authors noted that "the scope of a participant's rights under § 405.1010 is limited" so as to deny a participant the "cornerstone elements . . . [of] an adversarial proceeding." 74 Fed. Reg. 65,316 - 65,317 (Dec. 9, 2005).

The preamble then notes that -

> the policy prohibiting CMS or its contractors from being called as a witness when it has chosen to participate as a non-party . . . is consistent with the Department's Touhy regulations at 45 CFR Part 2, which leaves to agency discretion the decision whether to permit agency officials or certain contractors to testify or produce evidence in proceedings in which the agency is not a party.

74 Fed. Reg. at 65,318.

The preamble continues reiterating both that CMS and its contractors have the discretion to determine the manner and extent of their participation in an ALJ hearing and that, under 42 C.F.R. § 405.1010, the limits of that participation can extend to a refusal to be cross-examined. 74 Fed. Reg. 65,318.

Having examined the pertinent pre-hearing documentation and correspondence in the record (generally, Exhibits 4-16), the Council finds no clear statement of intent from either Cahaba GSB or Cahaba Safeguard, delineating the manner of their participation in the ALJ hearing.[3] The lack of clarity in the regulations, and the contractors' failure to identify their manner of participation prior to the start of the hearing,

[3] The Council recognizes that the words "participant" or "participate" appear in numerous pre-hearing documents, mostly those emanating from the ALJ's office. However, the usage of these words there is in the common grammatical sense, rather than in the more specific sense anticipated by the regulations.

undoubtedly left their status unclear to the appellant, as contended. The Council finds no clear characterization of the nature of the contractors' participation until an objection at the ALJ hearing, by counsel for Cahaba Safeguard (Attorney Wood), when counsel for the appellant (Attorney West) attempted to cross-examine Mr. Casselman. However, this lack of clarity did not rise to the level of a due process violation.

The Sample and Extrapolation

As noted in the legal authority discussed above, CMS retains a wide degree of latitude in the use of sampling and extrapolation to recoup overpayments to providers. That latitude aside, however, the Council finds that not all relevant and material information relating to the sampling methodology, to which the appellant is entitled, has been provided to the appellant or submitted for the appeals record in this case. Thus, we are reluctant to uphold the extrapolation from the sample to the universe in this case.

The appellant asserted during the hearing, and in post-hearing briefing, that neither CMS nor its contractors provided documented educational intervention prior to the extrapolation in issue. *See* Exh. 19 at 3 (**Supplemental Brief of the Appellant** (June 8, 2009)). Further, in its **Second Supplemental Brief** (June 25, 2009), the appellant argues that the PSC's finding that the appellant had a high level of payment error rate resulted from the audit sample itself and was not a preexisting condition, providing a basis for the audit, as required by the Medicare Modernization Act and applicable Program Memorandum. Exh. 22 at 4. As explained below, these specific arguments do not invalidate the extrapolation.

Section 1893(f)(3) of the Act provides:

> *Limitation on use of extrapolation* - A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that - (A) there is a sustained or high level of payment error; or (B) documented educational intervention has failed to correct the payment error.

There is no judicial or administrative review of a determination of a sustained or high payment error rate by the Secretary, and, by extension, the contractors. Section 1893(f)(3) of the Act further provides that "[t]here shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph." Therefore, neither the ALJ, nor the Council, has jurisdiction to consider any aspect of a contractor's determination that a high payment error rate exists, which extends to the contractor's decision to perform extrapolation.

However, the appellant has argued persuasively that it has not, at any point of the appeal process, been supplied with certain portions of the "data and documentation needed to replicate the statistical study." Exh. 22 at 5. Referencing Cahaba Safeguard's June 5, 2009, post-hearing submission (Exhibit 23), the appellant, in its Second Supplemental Brief, asserts that the PSC's –

> submission states that information is being provided on a CD or DVD. However, no such CD or DVD was provided to Appellant with their [the PSC's] submission. Nor were Appendices C, D, or E provided to counsel. If, as appears likely, the CD contains the same materials contained in a CD previously given to the Appellant, such does not contain the following:
>
> - The random numbers used in the study
> - How the random numbers were selected
> - The sampling frame
> - The working papers and all calculations of the statistician.

Exh. 22 at 5.

In its post-hearing submission, the PSC reiterated its position that it –

> fully documents its sampling and overpayment extrapolations, meeting all requirements for Medicare contractors when conducting a statistical study. Along with this document, all . . . [PSC] sampling and projection documentation is being provided once again including the universe, the sampling frame including the random number

> seed and the random numbers, and the method of randomization (these are included in the appendices on the CD accompanying this document). This documentation meets all guidelines for Medicare contractors and guarantees that the entire process is being replicated. The documentation files are listed below with descriptions of the information contained in the files. [A description of the contents of CD Appendices B-E followed.]

Exh. 23, Tab - **Statistician's Response to Post Hearing Orders**, at 2.

The CD referenced by the PSC is formally labeled as **Cahaba Safeguard's Post Hearing Submission for ALJ Appeal Number 1-373708584.** The post-hearing CD's Table of Contents, which the Council has printed and entered into the record as Exhibit MAC-2, indicates that the CD's contents would replicate that of Exhibit 23. However, the CD is otherwise password protected. That password is not specifically available in the record before the Council.

The case file also contains another CD with the following identification, handwritten, in black indelible marker: "**1-350874561 CAHABA GBA**." That CD's table of contents contains a file/folder titled "Dr. Rondric Williamson CSA Case Encryption." However, this "first" CD is also otherwise password protected. An e-mail, originating from an individual identified as a Cahaba GBA, Part A/B Appeals Manager, dated December 10, 2008, with a subject line title: "Passcode" to another individual of unknown address is folded and taped to this "first" CD. The passcode referenced in the e-mail is also printed, in blue indelible marker, on the "first" CD.

The passcode opens neither the "first" CD, nor the "post-hearing" CD submitted by Cahaba PSC.

In its second supplemental brief, the appellant, by way of comparison, vaguely references the contents of "a CD previously given to the Appellant." Exh. 22 at 5. It is not clear if this is a reference to the "first" CD or if the appellant was able to actually access the substantive information contained in that or the "post-hearing" CD. There is no indication from the decision whether the ALJ had access to the information on either CD. Certainly the fact that the PSC alleges that the necessary audit-related information is on these CDs, and that the

appellant has continually asserted that is has not been provided that information (rather than arguing that the information is incorrect or substantively inadequate), lends support to a conclusion that the PSC has not provided all of the relevant and material sampling information to the appellant despite repeated requests. If provided at all, that information has not been provided in a timely manner despite repeated requests, or has not been provided in usable or accessible form.

Thus, regardless of the possible substantive merit to the PSC's extrapolated overpayment determination, the above-discussed circumstances appear to give credibility to the appellant's allegations that it has encountered significant impediments in obtaining the information to which it is entitled from the Carrier and the PSC in this case.

Given the inability to access the CDs, specifically the "post-hearing" CD, the record before the Council does not, in spite of the PSC's contentions to the contrary, contain the documentation referenced in Appendices C-E of the PSC's post-hearing submission. Specifically, that documentation is identified, by the PSC as – (Appendix C) the "Sample," the "Sample Frame" and the "Universe;" (Appendix D) the *Overpayment Projection – CSA [PSC] Review*; and (Appendix E) *Overpayment Projection – After Latest Appeals*. Exh. 23, Tab - **Statistician's Response to Post Hearing Orders,** at 2.

The regulation at 42 C.F.R. § 405.1000(b) provides that "the parties may submit evidence . . . [and] examine the evidence used in making the determination under review . . . ." This would, to a reasonable degree, presuppose that the evidence to be reviewed would generally be available to an appellant prior to the hearing. As noted above, the "first" CD with purported audit-related information, apparently provided to the appellant in December 2008 was inaccessible. Thus, not only was the audit-related evidence sought by the appellant not provided prior to the hearing, it was not present at the hearing and not voluntarily forthcoming post-hearing. Even when finally provided, *sua sponte,* by the ALJ following the first round of post-hearing submissions, the "post-hearing" CD then purporting to contain audit-related information was inaccessible. The Council remains unable to access some of the statistical sampling data (including the frame) because of access restrictions on the CDs in the record.

It is well-established that due process affords an appellant provider the right to examine audit results in order to mount a proper challenge in the appeals process. Not only was pertinent audit-related information withheld from the appellant, the inaccessibility of the CDs in the record forwarded to the Council by the ALJ leads to the conclusion that the record upon which the ALJ relied in upholding audit extrapolation was incomplete. An ALJ decision must be based on evidence offered at the hearing or otherwise admitted into the record. 42 C.F.R. § 405.1046(a). Absent supporting evidence, the appellant is deprived of its ability to review the extrapolation in question.

For these reasons, the Council reverses the extrapolation of the audit results at issue here. The Council further notes that this reversal may have been wholly avoidable had the PSC been both attentive and timely in providing the information in usable form to both the appellant and the ALJ.

The remaining questions before the Council go to coverage for the allegedly overpaid claims actually reviewed by the PSC and the appellant's liability for any such overpayment.

Claims Coverage

Basically, in order to receive Medicare Part B coverage for the claims at issue, the appellant must show that the provided services were medically reasonable and necessary pursuant to section 1862(a)(1)(A) of the Act. Pursuant to section 1833(e) of the Act, the appellant bears the burden of properly documenting that medical necessity.

The Council has reviewed the claims for the twenty-five beneficiaries addressed in the ALJ decision. As the ALJ found, the documentation in many of those files ranges from nonexistent to, at best, minimal. Six files have no documentation at all. An additional six files contain only a one-page document titled "Podiatry Progress Note" (PPN). Another file contains two, one-page PPNs. Even in the remaining twelve case files which contain more than one or two pages of documentation, that additional documentation does not support a determination that that the services provided to the associated beneficiary constituted anything more than routine foot care. Accordingly, the Council finds that the twenty-six claims associated with the

twenty-five beneficiaries identified in the Attachment to this decision are not covered by Medicare.

Liability

Other than to assert that the overpayment should be limited to the claims actually reviewed by the PSC, the appellant did not challenge the ALJ's determination that, pursuant to section 1879 of the Act, the appellant was liable for the non-covered services and that the appellant's liability could not be waived under section 1870(b) of the Act. *See* Exh. MAC-1 at 38. Accordingly, the Council upholds the appellant's liability for the cost of the non-covered services resulting from those claims actually reviewed by the PSC.

DECISION

It is the decision of the Medicare Appeals Council that the evidence of record does not support the extrapolated overpayment at issue. However, the overpayment resulting from the claims associated with the beneficiaries identified in the Attachment to this decision is supported by the record before the Council. The appellant is liable for the cost of those non-covered services.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

Date: June 22, 2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-10-321

In the case of	**Claim for**
Michael King, M.D. and Kinston Medical Specialists, P.A. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiaries)	**** (HIC Numbers)
CIGNA Government Services (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision, partially favorable to the appellant, dated September 29, 2009. The ALJ's decision concerned a Medicare overpayment assessed against the appellant for various diagnostic services provided by the appellant between July 1, 2004, and June 30, 2006. The ALJ first determined that the underlying sampling methodology and associated extrapolation were valid. The ALJ then found that Medicare coverage was warranted for claims associated with thirty-two of the beneficiary-specific claims at issue, but denied coverage for some or all of the claims associated with thirteen beneficiaries. The ALJ directed the Medicare contractor to recalculate the overpayment accordingly and found that the appellant's liability for the remaining overpayment could not be waived. The appellant has asked the Medicare Appeals Council to review this action as it applies to the general sampling issues and specific coverage findings for twelve beneficiaries.

The appellant's request for review (December 1, 2009) is entered into the record as Exhibit (Exh.) MAC-1. The appellant's letter (March 30, 2010), offered as an explanation of good cause for submitting new evidence, earlier with its request for review,

and later with the March 30, 2010 letter, is entered into the record as Exhibit MAC-2.[1] The appellant's brief (August 12, 2010) is entered into the record as Exhibit MAC-3.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c).

As set forth below, the Council upholds the sampling and extrapolation underlying the overpayment, but reverses, in whole or in part, the ALJ's decision as it pertains to certain beneficiary-specific claims for coverage.

BACKGROUND

On November 28, 2007, AdvanceMed, a Center for Medicare & Medicaid Services (CMS) program safeguard contractor (PSC), provided the appellant with preliminary notification that it had received a Medicare overpayment projected to total $919,644 for claims associated with services provided by the appellant between July 1, 2004, and June 30, 2006. Exh. 1 at 164. The PSC indicated that:

> To determine the overpayment amount due, AdvanceMed used RAT-STATS (a software tool developed by the Office of Inspector General to assist in performing random samples and evaluating the results), to select a sample of claims from a list of all relevant claims paid or partially paid to you. An average overpayment was then calculated and multiplied by the total number of relevant paid and partially paid claims to reach a point estimate. Using the standard statistical formulas found in RAT-STATS, a confidence interval was built around the point estimate. AdvanceMed used the lower limit of the 90% two-sided confidence interval to establish the amount of the overpayment.

Exh. 1 at 164-165.

The PSC also provided the appellant with a CD containing "the sampling methodology and supporting documents." Exh. 1 at 165.

[1] The Council rules on the admissibility of new evidence, below.

In an associated internal memorandum, the PSC indicated that it had reviewed a "total of 90 claims, 80 medical records, and 399 CPT line items." Exh. 1 at 252.

On December 3, 2007, the Medicare contractor formally notified the appellant of the overpayment. Exh. 1 at 159. The appellant requested redetermination. The Medicare contractor issued an unfavorable redetermination. *See* Exh. 1 at 115-128. The Medicare contractor indicated that the PSC audit had resulted in a denial or down coding of 276 services provided to 74 beneficiaries resulting in an actual overpayment of $13,210.52, extrapolated to $919,644. Exh. 1 at 116.

The appellant requested reconsideration by a Qualified Independent Contractor (QIC). The QIC issued a partially favorable reconsideration, finding coverage for claims for twenty-nine beneficiaries and upholding overpayments for the remaining forty-five. *See* Exh. L, Item I.

The appellant requested a hearing before an ALJ. The ALJ conducted a hearing over the course of two days, March 6 and July 22, 2009. Both the appellant and the PSC provided expert testimony on the statistical sampling/extrapolation issues, as well as testimony on the unresolved coverage issues. *See* Dec. at 2. The decision which followed first addressed the overarching issues on appeal. Based on consideration of the evidence and a comparative analysis of expert testimony, the ALJ determined that the underlying statistical sampling was valid. The ALJ found the universe was clearly defined; the sample size adequate; the sample capable of replication (noting that the appellant's expert had not attempted replication of the sample and extrapolation); and the use of the Central Limit Theorem appropriate. Dec. at 10-11.

The ALJ also found the appellant liable for the overpayment and that the appellant "could not avail itself" of the Social Security Act (Act) provisions pertaining to waiver of liability for recoupment of the overpayment. Dec. 12; *see, also,* sections 1870(b) and 1879(a)(1) of the Act. The ALJ directed that the case be "remanded to the carrier to recalculate the extrapolation based on . . . [the ALJ's] decisions" on beneficiary-specific claims. In so doing, the ALJ denied the appellant's request that the overpayment be limited to the non-covered claims actually sampled and not be extrapolated to the universe of claims. Dec. 12.

The ALJ then addressed the coverage issues presented in the forty-five beneficiary-specific claims before him. The ALJ issued thirty-two fully favorable and thirteen partially favorable or fully unfavorable, beneficiary-specific "decisions." *See, generally*, ALJ Decision, Attachment A at 1-74; *see, also*, Dec. at 2.

In its brief to the Council, the appellant takes exception to the ALJ's universal findings regarding sampling and extrapolation. Generally, the appellant asserts that –

- AdvanceMed (the PSC) has not met the requirements to use extrapolation;
- AdvanceMed's sample results do not achieve acceptable precision;
- AdvanceMed did not verify the correct amount of Medicare claims paid to the appellant for the audit period;
- AdvanceMed's sampling methodology was statistically invalid because it failed to consider the variability in population;
- AdvanceMed did not verify that it correctly determined the overpayments because it failed to address "nonsampling error" resulting in the application of the wrong sampling protocol and production of an "unfair and inaccurate" overpayment estimate;
- AdvanceMed has not shown that it applied all generally recognized procedures for statistical sampling; and
- AdvanceMed has not proven that "its errors are wiped clean" by its practice of choosing the lower limit of extrapolated overpayments.

Exh. MAC-3 at 12-20.

The appellant also challenges the ALJ's coverage findings for twelve of the thirteen partially or fully unfavorable beneficiary-specific decisions. The appellant presents specific exceptions for six of those "decisions" and relies upon its

prior submissions of record for the remaining six "decisions." Exh. MAC-3 at 3-10.

The Council sets out the appellant's sampling and coverage arguments in more detail in the analysis below.

APPLICABLE LEGAL STANDARDS

Statistical Sampling

In the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress established the Medicare Integrity Program (MIP), under which "the Secretary shall promote the integrity of the Medicare program by entering into contracts in accordance with the section with eligible entities to carry out the activities" listed. Section 1893(a) of the Act. Congress specified that those activities include review of activities by providers and other entities and individuals furnishing items or services covered and/or paid for by Medicare, including medical and utilization review and fraud review. Section 1893(b)(1) of the Act. Congress also authorized the Secretary to enter into such contracts without having promulgated final rules. Section 1893(d) of the Act.

Under the MIP, Congress authorized the Secretary to enter into a plan with providers or suppliers for repayment of overpayments. Section 1893(f)(1)(A) of the Act. Congress also circumscribed the authority of the Secretary to recoup overpayments during the appeals process. Section 1893(f)(2) of the Act. With respect to extrapolation, Congress stated:

> LIMITATION ON USE OF EXTRAPOLATION. – A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that –
>
> > (A) there is a sustained or high level of payment error; or
> >
> > (B) documented educational intervention has failed to correct the payment error.
>
> There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of

> determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

Section 1893(f)(3) of the Act.

CMS (formerly HCFA) Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers. The Ruling also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation by CMS in calculating overpayments. We incorporate that discussion by reference here. The Ruling provides, in part:

> Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

CMS Ruling 86-1 at 9-10.

CMS's sampling guidelines are found in chapter 3, section 3.10 of the Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08. Neither an ALJ, nor the Council, is bound by CMS program guidance, but will give substantial deference to such policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

The MPIM guidelines reflect the perspective that the time and expense of drawing and reviewing the claims from large sample sizes and finding point estimates which accurately reflect the estimated overpayment with relative precision may not be

administratively or economically feasible for contractors performing audits. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the carriers to assess the overpayment at the lower level of a confidence interval – generally, the lower level of a ninety-percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety-percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. *See* MPIM, ch. 3, § 3.10.5.1. As a result of the above policy decision, the question becomes whether the sample size and design were sufficiently adequate to provide a meaningful measure of the overpayment, and whether the provider/supplier is treated fairly despite any imprecision in the estimation.

The MPIM provides guidance to contractors in conducting statistical sampling for use in estimating overpayment amounts. The instructions are intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments where review of claims indicates that overpayments have been made. The MPIM describes the purpose of its guidance as follows:

> These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC or the ZPIC BI unit or the contractor MR unit to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. **Failure by the PSC or ZPIC BI units or the contractor MR units to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.**

MPIM, ch. 3, § 3.10.1.1 (emphasis added).

The MPIM further provides that a contractor may employ any sampling methodology that results in a "probability sample." The MPIM explains:

> [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, especially if the number of possible distinct samples is large - possibly billions. It is merely meant that one could, in theory, write down the samples, the sampling units contained therein, and the probabilities if one had unlimited time; and
>
> - Each sampling unit in each distinct possible sample must have a known probability of selection. For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.
>
> For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. **If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the**

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

MPIM, ch. 3, § 3.10.2 (emphasis added). The MPIM recognizes that a number of sampling designs are acceptable, including: simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these. *Id.* at § 3.10.4.1. Stratified sampling is a design that "involves classifying the sampling units in the frame into non-overlapping groups or strata." The objectives are to "define the strata in a way that will reduce the margin of error in the estimate below that which would be attained by other sampling methods, as well as to obtain an unbiased estimate or an estimate with an acceptable bias." *Id.* at § 3.10.4.1.3.

The MPIM further provides that:

> 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 projection of overpayment issued.**

MPIM, ch. 3, § 3.10.9.2 (emphasis added).

The MPIM further explains that variable precision in sampling design may be accounted for through the use of the lower limit of a one-sided ninety-percent confidence interval, which is a conservative method that works to the financial advantage of the supplier, as follows:

> In simple random or systematic sampling the total overpayment in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame. In this estimation procedure, which is unbiased, the amount of overpayment dollars

> in the sample is expanded to yield an overpayment figure for the universe. The method is equivalent to dividing the total sample overpayment by the selection rate. The resulting estimated total is called the point estimate of the overpayment, i.e., the difference between what was paid and what should have been paid. In stratified sampling, an estimate is found for each stratum separately, and the weighted stratum estimates are added together to produce an overall point estimate.
>
> In most situations the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier. The details of the calculation of this lower limit involve subtracting some multiple of the estimated standard error from the point estimate, thus yielding a lower figure. This procedure, which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment, and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate. However, the PSC or ZPIC BI unit or the contractor MR unit is not precluded from demanding the point estimate where high precision has been achieved.

MPIM, ch. 3, § 3.10.5.1.

Medically Reasonable and Necessary Services

Section 1862(a)(1)(A) of the Act provides that only items and services that are "reasonable and necessary" for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member are covered under the Medicare program. *See, also,* 42 C.F.R. § 411.15(k).

Section 1833(e) of the Act prohibits payment "to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due." It is the responsibility of the provider or supplier to furnish sufficient information to enable

the contractor to determine whether payment is due and the amount of the payment. 42 C.F.R. § 424.5(a)(6).

ANALYSIS

New Evidence

The Council limits its review to the evidence contained in the record of the proceedings before the ALJ, unless there is good cause for submitting new evidence for the first time at the Council level. 42 C.F.R. §§ 405.1122(a) and (c).

As part of its request for review the appellant submitted twenty-one pages of what the appellant conceded was new documentation pertaining to claims involving seven of the twelve beneficiaries[2] for which the appellant seeks review. There the appellant noted that it was providing this material to fully respond to "issues and concerns which could not reasonably have been anticipated . . . prior to [the appellant's] submission of documents to the QIC and ALJ." *See* Exh. MAC-1 (transmittal letter) and succeeding pages MBK-MAC 001-021.

By letter dated March 10, 2010, the Council directed the appellant to show cause for submission of this new evidence at this stage of review. In response, the appellant explained that, although it had made a good faith effort to submit all material relevant to questions of claims coverage, submission of this new evidence was warranted as a response to questions posed by the ALJ during the course of the hearing. Exh. MAC-2 at 2-3.

In addition to its statement on "good cause" regarding the new "coverage" evidence, as part of its response, the appellant also submitted seven additional pages (MBK-MAC 022-028) of new evidence pertaining to its arguments on the unreliability (*i.e.*, lack of precision) of the PSC's overpayment calculations throughout the various stages of appeal. The appellant asserts that these "AdvanceMed documents (. . . MBK-MAC 022 through 028) were created after, and as a result of, the ALJ Decision in this matter" and therefore could not have been submitted earlier. Exh. MAC-2 at 1-2.

The Council excludes from evidence the coverage-related documentation (MBK-MAC 001-021) submitted with the appellant's request for review. The question of coverage for all claims under review has been an issue since well before the post-

[2] Those were Beneficiaries R.A., M.F., D.H., A.H., E.N., R.S. and E.W.

payment review and subsequent overpayment determination. A comparison of the "new" documentation to that already contained in the associated beneficiary claim files indicates that the "new" evidence is nothing more than what would reasonably be considered routine medical documentation pertaining to the various beneficiaries' conditions.

An appellant bears the burden of documenting its claims for coverage and payment. *See* section 1833(e) of the Act. An example of good cause for untimely submission of evidence is "when the new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as material prior to the QIC's reconsideration." *See* 42 C.F.R. § 405.1028(b), *incorporated by reference at* 42 C.F.R. § 405.1122(c)(3)(ii). The appellant's "new" material is the type of evidence that the Council (as well as the contractor, QIC, and the ALJ) would routinely expect to have been provided at the outset of a claim for coverage. The Council does not find persuasive the appellant's contention that this submission was made necessary based on the ALJ's line of inquiry at the hearing. The appellant has not shown that could not submit, or otherwise was precluded from submitting, this documentation prior to the QIC's reconsideration of the associated beneficiaries' claims.

Even assuming that the appellant saw a need to submit additional argument and/or proffer new documentation in response to the ALJ's questioning during the hearing, then, presumably, the appellant could have asked the ALJ for an opportunity to do so either during the course of the two-day hearing, which commenced on March 6, 2009, and did not conclude until many months later, on July 22, 2009, or sometime between March 6 and July 22, 2009. Alternatively, the appellant could have asked the ALJ for a post-hearing opportunity to submit a brief and/or additional documentation for the ALJ's consideration prior to the ALJ's issuance of a written decision. *See, e.g.,* 42 C.F.R. §§ 405.1030(b) and (c) (an ALJ may accept documents during the hearing, and may temporarily stop the hearing to obtain necessary material evidence); 405.1040 (an ALJ may, *sua sponte*, or at a party's request, hold prehearing and posthearing conferences).

As for the appellant's argument that there is good cause for the submittal of such new medical documentation to the Council because the ALJ "liberally referenced hearing testimony in support of his conclusions" and, "[o]ften, the analysis and

explanation of his decisions raised and relied upon issues and concerns which could not have been anticipated" (*see* Exh. MAC-2), by exercising its right to further review before the Council, as is the case here, an appellant is afforded an opportunity for our consideration of the ALJ's "analysis and explanation" in the ALJ's written decision. As for referring to hearing testimony within the ALJ's written decision, it is more than appropriate for any ALJ to do so; indeed, the regulations mandate that an ALJ give, in his or her written decision, "the findings of fact, conclusions of law, and the reasons for the decision," which "must be based on evidence offered at the hearing or otherwise admitted into the record." 42 C.F.R. § 405.1046(a). We further note that the appellant does not specifically contend that the ALJ considered any new issue(s) for which the notice provisions in 42 C.F.R. section 405.1032(b) would apply.

We also are not persuaded that "[i]t was only after the [appellant's] review of [the ALJ's] [d]ecision that [the appellant was] able to identify the additional patient/beneficiary records, as relevant and probative in response to the positions taken by [the ALJ]." Exh. MAC-2. The appellant's argument, by logical extension, could mean that any appellant (i.e., a provider or supplier, or a beneficiary represented by a provider or supplier) may cite as good cause an ALJ's analysis or references to hearing testimony to bootstrap its case for coverage of the underlying claims for further review at the Council's level with new medical documentation that was long in existence and could (and should) have been proffered earlier, before the post-payment review. *See* 42 C.F.R. §§ 405.1122(c) and 405.1018(a), (c), (d).[3] We do not read the applicable regulations to contemplate the Council's admission of new medical documents of the type the appellant

[3] As beneficiary-specific explanation of good cause, the appellant explains, for example, that newly offered evidence of lab tests taken prior and subsequent to a date of service responds to the ALJ's comment that there were no signs and symptoms of a urinary tract infection (UTI) and supports the appellant doctor's testimony that the beneficiary had recurrent UTIs that required monitoring. *See* Exh. MAC-2. This argument is not convincing. As a general matter, records contemporaneous to a particular service, for a particular date of service, is the most probative evidence, in terms of written documentation. More specifically, if the underlying point of a service was that a physician's monitoring was necessary, then the physician should have submitted all the information, data, opinions, etc., needed to support a finding of necessity of such physician monitoring when the claim was filed, even if some of that medical documentation pre-dated the actual date of service.

proffers based on the type of good cause rationale offered herein.

While excluded from consideration as evidence, the appellant's documentation identified as MBK-MAC 001-021 will be retained in the record for the purposes of identification, and in light of the Council's admissibility ruling herein.

The Council admits into evidence the sampling-related documentation (MBK-MAC 022-028) provided to the Council with its submission identified as Exhibit MAC-2. Here, the appellant's "new" documentation is being offered in connection with an argument responsive to various changes in the number of claims covered or denied over the course of the appeals process and the ensuing revision of the overpayment recalculations. The Council distinguishes these documents from medical documentation that relates to the coverage of specific underlying claims that would (or could) have been created contemporaneously on or around the dates on which the services in question were furnished (here, between mid-2004 through mid-2006). An appellant would have been charged with the responsibility for early and full presentation of any such documents to Medicare's adjudicators, for the purposes of its claims for coverage, subject to the regulations governing their admissibility at various stages of review. The documentation at issue (MBK-MAC 022-028), in contrast, addresses the appellant's global argument that the overpayment calculation is inherently unreliable, rather than a question of whether a specific claim is, or is not, covered. The Council finds good cause for admission of the documentation at MBK-MAC 022-028 into the record.

Sampling and Extrapolation

The appellant recounts the Act's basis for using extrapolation to calculate an overpayment, *i.e.,* that there is a determination of a sustained or high level of payment error or a failure of documented educational intervention. The appellant notes that there is no evidence of a documented failed educational intervention. Similarly, the appellant asserts, there is no evidence of a sustained or high level of payment error. The appellant recognizes the ALJ's conclusion that a determination of a sustained or high level of payment error is not appealable. However, the appellant contends that neither the ALJ nor the Council is precluded from reviewing a contractor's decision "to utilize sampling or extrapolation to determine the amount of an overpayment." The appellant generally argues that the record is

devoid of evidence that sampling and extrapolation were appropriate in this instance. Exh. MAC-3 at 12-14.

The criteria in section 1893(f)(3) of the Act, sustained or high level of payment error or a failure of documented educational intervention, are independent requirements. The existence of either criterion provides a sufficient basis for the use of sampling and extrapolation to determine an overpayment. Here, CMS, through its contractor (AdvanceMed), found a sustained or high level of payment error. There is, therefore, no need to ask whether there was "documented educational intervention." By law, the determination of a sustained or high error rate is not an appealable finding. *See* section 1893(f)(3) of the Act; *see, also*, MPIM, ch. 3, § 3.10.1.4.

As noted, above, the specific guidelines for Medicare audits can be found at chapter 3, sections 3.10 through 3.10.11.2 of the MPIM. Generally, the MPIM provides that stratification sampling, here, by amounts paid, is permissible and results in greater precision of overpayment estimation than a non-stratified simple random sample. MPIM, ch. 3, § 3.10.11.1.

The Council need not find that CMS or its contractor undertook statistical sampling and extrapolation based on the most precise methodology that might be devised in order to uphold an overpayment extrapolation based on that methodology. Rather, as the above-quoted authorities make clear, the test is whether the methodology is statistically valid. Pursuant to CMS Ruling 86-1, the use of statistical sampling "creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment." The Ruling goes on to state that "the burden then shifts to the provider to take the next step." Thus, the provisions of CMS Ruling 86-1 establish that the burden is on the appellant to prove that the statistical sampling methodology was invalid, and not on the contractor to establish that it chose the most precise methodology.

The appellant challenges the sample's reliability. The appellant asserts that the PSC did not demonstrate that the sample was representative of the patient population or that, in its design, had adequately considered patient population variability. The appellant contends that the PSC had not demonstrated that it correctly determined the overpayments in the specific sampled claims. The appellant asserts that there was no evidence that the sampled claims accurately reflected

actions subsequent to original payment, such as adjustments or reversals. The appellant argues that the sample did not satisfy generally recognized statistical sampling procedures, nor did its results reflect acceptable sampling precision. The appellant maintains that the lack of precision is not overcome by estimating an overpayment based upon the lower bound of the confidence interval. *See, generally*, Exh. MAC-3 at 14-20.

The appellant's arguments largely restate its position before the ALJ. Finding the sample statistically valid and the extrapolation appropriate, the ALJ noted that the appellant's statistical expert had conceded that the sample size was adequate, the universe clearly defined, and that the sample could be recreated by independent means. The ALJ recounted that the appellant had not replicated the sample and extrapolation. Further, the appellant did not dispute that the Central Limit Theorem was appropriate and valid. Dec. at 10-11.

The appellant's challenge to this sample is based on its theory as to the manner in which an audit of a Medicare provider should be conducted. While there may well be theories on the "right way" to conduct a sample, there is no formal recognition of "generally accepted statistical principles and procedures." At a practical level, there are a variety of factors impacting Medicare audits, which generally do not exist outside the Medicare arena. The MPIM guidelines reflect the perspective that the time and expense of drawing and reviewing the claims from large sample sizes and finding point estimates which accurately reflect the estimated overpayment with relative precision may not be administratively or economically feasible for contractors performing audits. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the carriers to assess the overpayment at the lower limit of a confidence interval – generally, the lower limit of a ninety-percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety-percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. As a result of the above policy decision, the question becomes whether the sample size and design employed here were sufficiently adequate to provide a meaningful measure of the overpayment, and whether the provider/supplier is treated fairly despite any imprecision in the estimation.

Here, the PSC used the lower limit of a two-sided ninety-percent confidence interval. *See* Exh. 1 at 165. As the PSC statistical expert explained in more detail:

> Furthermore, the RAT-STATS standard statistical formulas for stratified analysis were used to develop a confidence interval around the point estimate associated with the 90% confidence level. AdvanceMed uses the lower limit of the two-sided 90% confidence interval as the amount of overpayment demanded for recovery. These results mean that there is 95% probability that the true overpayment amount is greater than or equal to the requested overpayment amount. In other words, this procedure is a conservative method that works to the financial advantage of the provider because it yields a demand amount for recovery that is very likely less than the true amount of overpayment.

Exh. 2 at 190.

The appellant contends that the relative precision in the original sampling did not meet the PSC's policy guidelines for a 10% or less error rate. Moreover, the appellant argued that the relative precision in the estimation increased, significantly, from 13.66% at the time of the original sampling and extrapolation by the PSC to 21.02% after the QIC reconsideration and to 39.28% after the ALJ decision. Thus, the appellant argued, the sampling results should not be extrapolated and the overpayment should be limited to the sampled claims. Exh. MAC-3 at 15. In support of this argument, the appellant relied upon the opinion of its statistical expert, who stated that "estimating at the lower bound of the confidence interval is not an adequate step to overcoming the failure to achieve adequate precision." Exh. MAC-3 at 15.

However, the guidance found in the MPIM does not require a specific level of sampling precision. The MPIM clearly expresses CMS's policy to trade off time and resources which would be required for obtaining a precise estimate in an overpayment case, in favor of a lower overpayment amount, i.e., an assessment at the lower confidence bound rather than at the point estimate. *See* MPIM, ch. 3, § 3.10.5.1. Under these guidelines, the Council has upheld the results of many extrapolated overpayment assessments in Medicare cases. As the relative precision in estimating an overpayment decreases as the

result of changes to the overpayment findings in the sampled claims, the confidence interval widens and the lower confidence bound is reduced to a proportionately lower overpayment assessment. The Council finds no fatal flaw in such a process which would compel it to overturn the sample and extrapolation in this case.

As previously noted, the Council is required to give substantial deference to manual instructions in a particular case. The appellant has not demonstrated that the alleged imprecision in the sample and extrapolation invalidates the sample or resulting overpayment calculation. The appellant failed to offer sufficient affirmative evidence to establish that the PSC's sampling methodology and extrapolation did not comport with the guidelines established by CMS Ruling 86-1 and the MPIM.

Beneficiary-Specific Claims

The appellant provided argument in support of coverage for claims associated with six beneficiaries. The appellant rested on its arguments before the ALJ for the claims associated with the six remaining beneficiaries.[4]

Beneficiaries with Additional Arguments for Review

Beneficiary - J.B.[5]
Date of Service - April 13, 2005

The beneficiary's pertinent medical history included coronary artery disease, heart murmur and a pre-existing placement of a pacemaker. On March 23, 2005, the beneficiary was hospitalized for chest pain. On April 8, 2005, the beneficiary underwent an adenosine cardiolite stress test (identified by the appellant as a SPECT test). *See* Exh. MAC-3 at 5. On April 13, 2005, the appellant performed a multiple gated acquisition (MUGA) scan on the beneficiary and billed Medicare using CPT[6] codes 78472

[4] That is to say the appellant attempted to submit new documentation even for the beneficiaries for whom it submitted no additional argument. The exclusion of the untimely submitted evidence had no impact on the Council's consideration of the claims for coverage of involving those beneficiaries.

[5] The beneficiary-specific procedural case histories are presented in abbreviated fashion, beginning with the QIC reconsideration.

[6] CPT (Current Procedure Terminology) codes were designed by the American Medical Association to describe medical and surgical services performed by providers. Based upon the CPT system, CMS developed the Healthcare Common

(Cardiac Blood Pool Imaging/MUGA) and A4641 (Supply of Radiopharmaceutical Diagnostic Imaging Agent). On reconsideration, the QIC denied coverage finding that the April 8th SPECT test produced the same information captured in the MUGA performed five days later. Decision, Att. A at 6.

The ALJ denied coverage noting that upon admission (March 23, 2005), the appellant found the beneficiary's chest discomfort to be more musculoskeletal, rather than cardiac. The ALJ reasoned that the April 8th test did not identify any definite evidence of ischemia and there was no "clinical indication" identifying the need for a test on April 13th. Decision, Att. A at 6-7.

The appellant recounts its hearing testimony to be that while information from the SPECT test might have eliminated the need for the MUGA scan, the MUGA ("the gold standard test for heart function") would not necessarily have ruled out the need for the SPECT test. The appellant ordered both tests at the same time knowing, from professional experience, that there would be a delay in obtaining the isotope needed for the MUGA test. The appellant reasoned that if the SPECT test results were acceptable, the MUGA could be canceled. However, if the tests were not ordered simultaneously, and the MUGA later determined to be necessary, there would be an additional delay encountered waiting for the isotope. *See* Exh. MAC-3 at 5. Characterizing SPECT test results as "difficult to interpret," because the beneficiary had moved during the procedure, the appellant asserts that the SPECT test did not rule out the need for the MUGA. Consequently, the appellant conducted the MUGA scan. *Id.* Asserting that the measure of medical necessity should be the greater accuracy obtained with a MUGA scan, rather than the ultimate similarity of the SPECT-MUGA test results, the appellant characterizes questions regarding the MUGA's necessity as "Monday-morning quarterbacking." Exh. MAC-3 at 6.

The Council has considered the appellant's arguments in the context of the applicable legal authority, the evidence of record, particularly this beneficiary's medical records. In spite of the appellant's contentions, the Council finds no error in the ALJ's denial of coverage for the April 13, 2005, MUGA scan. The appellant concedes that the MUGA test is more accurate, yet acknowledges that the MUGA results would not

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Procedure Coding System (HCPCS) for processing, screening, identifying, and paying Medicare claims. *See* 42 C.F.R. §§ 414.2 and 414.40. For our purposes here, the coding systems are identical and the Council simply cites the CPT code.

necessarily have eliminated the need for the SPECT test. The tests results, however, are essentially repetitive. In spite of the beneficiary's medical history, his medical records from admission up to the April 13th date of service do not show the medical necessity for the MUGA testing provided on that date.

Accordingly, the Council finds that the appellant's April 13, 2005, claim for Beneficiary J.B., billed under CPT codes 78472 and A4641, is not covered by Medicare.

Beneficiary – M.F.
Date of Service – May 22, 2006

The beneficiary's medical history included multiple sclerosis and edema. On May 22, 2006, the appellant performed an echocardiogram on the beneficiary, subsequently billing Medicare under CPT codes 93307, 93320 and 93325. The QIC denied coverage for this claim essentially finding that the beneficiary's shortness of breath (SOB) was not adequately documented throughout the pertinent medical history. The ALJ denied coverage, adopting the QIC's reasoning that the beneficiary's SOB had not been clearly documented, principally because of the physical area in the medical records where the SOB was noted. Decision, Att. A at 16.

The appellant restates its hearing testimony that the beneficiary experienced SOB, and reasserts that the echocardiogram was medically reasonable and necessary. Further, the appellant notes that the PSC witness at the hearing testified that had the beneficiary's SOB been better identified in the medical records, the PSC would have conceded the medical necessity of this service. The appellant argues that there is no actual dispute as to the existence of the beneficiary's SOB. Rather, coverage has been denied because of the manner in which this information was recorded in the beneficiary's medical records. The appellant also asserts that the beneficiary's "pedal edema" is a causal factor in ordering the echocardiogram, but this acknowledged condition was not considered by the ALJ in denying coverage. Exh. MAC-3 at 3-4.

The Council has considered the appellant's arguments in the context of the applicable legal authority, the evidence of record, particularly this beneficiary's medical records. The Council finds that the beneficiary's medical record adequately identifies the presence of SOB in her May 12, 2006, examination (as well as being noted in the May 22nd

Echocardiographic report) and the existence of lower extremity edema. There is no question that the SOB, standing alone, would justify coverage of the echocardiogram.

Based upon our review of the medical records in this case and the totality of the beneficiary's condition, the Council finds that the appellant's May 22, 2006, claim for Beneficiary M.F., billed under CPT codes 93307, 93320 and 93325, is covered by Medicare.

Beneficiary - D.H.
Date of Service - February 16, 2005

The beneficiary presented to the appellant on February 2, 2005, with a heart murmur, sore throat, low potassium, high cholesterol and a "Syncopal [fainting] episode in the past." On February 16th the appellant performed an echocardiogram and carotid Doppler on the beneficiary. The appellant sought Medicare coverage for the echocardiogram, under CPT codes 93307, 93320 and 93325-59 and the carotid Doppler, under CPT code 93880. The QIC denied coverage for the echocardiogram because the date of the fainting episode was not identified in the beneficiary's medical history.[7]

Based on the general nature of the beneficiary's medical history, as well as the unknown date of the beneficiary's fainting episode, the ALJ denied Medicare coverage for the echocardiogram. Decision, Att. A at 19-20.

The appellant concedes that it has no further information regarding the date of the beneficiary's fainting episode. However, the appellant contends that the ALJ failed to consider the evidence in its entirety, citing the appellant's notation in a subsequent "patient summary" that "the echocardiogram was obtained to evaluate the heart murmur" for underlying idiopathic hypertrophic cardiomyopathy.

The Council has considered the appellant's arguments in the context of the applicable legal authority, the evidence of record, particularly this beneficiary's medical records. The Council finds that the beneficiary's medical record adequately identifies the presence of heart murmur in her

[7] The QIC also denied coverage for the carotid Doppler. However, at the ALJ hearing the PSC conceded that Medicare coverage for the carotid Doppler was appropriate. Decision, Att. A at 19.

February 2, 2005, examination, as well as being noted in the related February 16th Echocardiographic report.

Read in conjunction with the remainder of the beneficiary's Medical history, the Council finds that the appellant's February 16, 2005, claim for Beneficiary D.H., billed under CPT codes 93307, 93320 and 93325-59, is covered by Medicare.

Beneficiary - A.H.
Date of Service – November 4, 2005

The beneficiary's medical history included implantation of a pacemaker, uncontrolled hypertension, arteriosclerotic heart disease, diabetes and dizziness with palpitations.

On November 4, 2005, the appellant performed a transcranial Doppler study on the beneficiary. The study was inadequate for the appellant's purposes and was repeated on November 17, 2005. The appellant billed Medicare for a transcranial Doppler study (CPT code 93886), a noninvasive physiological study of the lower extremity (CPT code 93923) and an arterial Doppler study (CPT code 93925).

The QIC denied coverage for the November 17th transcranial Doppler testing because there was "no indication when recent carotid noted in chart was done. Unsure why doing this testing." The QIC denied coverage for the noninvasive physiological study of the lower extremity (CPT code 93923) based on the lack of signs & symptoms justifying its necessity. The QIC denied coverage for the arterial Doppler study (CPT code 93925) based on the absence of a "report for lower extremity doppler found in the file, have report for upper extremity arterial duplex study." Exh. L, Item I, Attachment to QIC Reconsideration at 7.

The ALJ denied coverage for all three codes. The ALJ recounted the appellant's hearing testimony as being that the appellant had not charged for the November 4th transcranial Doppler study. The ALJ then referenced an October 31, 2005, progress note which states: "No headaches." Decision, Att. A at 23.

Turning to CPT code 93925, the ALJ noted that the November 4th arterial duplex study lists arm weakness, not headaches, as the clinical indication and that the October 31st progress notes do not identify arm weakness, but state: "Muscle strength adequate." Decision, Att. A. at 24.

The ALJ then found that the record did not contain "a noninvasive physiological study of lower extremity (93923)." The ALJ acknowledged the appellant's hearing testimony that this claim had been misidentified for billing purposes and that CPT code 93930 (Duplex scan of upper extremities) should have been billed. The ALJ determined that as there had been no preliminary coverage consideration of a billing under CPT Code 93930 he was without authority to assess the merits of coverage for that claim. The ALJ recommended that the appellant resubmit that particular claim for an initial coverage determination. Decision, Att. A. at 24.

CPT code 93886 - The appellant acknowledges confusion surrounding the performance and billing of November 4th and 17th transcranial Doppler studies. The appellant restates that the November 4th study was inadequately performed and thus was repeated on November 17th. The appellant indicates that it only sought and received coverage for a single transcranial Doppler study associated with this beneficiary. The appellant cited evidence in the record (Exhibit D, Third Attachment) demonstrating that it had in fact been paid for a single transcranial Doppler study. The appellant indicates that it is not seeking coverage for another, identical test, but would like the assumption of an unfavorable determination on this claim (*i.e.*, what was in effect, a perceived double-billing), rectified for the purposes of accurate overpayment recalculation. The appellant recounts the PSC hearing testimony to the effect that if evidence supported a finding that the transcranial Doppler had only been billed once, the PSC would treat the November 17th test as appropriately billed. Exh. MAC-3 at 7.

The appellant's evidence supports its recitation of the facts. Although it followed a somewhat confusing path, the evidence supports a conclusion that the appellant has sought and received coverage for this testing, but only once. Recalculation of the overpayment should reflect these facts. Based upon the fact of coverage, the Council need not address the issue of the test's medical necessity.

CPT code 93925 - The appellant concedes that it erroneously billed Medicare for lower extremity testing (CPT code 99352) instead of the upper extremity testing it actually provided (CPT code 93930). The appellant takes issue with the ALJ's conclusion that he was without authority to entertain, for the

first time at his level of review, what was, in effect, a new claim for coverage. The appellant cites testimony from the PSC's witness indicating that the ALJ could "recode" this claim to reflect the correct nature of the service performed. Exh. MAC-3 at 7.

The ALJ is correct in noting that he is generally without jurisdiction to consider an issue for which a party has not received an unfavorable QIC reconsideration. *See, generally,* 42 C.F.R. § 405.1000. Nor may an ALJ add a claim to a pending appeal unless it has been adjudicated at the lower appeals levels. 42 C.F.R. § 405.1032(c). Here, the appellant has not filed a claim for CPT code 93930. Although the Council is unaware of the underlying basis for the PSC's assertion that the ALJ did have the authority to recode the claim, the PSC or contractor may well have that authority under 42 C.F.R. §§ 405.980 and 405.986 or make any necessary allowance for the appellant's resubmission of the claim, properly coded. Again, the Council notes that the PSC or contractor will be recalculating this overpayment to reflect changes brought on by the Council's decision. Having conceded that this claim was not properly coded, as initially submitted, the appellant's claim for coverage remains denied.

CPT code 93923 – The appellant has added no further argument regarding this code, asserting that it is derivative and if the 93925 claim is reimbursed, reimbursement for this code will follow. Based on the preceding analysis, coverage for the claim submitted under CPT code 93923 remains denied.

The Council finds that the appellant has submitted and received coverage for one claim associated with CPT code 93886. The record is corrected to reflect a single payment for a single service.

The appellant's claim for coverage of CPT codes 93925 and 93923 remains denied due to errors in their initial billing.

Beneficiary - A.J.
Date of Service – November 30, 2005

The beneficiary's medical history included chronic obstructive pulmonary disease, diabetes, sleep apnea, high cholesterol and hypertension.

Based on a referral, the appellant performed a CT scan on the beneficiary on November 30, 2005 to determine the cause of her chest discomfort. The appellant billed Medicare for a computed tomographic angiography (CTA), chest, without contrast, under CPT code 71275TC.[8] The appellant also billed Medicare for a computed tomography, thorax, with contrast material(s), under CPT code 71260TC.

The QIC denied coverage for CPT code 71260TC, finding that someone other than the appellant-physician interpreted the procedure, and that there was no indication that the appellant-physician was the supervising physician. The QIC denied coverage for CPT code 71275TC, finding that the "CPT descriptor says with and without contrast. No indication testing was done without contrast. Exh. L, Item I, Attachment to QIC Reconsideration at 9.

The ALJ recognized the appellant's hearing-testimony concession that CPT code 71260TC was billed erroneously. Further, the appellant also testified that it had mistakenly billed 71275TC "without contrast" noting that "without contrast," there would be nothing to see on the scan. The appellant contended that CPT code 71275TC should be paid. Regardless, the ALJ denied coverage, finding that the appellant had not addressed the QIC's rationale for denying coverage.[9] Decision, Att. A. at 31-32.

Before the Council, the appellant reemphasizes that it billed only for the technical component of this service. The appellant recounts that the CT scan was ordered by the appellant-physician and interpreted by the appellant-medical specialist group. The appellant notes that neither the QIC, nor the ALJ, questioned the medical necessity of this diagnostic test. Rather, the QIC based its denial on the absence of any indication that the appellant-physician was the supervising physician and the ALJ, in the appellant's characterization, merely adopted the QIC rationale. Exh. MAC-3 at 9-10.

The appellant argues that the QIC/ALJ reasoning "would make sense" if the appellant "had billed Medicare for the

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[8] The "TC" modifier indicates - **Technical Component**: Certain procedures are a combination of professional and technical components. When only the technical component is reported, the service is identified by adding modifier TC to the procedure code.

[9] The ALJ also surmised, after acknowledging the appellant's hearing concession that it "was a mistake to bill 71260," that the appellant had conceded 71275TC was "a billing error." Decision, Att. A. at 31.

professional component of the tests. However, . . . [the appellant asserts that it] billed only the technical component." Exh. MAC-3 at 10. The appellant continues to point out some potential confusion in the appellant-physician's testimony. The appellant notes that it is conceding that CPT code 71260TC was billed erroneously and avers that it is not seeking Medicare coverage for that test. Citing the associated test report as support, the appellant contends that "all components of . . . [CPT code 71275] were performed . . . both with and without contrast . . . ." and requests payment for that billing. Exh. MAC-3 at 10; *see, also,* Exh. F at 850.

As with several of the appellant's claims, the factual/billing pattern for this beneficiary is less than clear. However, given the nature of an ALJ's review is *de novo* (*see* 70 Fed. Reg. 36386 (June 23, 2005)), as well as the content of the appellant's argument, it is reasonable to expect that the ALJ's analysis of this claim would have consisted of more than a mere "adoption" of the QIC reconsideration based on a perception that the appellant failed to address the QIC rationale.

The record supports the appellant's claim. As it argued, the appellant billed (and the PSC reviewed) claims for only the technical components of CPT codes 71260 and 71275. *See* Exh. L, Item I, Attachment to QIC Reconsideration at 8-9. The appellant has withdrawn its claim for coverage involving code 71260 and clarified that it was seeking coverage for the CPT code 71275TC procedure with contrast.

In light of the clarified facts of the appellant's claim and the pertinent medical evidence, the Council finds that the appellant's claim for CTP code 71275TC is covered by Medicare.

Beneficiary - E.W.
Date of Service – March 30, 2006

The beneficiary's medical history included diabetes, congestive heart failure and arteriosclerotic heart disease. On March 30, 2006, the appellant performed a noninvasive physiologic study of the lower extremity (CPT code 93923) and a duplex scan of the lower extremity arteries (CPT code 93925) on the beneficiary. On reconsideration, the QIC denied Medicare coverage for both codes, reasoning that the beneficiary was "[s]eeing another provider for foot problem. Unsure why this testing is being done . . . [by appellant]. Diagnosis on report is not supported

by office visit notes." Exh. L, Item I, Attachment to QIC Reconsideration at 15.

After recounting the appellant's arguments and pertinent evidence, the ALJ indicated that a "March 21, 2006 progress note does not mention that the beneficiary had problems walking, problems with her legs, vascular problems, or claudication." Consequently, the ALJ found that the services were not "reasonable and necessary" and not covered by Medicare. Decision, Att. A. at 63-64.

The appellant notes that "claudification" was listed on the March 30th test report, but concedes, as it had in hearing testimony, that such information was not contained in the March 21st progress note. The appellant asserts that any perceived deficiency in the March 21st progress note was cured by the appellant's hearing testimony. There, the appellant-physician explained that the testing was predicated on the possibility that the beneficiary's mobility problems were caused by "ischemia (restriction or obstruction of blood flow)." Exh. MAC-3 at 8. The appellant contends that, in the context of "the treating physician rule," its hearing testimony and the documentary evidence support coverage of these claims.

The "treating physician rule" does not provide a basis for changing the ALJ's action. CMS Ruling 93-1 provides that no *presumptive* weight should be assigned to a treating physician's medical opinion in determining the medical necessity of inpatient hospital or skilled nursing facility services. The Ruling provides that "if the medical evidence is inconsistent with the physician's certification, the medical review entity considers the attending physician's certification only on a par with the other pertinent medical evidence." CMS Ruling 93-1. Moreover, the Ruling adds, parenthetically, that the Ruling does not "by omission or implication" endorse the application of the treating physician rule to services not addressed in the ruling. *Id*. Therefore, the Council need not defer to a treating physician's medical opinion, but rather considers it within the context of other pertinent evidence of record. Having done so, and considered the ALJ's rationale for his findings and conclusions, the Council concurs with the ALJ's action.

An appellant seeking Medicare coverage and reimbursement for services is responsible for properly documenting the medical necessity of those services. *See* section 1833(e) of the Act and 42 C.F.R. § 424.5(a)(6).

There is minimal documentation in the beneficiary's record. The existing documentation largely post-dates the provision of the services at issue and does not demonstrate, clearly, the medical necessity underlying these diagnostic services. **Accordingly, the Council finds that the appellant's March 30, 2006, claim for CPT codes 93923 and 93925 is not covered by Medicare.**

Beneficiaries without Additional Arguments on Review

The appellant acknowledged that the ALJ issued unfavorable, beneficiary-specific decisions for **Beneficiaries R.A., A.L, E.N., J.R., R.S. and S.W.** However, the appellant rests on its previous arguments of record for those beneficiaries. Exh. MAC-3 at 10. The Council has reviewed the ALJ's findings and conclusions for these six beneficiaries. Based upon the absence of any new argument suggesting why the ALJ's findings and conclusions for these beneficiaries are wrong, the Council affirms them without further comment. *See* 42 C.F.R. § 405.1112(c).

Liability and Waiver of Recoupment of Overpayment

The ALJ determined that the appellant was liable for the non-covered costs arising from the overpayment and that the appellant was not eligible for waiver of recoupment of the overpayment. *See*, Dec. at 13; *see, also*, sections 1879(a)(1) and 1870(b) of the Act. The appellant did not challenge these findings and the Council affirms them without further comment.

DECISION

Consistent with the detailed analysis above, it is the decision of the Medicare Appeals Council that:

Medicare coverage is available for the May 22, 2006, claims billed for Beneficiary M.F. (CPT codes 93307, 93230 and 93325);

Medicare coverage is available for the February 16, 2005, claims for Beneficiary D.H. (CPT codes 93307, 93230 and 93325-59);

Medicare coverage is available for the November 17, 2005, claim for Beneficiary A.H. (CPT code 93886); **the claims for CPT codes 93923 and 93925 remain denied**;

Medicare coverage is available for the November 30, 2005, claim for Beneficiary A.J. (CPT code 71275TC); **the claim for CPT**

code 71260 remains denied.

All claims at issue for Beneficiaries **R.A., J.B., A.L, E.N., J.R. R.S., E.W. and S.W.** remain denied.

The appellant is liable for all non-covered costs and is not eligible for waiver of recoupment of the resulting overpayment.

The Medicare contractor is directed to recalculate the resulting overpayment in according with the findings and conclusions above.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

/s/Constance B. Tobias, Chair
Departmental Appeals Board

Date: May 10, 2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-869

In the case of	**Claim for**
John Sanders, M.D. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiaries)	**** (HIC Numbers)
CIGNA Government Services (Contractor)	**** (formerly ****) (ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated December 14, 2010, because the decision contains errors of law which were material to the outcome of the claim before the ALJ. *See* 42 C.F.R. § 405.1110(c). Although the Council agrees with the ALJ's ultimate conclusion that the overpayment should be limited to the sum total of overpayments in the individual sampled claims, the Council does not entirely adopt the reasons the ALJ provided for invalidating the extrapolated overpayment as they are not fully consistent with the Medicare policies contained in the Medicare Program Integrity Manual. The Council issues this modifying decision to address the points raised by CMS in the agency referral memorandum.

The case before the ALJ involved an audit-based, extrapolated overpayment for evaluation and management (E&M) services provided by the appellant physician to beneficiaries on dates of service from January 1, 2004, through December 31, 2005. In an initial decision dated November 27, 2009, the ALJ found*, inter alia,* that the statistical sampling methodology used to calculate the extrapolated overpayment was invalid, and

therefore only the actual overpayment could be recovered. Dec. I at 35, filed in the record as Exh. 4 at 38.[1]

The Council subsequently remanded the case on the grounds that the Centers for Medicare & Medicaid Services (CMS) and/or its contractors, including AdvanceMed, the Program Safeguard Contractor (PSC) that performed the audit in this case, had not been afforded an opportunity to participate in the ALJ hearing. *See* Council Order of Remand in *John Sanders, MD,* Docket No. M-10-564, issued March 26, 2010. On remand, the ALJ provided the PSC with an opportunity to testify, and incorporated the earlier testimony of the appellant's expert statistician, and the independent expert statistician retained by the Office of Medicare Hearings and Appeals (OMHA) into the record, by agreement. The ALJ then issued a new decision, dated December 14, 2010, determining that "on the whole, . . . the sampling methodology utilized by AdvanceMed did not comply with Medicare requirements, and the extrapolated overpayment calculation was invalid." Dec. II at 9.

The appellant did not request Council review of the second ALJ decision. However, CMS filed a referral memorandum, seeking own motion review by the Council. The CMS memorandum is entered into the record as Exhibit MAC-1. The CMS memorandum contests the ALJ's determination that the sampling methodology did not comply with Medicare requirements and therefore the extrapolated overpayment calculation was invalid. Exh. MAC-1. The appellant has filed a timely response to the CMS memorandum, which is entered into the record as Exh. MAC-2.

The Council has carefully considered the record before the ALJ, as well as the CMS memorandum and the appellant's response. The Council hereby modifies the ALJ's second decision, concurring in the determination that the sampling was sufficiently flawed to preclude calculation of an overpayment by extrapolation. However, the Council's reasons for this determination differ from the reasons set forth in the ALJ's second decision. Specifically, as explained in the Council's Analysis below, many of the reasons cited in the Analysis section of the ALJ's second decision do not provide a basis for concluding that the sample was invalid.

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[1] The ALJ decision issued November 27, 2009 (which was earlier vacated by the Council), is referred to herein as Dec. I. The ALJ decision issued December 14, 2010 (after the Council's remand), is referred to as Dec. II.

However, there were two sampling issues raised by the appellant, which were neither sufficiently explained nor corrected by the PSC, and which were the subject of testimony from the independent expert statistician. These two errors are not addressed in or rebutted by the CMS memorandum. The errors are: 1) the PSC provided the independent statistical expert with sample data which assigned some claims to the wrong stratum; and 2) the PSC provided the independent expert with a second CD containing an Excel set of sample data with significant discrepancies from the first set of data, and the PSC was unable to clarify the discrepancies, to identify which set of data was applicable, or to explain the significance of the second set of data. The Council finds that these errors and inconsistencies in the original sampling preclude use of the sample to extrapolate an overpayment to the full universe of claims. Therefore, the Council modifies the reasoning that underlies the ALJ's conclusion in his second decision, but concurs in the conclusion that the results of the sampling cannot be used to extrapolate an overpayment amount. The appellant remains financially liable for the overpayments shown in the individual claims within the sample, but is not financially liable for any extrapolated amount.

BACKGROUND

Below, the Council sets out a brief synopsis of the pertinent background and procedural history of this case. Further information can be found in the Council's earlier remand order (*John Sanders, MD,* Docket No. M-10-564, issued March 26, 2010).

AdvanceMed Corporation, a Program Safeguard Contractor (PSC), conducted a post-payment review of claims submitted to Medicare for evaluation and management (E&M) services furnished by the appellant physician, with dates of service between January 1, 2004 and December 31, 2005. Exh. 1 at 151-52. In a sample of approximately sixty claims reviewed, the PSC denied or downcoded 227 of the 235 line items (each consisting of one HCPCS code). *Id.* at 165.[2] Based on this review and on an extrapolation from the statistical sampling, CIGNA, the Medicare Administrative

[2] The Centers for Medicare and Medicaid Services (CMS) has established uniform national definitions of services, codes to represent services, and payment modifiers to the codes. 42 C.F.R. § 414.40(a). The Medicare coding system, Healthcare Common Procedural Coding System (HCPCS) is based on the American Medical Association's (AMA's) Physician's Current Procedural Terminology (CPT).

Contractor (MAC), requested a return of $211,218 that it claimed was paid to the appellant in error. *Id*. at 138. Upon redetermination, the contractor upheld the overpayment determination. *Id*. at 130-133.

The appellant requested reconsideration, and advanced contentions about both the findings of overpayments in individual claims and the methodology used in the statistical sampling and extrapolation of the overpayment amount. Exh. 1 at 115-29. The Qualified Independent Contractor (QIC) upheld a majority of the fully or partially denied claims in the sample for generally the same reasons as the contractor. *Id*. at 73-102. However, the QIC did adjust payment upwards for approximately eighteen of the claims based on the appellant's contentions. *Id.* The QIC also found the appellant liable for the extrapolated overpayment, rejecting the appellant's contentions as to the invalidity of the sampling and extrapolation methodologies. *Id.* at 95-96.

The appellant requested an ALJ hearing on March 18, 2008. Exh. 1 at 7-15. The ALJ held a prehearing conference, and a hearing on June 9, 2009. Prehearing Conference CD (June 20, 2008); ALJ Hearing CD (June 9, 2009). The ALJ heard testimony from the appellant on services and billing for the claims in the sample, and from an independent statistical expert and the appellant's statistical expert on the methods used in the sampling and extrapolation. ALJ Hearing CD (June 9, 2009) at approximately 11:43 a.m. to 12:01 p.m., and 1:00 to 3:00 p.m.

On November 27, 2009, the ALJ issued a partially favorable decision in which he determined some services in the sample (in parts of approximately 35 claims) were reasonable and necessary and met coverage guidelines. *Id*. at 15-33. For services that remained denied, the ALJ found the appellant liable for the overpayment pursuant to section 1879 of the Social Security Act (Act) and not entitled to waiver under section 1870 of the Act. *Id*. at 33-34.

With regard to the statistical sampling used to calculate the overpayment, the ALJ noted that while CMS contractors may use statistical sampling to calculate overpayments, the "sampling study must be based upon appropriate sampling and computed by valid statistical methods to establish *prima facie* evidence of the number and amount of claims or requests for payment." *Id*. at 15. In this case, both the appellant's statistical expert and the independent statistical expert, "testified as to flaws

in the sampling size and the stratification of the sample utilized by PSC." *Id*. Based on "unanimous expert testimony," the ALJ determined that "the sampling methodology utilized by the PSC did not comply with Medicare requirements, and therefore the extrapolated overpayment calculation was invalid." *Id*. at 15. The ALJ concluded that the appellant remained liable for a number of services in the sample that were not payable by Medicare. *Id*. at 35. The ALJ further concluded also that the statistical sampling methodology used to calculate the extrapolated overpayment was invalid and therefore only the actual overpayment could be recovered. *Id*.

CMS requested own motion review of the ALJ's decision by the Council, on the ground that the record did not show that potential participants, including the PSC, were afforded notice and an opportunity to participate in the hearing. Exh. MAC-1 at 1-11, *citing* 42 C.F.R. §§ 405.1010, 405.1020, and 405.1022.[3]

On March 26, 2010, the Council remanded the case to the ALJ to provide an opportunity for the PSC to participate in a hearing, and to make a complete record of the evidence. The Council noted that Medicare regulations provide that CMS and/or one or more of its contractors may elect to participate in the hearing process. 45 C.F.R. § 405.1010(a). Because the PSC had performed the sampling and had provided a copy of its data to the other statisticians to review, it was both fundamentally fair and required by regulation that it be given an opportunity to participate in the ALJ hearing when the validity of the sampling was at issue.[4]

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[3] In its referral memorandum, dated January 20, 2010, CMS also contended that the types of concerns raised by both statistical experts in the case should not have served as a basis for invalidating the extrapolation of the overpayment. Exh. 1 at 6-7.

[4] The Council disagrees with the ALJ's characterization of its remand as based on an "expansive" interpretation of 42 C.F.R. § 405.1020. Precisely because § 405.1010(a) allows CMS and/or its contractor(s) to elect to participate in the hearing process, those entities must receive notice under § 405.1020 in order to exercise their right to participate. In fact, subsection 405.1020(c)(2) makes explicit reference to the fact that the notice of hearing requires "all parties to the ALJ hearing <u>(and any potential participant from CMS or its contractor who wishes to attend the hearing)</u>" to reply to the hearing notice. (Emphasis added.) In this case, where the validity of the PSC's sampling and extrapolation was at issue, and where the ALJ invalidated the sampling and extrapolation for the first time during the appeal process, it was particularly important for the PSC to be afforded the opportunity to participate in the hearing. On remand, the PSC did elect to participate.

On remand, after a prehearing conference, the ALJ held a hearing and took testimony from a representative of the PSC, Mr. Landtroop. The earlier testimony of the two statistical experts, Dr. Haller and Dr. Rhode, was incorporated into the record, by agreement.

In accordance with the Council's remand order, the ALJ issued a new decision. That decision reviewed the background of the case, the earlier testimony of the two statistical experts, and Mr. Landtroop's testimony on behalf of the PSC. Dec. II at 1-3. Based on the testimony, the ALJ found that because certain parts of the sampling methodology utilized by the PSC did not comply with Medicare requirements, the extrapolated overpayment calculation was invalid and the appellant was not required to reimburse the claimed extrapolated amount. *Id.* at 9. As explained above, this is the ALJ decision that CMS seeks to challenge in its request for own motion review. Six parts of the record are of particular relevance to deciding the issues presented in the CMS request and the appellant's response. These parts of the record are each summarized below.

SUMMARY OF ISSUES AND POSITIONS

Testimony of Appellant's Statistics Expert

During the hearing, the appellant's statistical expert, Dr. Rhode, testified that in a number of respects he did not have enough information to opine on whether the statistical sampling was valid. ALJ Hearing CD (June 9, 2009) at 11:45 to 11:57 a.m. He testified that he lacked information about why the sampling unit was the claim rather than the billing line. He also lacked information on the distribution of the sample (i.e., whether it was normal (bell-shaped) or skewed in some manner). *Id.* He further opined that since fully denied claims had been omitted from the sampling and it was not clear how the overpayment rate was defined, such factor could have affected the numbers used to compute the overpayment projection. *Id.*

Testimony of Independent Statistical Expert

The statistical expert retained by the ALJ, Dr. Haller, prepared a written report, or "case review," submitted prior to the hearing. Exh. 3 at 1-6. Initially, Dr. Haller reported that the first Excel CD file he received from the PSC (entitled MedicalReviewSpreadSheetwithoverpayment.xl) had what appeared to be data from the audit of the random sample defined in PSC

former statistician Dr. Moody's (Dr. Moody's) memo of January 30, 2007 (Exh. 1 at 171-175). Exh. 3 at 1-6. However, when Dr. Haller sorted the data, there were 23 beneficiaries for Stratum 1 (amounts paid < $350) and 29 beneficiaries for Stratum 2 (amounts paid > or = $350), and some of the beneficiaries were identified as being in the wrong stratum. *Id.* at 2. This was inconsistent with Dr. Moody's plan for the sampling, which envisioned 30 beneficiaries in each stratum. Exh. 1 at 171-72.

Dr. Haller explained that a second Excel CD file (entitled Samplecollapse.xl) was furnished by the PSC for his review. Exh. 3 at 2. This second file contained data on amounts paid and overpaid for 30 beneficiaries in each of the two strata. *Id.* However, Dr. Haller stated that he could not explain the differences between the two Excel files. *Id.* at 2-3. His report concludes by asking that AdvanceMed clarify the discrepancy between the data in the two files. *Id.* at 4. The PSC has been unable to do so, as Dr. Moody is no longer with the PSC.

In his written testimony, Dr. Haller also explained that based on the use of an Optimum Allocation strategy, he believed the sample size should have been 34 beneficiaries for Stratum 1 and 55 beneficiaries for Stratum 2. Exh. 3 at 3. However, acknowledging the language in the Medicare Program Integrity Manual that discourages challenges to sample size alone (MPIM, ch. 3, § 3.10.4.3.), he referred to the sample size as "adequate if other conditions to be discussed below are met." Exh. 3 at 3.

Then Dr. Haller explained that given the 90% two-sided confidence interval, and the 15.7% precision, it is important to examine the *distribution* of the determined overpayments. Exh. 4 at 3-4. Based on his analysis, he identified the determined overpayments as skewed to the right, and therefore he used a "natural logarithm transformation" to render the data in a normal distribution before he calculated the confidence interval for the mean overpayment to the universe (point estimate). *Id.* at 4. Based on this procedure, he calculated a 95% probability that the total overpayments to the appellant were at least $145,740, rather than the $211,218 amount computed by AdvanceMed. *Id.*

Testimony of PSC Representative on Statistics Issues

During the hearing on remand (on November 3, 2010), Mr. Landtroop, who holds a Masters degree and now serves as chief statistician for AdvanceMed, testified about the statistical issues in the case. ALJ Hearing CD (Nov. 3, 2010) at 10:11 to 10:32 a.m. Mr. Landtroop had reviewed the written testimony from Dr. Haller and the summary of Dr. Rhode's testimony contained in the ALJ's written decision. *Id.* at 10:23 a.m.; *see also* Dec. I. at 3, 18, 35. Dr. Moody, who had supervised the audit in 2006 to 2007, was no longer employed by AdvanceMed. *Id.*

Mr. Landtroop stated first that although the confidence interval of the AdvanceMed data was only to 15% precision, and Dr. Moody's memo planned for 10% precision, there is no requirement in Medicare policy guidelines which require a precision percentage of 10% or less. ALJ Hearing CD (Nov. 3, 2010) at 10:13 to 10:17 a.m. He also stated that although he had read Dr. Haller's testimony about the mix-up on the files that were sent, he "really couldn't speak to that, really couldn't say what had happened." *Id.* at 10:17-10:18 and 10:30 a.m.

Mr. Landtroop addressed Dr. Haller's testimony about the sampled overpayments being skewed to the right in two ways. ALJ Hearing CD (Nov. 3, 2010) at 10:20 to 10:23 a.m. First, he asserted that simply saying the overpayments are not distributed normally is not enough to invalidate the extrapolation. *Id.* at 10:20 a.m.. According to Mr. Landtroop, given the statistical assumptions of the Central Limit Theorem, one would have to show that the distribution of the sample results was abnormal in comparison to the distribution of the results in the sampling frame. *Id.* He submits that it would not be realistic to perform such a procedure, and that the sample of 60 claims was more than enough to ensure the sample average was normally distributed. *Id.*

Second, Mr. Landtroop questioned Dr. Haller's use of a "natural logarithm transformation" to revise the data before doing an extrapolation. ALJ Hearing CD (Nov. 3, 2010) at 10:21 to 10:22 a.m. Because four or five of the sample claim overpayments were zeros or negative numbers (representing no overpayment or an underpayment), it would not be possible to use a natural logarithm process because zeros and negative numbers have no defined natural logarithms. *Id.*

Second ALJ Decision

In the decision issued December 14, 2010, the ALJ concluded that AdvanceMed's sampling methodology did not comply with Medicare requirements, the extrapolated overpayment calculation was invalid, and the appellant is not required to reimburse the assessed extrapolated amount. Dec. II at 9. The ALJ identified the following reasons for his conclusions:

- Dr. Haller stated that the confidence interval of the AdvanceMed data was only to 15% precision, and he estimated a correct extrapolation amount that was nearly one-third less than the AdvanceMed result.

- Dr. Rhode stated a variety of doubts about the AdvanceMed sampling.

- While Mr. Landtroop argued that the 10% precision is not a strict requirement, the Manual provides, "In most situations the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery from the provider or supplier."

- Mr. Landtroop did not agree with the recalculated extrapolation estimate of Dr. Haller. However, he did concede that the Central Limit Theorem assumes a normal distribution of results, and he did not challenge the assertion that the results in this case were skewed.

Dec. II at 9.

CMS Memorandum

In its request for own motion review by the Council, CMS asserts that there is an error of law material to the outcome of the claim, and that the ALJ's decision is not supported by a preponderance of the evidence. Exh. MAC-1 at 1. Overall, the CMS memo contends that none of deficiencies Dr. Haller and Dr. Rhode identified in the sampling and extrapolation methods are sufficient to invalidate the sampling and extrapolation. *Id.* at 2.

More specifically, the CMS memorandum defends the PSC's use of data with a 15.69% precision estimate, by explaining that the

Medicare Program Integrity Manual contemplates the use of the lower bound of a confidence interval to increase the probability that the overpayment demand is equal to or less than the actual overpayment. Exh. MAC-1 at 5-7, *citing*, Pub. 100-08, MPIM, ch. 3, §§ 3.10.2, 3.10.5.1.

The CMS memorandum also takes issue with the ALJ's reliance, in part, on Dr. Haller's testimony that the skewed distribution of the sampled overpayment results raises questions about the extrapolation, and with Dr. Haller's use of alternate computations to arrive at an extrapolation of $145,740. Referring to Mr. Landtroop's testimony, the CMS memo points out that the fundamental assumption of the Central Limit Theorem is that the *sample averages* will be normally distributed. The fact that the overpayment sampling units in one sample may be skewed does not mean that the sample averages, if successive samples were to be taken, are not normally distributed. Parsing Dr. Haller's testimony further, CMS also notes that Dr. Haller did not say that the PSC calculation of the extrapolation was invalid; rather, he testified that he had found "a better way to approach the problem," that resulted in "a more accurate estimate of the total overpayment to the universe." Exh. MAC-1 at 8, *citing* Exh. 3 at 4. CMS asserts that pursuant to CMS Ruling 86-1, the appellant has the burden of demonstrating that the sampling methodology used was invalid; it is not the contractor's responsibility to establish why it did not use a different (or more precise) design. Exh. MAC-1 at 8. To the extent that the ALJ relied on Dr. Haller's approach and calculation as a basis for finding the PSC's methodology invalid, CMS submits that his decision is erroneous.

Appellant's Response

In response to the CMS memorandum, the appellant asserts that the evidence the ALJ relied on demonstrates that the extrapolated overpayment amount was too high to be accurate. Exh. MAC-2 at 1-3. If this extrapolated (or estimated) overpayment amount is shown to be too high, then the appellant contends that the CMS memorandum and the CMS Ruling 86-1 state that the appellant has met its burden, and the extrapolation should be invalidated. *Id., citing* Exh. MAC-1 at 2.

The appellant also contends that there is a preponderance of evidence supporting the ALJ's conclusion that the sampling and extrapolation were invalid. Exh. MAC-2 at 2. In appellant's view, this evidence includes the fact that the initial data

supplied to Dr. Haller were erroneous and inconsistent; the fact that the sample size used did not comport with the Optimum Allocation theory; and the significantly lower extrapolation arrived at when Dr. Haller corrected for skewing in the data; *inter alia. Id.*

LEGAL AUTHORITY

CMS Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers. The Ruling also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation by CMS in calculating overpayments. The Council incorporates that discussion by reference here. The Ruling provides, in part:

> Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

CMS Ruling 86-1 at 86-1-9, 86-1-10.

The Medicare Program Integrity Manual provides guidance to contractors in conducting statistical sampling for use in estimating overpayment amounts. The instructions are intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments where a review of claims indicates that overpayments have been made. The MPIM describes the purpose of its guidance as follows:

> These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC . . . to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. Failure by the PSC . . . to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.

MPIM, ch. 3, § 3.10.1.1.

The MPIM further provides that a contractor may employ any sampling methodology that results in a "probability sample," and defines the requirements for a valid probability sample. *See* MPIM, ch. 3, § 3.10.2. The Manual then states:

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

MPIM, ch. 3, § 3.10.2. The MPIM recognizes that a number of sampling designs are acceptable, including: simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these. MPIM, ch. 3, § 3.10.4.1.

The MPIM provides the following guidance with respect to selecting the sample size:

> The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.
>
> In addition to the above considerations, real-world economic constraints shall be taken into account. As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC or ZPIC BI unit or the contractor MR unit shall also consider their available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design.

MPIM, ch. 3, § 3.10.4.3.

ANALYSIS

The Council concurs with the ALJ's conclusion that the sampling conducted in this case was substantively flawed, and therefore the Council limits the overpayment recovery to the sum of the actual sampled claims without extrapolation. However, the problem with the sampling is not the general methodology design issues identified by the ALJ in his Analysis and contested in the CMS memorandum. In fact, the Council agrees with a number

of the points made in the CMS memorandum, for the reasons explained below. The Council, however, finds that the actual performance of the sampling contained sufficient flaws and unanswered questions as to render any extrapolation in this case subject to substantial errors and inequities to the appellant.

Problems in the Assignment of Claims to Strata

There are two major, related shortcomings in the sampling here, which cannot be corrected at this juncture. Therefore, notwithstanding the significant resources that the PSC has expended in conducting this audit, and the detailed and thorough planning and design methodology for the audit thoroughly recorded in Dr. Moody's January 30, 2007 memo, the Council must limit the overpayment demand to the total sum of the individual overpayment amounts identified in the cases sampled and reviewed by the QIC and the ALJ.

The first of these two flaws is that either the samples themselves were not drawn correctly or the claims were not correctly assigned to the correct stratum in every case, consistent with the probability sample design. The use of one or more probability samples in calculating overpayments is premised, *inter alia*, on the accuracy and representativeness of the sample or samples in representing the stratum from which they are drawn. That is why, in explaining the statistical sampling procedures, the Medicare Benefits Policy Manual states:

> **If a particular probability sample design is properly executed,** i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made.

MPIM, ch. 3, § 3.10.2 (emphasis added).

However, in this case, the probability sample design set forth in Dr. Moody's January 30, 2007 memorandum was not properly executed. The design called for a stratified random sampling, with 30 cases in Stratum 1 (payment of < $350) and 30 cases in Stratum 2 (payment = or > $350). Exh. 1 at 171-175. This design was based on Dr. Moody's analysis of the characteristics of the universe to be sampled. *Id.* However, when Dr. Haller opened and sorted the first Excel file of audit data that the

PSC provided for his review, he found only 23 beneficiaries in Stratum 1 and 29 beneficiaries in Stratum 2. Exh. 3 at 2. Moreover, Dr. Haller found that the PSC had placed some beneficiaries in Stratum 2 for whom the total amount paid the provider was less than $350, which was inconsistent with the definition of Stratum 2. *Id.*

These errors are significant for a series of reasons. If claims in the sample were assigned to incorrect strata, it is possible, if not likely, that claims in the frame were also assigned to incorrect strata, but it is not possible to know at this juncture how widespread these errors were. If claims in the sample that were assigned to the wrong strata were in fact used in calculating key variables, such as error rates, average overpayments, point estimate(s), upper and lower confidence bounds, and precision estimate(s), then those variables and results would be inaccurate. Extrapolation might well have the effect of multiplying errors in this process.

At this point, it is not possible to perform a precise assessment of the nature and extent of any such errors in the way the sample was drawn. It is also not possible to identify and correct the errors without starting the entire audit process over, i.e., re-assigning every claim listed in the frame to assure that it is assigned to the correct stratum and then drawing a new random sample for review.

The second major concern the Council has with the sampling process, as raised by the appellant before the ALJ, relates to the uncertainty and inconsistency of the data recorded in two different and unidentified Excel CD files. Dr. Haller stated that the PSC submitted a second Excel file for his review. Exh. 3 at 2. This second file, according to Dr. Haller, did contain data on amounts paid and overpaid for 30 beneficiaries in each of the two strata, 1 and 2. *Id.* However, Dr. Haller stated that he could not explain the apparent difference between these two files, and he asked the PSC (in 2009) to clarify the discrepancy between the two files representing the probability sample. *Id.* at 2-4. The PSC did not respond to this request. At the hearing, the PSC's representative, Mr. Landtroop, stated:

> And you're right, your Honor, there does appear to be this confusion about the Excel file that Dr. Haller received . . . . I can't speak to that. I wasn't an employee here at the time that occurred.

ALJ Hearing CD (Nov. 3, 2010) at 10:30 a.m. No one has been able to explain which file represents the correct data, and none of the statistical experts nor the Council has been able to resolve the substantial discrepancy between the two sets of data.

Unfortunately, the submission of data to Dr. Haller on the second CD raises additional questions about the accuracy of the audit. The first CD had data on 52 sampled claims, the second CD had data on 60 sampled claims. Exh. 3 at 2. Thus, the second CD contained a probability sample which is different (in part or in whole) from the probability sample contained in the first CD. Dr. Haller did not become involved in the case until approximately two and one-half years after the medical reviews were performed, so he is unable to ascertain when the second CD was compiled. Not only does the second CD not answer the questions raised by the data errors on the first CD, it adds a number of additional questions and additional room for inaccuracies in the sampling and extrapolation process. Provisions in the MPIM requiring detailed documentation of the sampling are intended to prevent problems of this type. *See* MPIM, ch. 3, §§ 3.10.4.4 (requiring documentation of the sampling methodology); 3.10.4.4.1. (requiring documentation of the universe and frame); and 3.10.4.4.3. (requiring documentation of the review and sampling process). Unfortunately, because of a change in staffing, the PSC has not been able to address the apparent discrepancies and uncertainties in the execution of the sampling, and it does not appear that it would be able to do so at this point.

The Council recognizes that problems of this kind can occur, particularly with the turnover of personnel, and when a lengthy period of time elapses between conducting the sampling and the final levels of administrative review. Given the strengths in the design of this audit in a number of respects (discussed below), and the fact that the methodology was fully documented and described by Dr. Moody in a written summary, the Council does not reach the decision to invalidate the extrapolation lightly. However, for the reasons explained above, errors and inaccuracies in executing the probability sample design, particularly in assigning claims to the strata and possibly in drawing the sample, make further errors and inaccuracies in the results of the sample highly likely. In this case, because of the nature and degree of the uncertainty about the sample, and the inability to correct the errors and inaccuracies at this point, the extrapolation is not reliable.

Valid Parts of The Probability Sample Process in This Case

As noted above, the Council does not agree with many of the bases the ALJ identified in his Analysis for invalidating the extrapolation. In fact, the Council agrees with a majority of the points made in the CMS memorandum about the validity of the sampling methodology used in this case. The Council identifies these points in the paragraphs that follow, because they are consistent with the provisions in CMS Ruling 86-1 and the relevant provisions in chapter 3 of the Medicare Program Integrity Manual. Thus, while the extrapolation cannot not be upheld because of the errors and inaccuracies identified above, the Council finds the following:

- The precision estimate of 15.67% in this audit is fully adequate to meet CMS requirements, as set forth in the Medicare Program Integrity Manual. There is no CMS or MPIM requirement for a 10% or lower precision estimate. *See* Exh. MAC-1 at 5-7. In fact, the MPIM's statistical sampling guidelines do not require any specific level of precision, but take into account all factors used in a particular statistical sampling methodology. *Cf.* MPIM, ch.3, §§ 3.10.4.1. (a number of different sampling designs are acceptable); 3.10.4.3. (sample size should be weighed together with other factors involved in sample design). In this case, a 15% precision percentage is reasonably low in comparison to those found in a number of cases the Council has reviewed. Moreover, the guidelines anticipate the assessment of an overpayment at the lower confidence bound of a one-sided 90% confidence interval. *Cf.* MPIM, ch. 3, § 3.10.5.1 (suggesting use of the lower limit of a one-sided 90% confidence interval as a conservative method). Use of the lower bound of a two-sided 90% confidence interval, as used here, is even more conservative and results in an even lower overpayment assessment.

- Additionally, the sampling error (or "coefficient of variation") in this case was computed at less than 10% in the calculations performed on both November 13, 2006, and on January 30, 2007. *See* Exh. MAC-3.[5] This provides an

[5] This eight-page document with additional statistical information on the sampling in this case, was filed at the back of the evidence file, in a section labeled "Non-Probative Correspondence Communication." The Council has made a copy of the document and placed it in the front of the file as Exh. MAC-3.

additional measure of precision in the sample, and further demonstrates that it is within an acceptable range.

- The ALJ appears to have confused or conflated the concepts of confidence interval and sampling precision. Dec. II at 2-3, 9; *see also* Exh. MAC-1 at 6-7. Sampling precision measures the degree of variability within the sample results in relation to the point estimate. The point estimate is the estimated total overpayment based on the single sample. MPIM, ch. 3, § 3.10.5.1, However, the confidence interval is determined by applying various t-values and/or z-values to obtain a desired (pre-selected) confidence interval, e.g. 90% one-sided, 90% two-sided, 95% two-sided, etc. Thus, a two-sided 90% confidence level, as calculated in this case, is not dependent on a particular precision level, because any desired confidence level can be calculated once certain data (e.g., the standard deviation and point estimate) are obtained from the sample results, and a t-value or z-value is selected based on the confidence level sought.

- The Council also disagrees with the ALJ's assessment of Dr. Haller's statements regarding distribution of the sample. The ALJ found that in employing the Central Limit Theorem, the existence of a skew in the sampled overpayment amounts in a single sample provides a reason to invalidate the single sample. *See* Dec. II at 3, 9; Exh. 3 at 4 (Dr. Haller's written testimony). As Mr. Landtroop testified, under the Central Limit Theorem, the issue would be whether *sample averages from multiple samples* are normally distributed, not whether a single sample has normal distribution. ALJ Hearing CD (Nov. 3 , 2010) at 10:20 to 10:21 a.m. According to Mr. Landtroop, in the instant case, where only a single sample was taken and multiple sample averages are not available, there is no basis for invalidating a single sample based on skewness. *Id.; see also* Exh. MAC-1 at 7-8. The relevance of the Central Limit Theorem in this case, as in many of the overpayment cases involving statistical sampling, is that it demonstrates that a single sample of limited size (here, 60 claims) is sufficient to obtain a representative sample, even if the individual sample is skewed rather than normally distributed.

- In addition, insofar as the ALJ relied on Dr. Haller's logarithm adjustment to arrive at a different extrapolation

> amount ("a correct extrapolation that was nearly one-third less," Dec. II at 9), the Council does not use that logarithm adjustment calculation as a basis for instead imposing a lower extrapolated overpayment recovery. Dr. Haller testified that he used natural logarithm transformation to render the overpayment data normally distributed. Exh. 3 at 4. While we note Dr. Haller's extremely strong credentials in statistics and do not question his knowledge in choosing this methodology, the Council has been unable to understand this logarithm process. Moreover, Mr. Landtroop raised some questions as to how certain adjustments for zero and negative numbers were made in this process. *See* ALJ Hearing CD (Nov. 3, 2010) at 10:21 to 10:22 a.m. (B.L. testimony); MAC-1 at 8. In any event, for the reason stated above, the skewed distribution of the single sample would not *per se* invalidate the sampling which was done here.

For all of the reasons stated above, the Council finds that the positions taken in the agency referral memorandum supporting the sampling and extrapolation process in this case were well taken. However, CMS's referral did not address the inaccuracies and uncertainties reflected in the data the PSC provided to the independent expert, which are documented in his written report. Thus, while the CMS memorandum points to methodology issues which the ALJ found to be material errors, the Council finds that many of these were not, in fact, material flaws in the chosen methodology in this case. However, due to errors and discrepancies in the conduct of the sampling and subsequent potential data errors, the Council invalidates the extrapolation which occurs in this case.

DECISION

For these reasons, the Council modifies the ALJ's decision. The Council concurs in the ALJ's decision to invalidate the extrapolation in this case, but for reasons that differ in some manner from the reasons given by the ALJ in his decision. The Council determines that the extrapolation is insufficiently reliable because of shortcomings in the way the samples were drawn or the frames were sorted, and concerns about the PSC's provision of inconsistent data to the independent expert reviewing the sampling without explanation to the statisticians

or to the Council. The appellant remains financially liable only for the overpayments on individual claims in the sample.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair
Departmental Appeals Board

Date: May 12, 2011