I. When Can Statistical Sampling Be Used?

A. Seminal Case:

The seminal case allowing the use of statistical sampling to determine Medicare overpayments is *Chaves County Home Health Servs. v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991):

Though the Medicare Act does not expressly authorize use of statistical sampling to determine overpayments, the Court affords the agency deference in its interpretation of an ambiguous governing statute under *Chevron v. Nat. Res. Def. Council*, 467 U.S. 837 (1984), to conclude that sample adjudication represents a judicially approved procedure that can be reconciled with existing Medicare requirements for case-by-case considering on prepayment review of claims.

The Court acknowledges the use of statistical sampling in other contexts, citing to *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982) (Medicaid); *Michigan Dept of Educ. v. United States*, 875 F.2d 1196 (6th Cir. 1989) (vocational rehabilitation programs).

The Court further finds that absent an explicit provision in the statute that requires individualized claims adjudications for overpayment assessments against providers, the private interest at stake is easily outweighed by the government interest in minimizing administrative burdens. In light of the “fairly low risk of error so long as the extrapolation is made from a representative sample and is statistically significant, the government interest predominates.”

*See also Ratanasen v. Cal. Dept. of Health Servs.*, 11 F.3d 1467 (9th Cir. 1993).

B. Prerequisite Under the Medicare Act, Regulations and Guidance:

The Medicare Act states that a Medicare contractor may not use extrapolation to determine an overpayment unless documented educational intervention has failed to correct the payment error, or there is a sustained or high level of payment error.

“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.”

CMS manuals explain “a sustained or high level of payment error”, as follows:

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 Medical Review (“MR”) unit, Program -Safeguard Contractor (“PSC”), Zone Program Integrity Contractor (“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.


C. Threshold Determination Not Subject to Review:

The Medicare Act, CMS regulations and manual provisions state that the threshold determination made pursuant to 42 U.S.C. § 1395fff(d)(3) is not subject to administrative or judicial review.


“There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.”

2. 42 C.F.R. § 405.926(p):

“Determinations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act” are not “initial determinations” and “are not appealable under this subpart.”
3. MPIM, Ch. 8.4.1.2:¹

“By law, the determination that a sustained or high level of payment error exists is not subject to administrative or judicial review.”

II. Statistical Sampling Methodology:

A. No Generally Accepted Principles of Statistical Sampling:

Though statistical sampling has been upheld in courts as an accepted method of estimating Medicare overpayments, courts have not adopted specific guidelines for sampling methodologies. The Medicare Appeals Council of the Departmental Appeals Board (“MAC”) and federal courts have held that there is no formal recognition of “generally accepted statistical principles and procedures.”

1. MAC Decisions:

Michael King, M.D. and Kinston Medical Specialists, P.A. (Appellant) (Beneficiaries) Cigna Government Services (Contractor) Claim for Part B Benefits, 2011 WL 6960267 (May 10, 2011): 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.’


2. Court Decisions:

Transyd Enterprises, L.L.C. v. Sebelius, 2012 WL 1067561 (S.D. Tex.): Court accepts Medicare contractor’s contention that the Medicaid Program Integrity Manual does not “prescribe sample size, precision, or sampling design, and requires the contractor to consider real-world economic constraints when choosing a sampling methodology.”

Pruchniewski v. Leavitt, 2006 WL 2331071, 8:04-CV-2200-T-23TBM (M.D. Fla): Court notes that supplier’s own expert establishes that the term (generally accepted standards) was his and that there was no discrete body of generally accepted statistical principles at which to look as establishing minimal standards.


The ALJ found the statistical sampling method did not use a valid random sample based on an expert's report. The MAC found that the sample was valid and noted it was required to give substantial deference to manual instructions. District Court found that the MAC's decision was supported by substantial evidence in the record, and that the contractor's statistical sample was valid. "Given the deferential standard of review that this Court must apply, and having carefully reviewed the record and the MAC's determinations, the Court finds that the MAC's decision was supported by substantial evidence."

B. CMS Guidelines:

Statistical sampling has been used by the Medicare program since 1972 as an accepted method of estimating Medicare overpayments in light of the enormous administrative burden of auditing on an individual claim-by-claim basis. Currently, CMS’s statistical sampling and extrapolation methodology guidelines appear in its Medicare Program Integrity Manual (“MPIM”), Pub. 100-08.

1. PIM, Ch. 8.4.1.1 - - General Purpose:

“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 overpayment have been made.”

“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.

2. Basic Requirements:

Regardless of the method of sample selection used, the PSC or ZPIC BI unit or the contractor MR 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 (PIM, Ch. 8.4.2):

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. 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 section. 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.

If a particular probability sample 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.’

3. Major Steps:

a. Selecting the provider or supplier;

b. Selecting the period to be reviewed:

The number of days, weeks, months or years for which sampling units will be reviewed. May depend upon how long the pattern of sustained or high level of payment error is believed to have existed, the volume of claims, etc.

c. Defining the universe, the sampling unit and the sampling frame:

**Sampling units** are the elements that are selected according to the design of the survey and the chosen method of statistical sampling. Possible sampling units may be specific beneficiaries seen by a physician during the time period under review, or claims for a specific item or service.

The **sampling frame** is the listing of all the possible sampling units from which the sample is selected.

d. Designing the sampling plan and selecting the sample:

**Sample design** can be simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these.

Simple random sampling, involves using a random selection method to draw a fixed number of sampling units from the frame without replacement.
Stratified sample 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. Given a sample in which the total frame is covered by non-overlapping strata, if independent probability samples are selected from each of the strat, the design is called stratified sampling.

The size of the sample, or the number of sampling units, has a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. Other factors include: (1) the underlying variation in the target population; (2) the particular sampling method that is employed (simple random, stratified, or cluster sampling); and (3) the particular form of the estimator that is used (such as simple expansion of the sample total by dividing the selection rate, or more complicated methods, such as ratio estimation). It is therefore neither possible, nor desirable, to specify a minimum sample size that applies to all situations.

“As long as proper procedures for the execution of probability sampling have been followed,” a challenge that the sample size is too small ‘is without merit as it fails to take into account all of the other factors that are involved in the sample design.’” While a larger sample size may produce greater prevision, the sample design incorporates the sample’s uncertainty into the overpayment in such a way that the provider will always benefit.

e. Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable;


The Point Estimate, the difference between what was paid and what should have been paid.

Lower-limit of 90% confidence interval shall be used as the amount of overpayment to be demanded in most situations. This procedure incorporates the uncertainty inherent in the sample design and is a conservative method that works to the financial advantage of the provider or supplier. 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.

“A 90% confidence interval means that there is a 10% probability that the true value of the error rate falls outside the confidence interval; or a 5% probability that the true value is greater than the upper limit or bound of the confidence interval, and a 5% probability that it is below the lower limit. Thus, since the disallowance was based on the lower limit of the confidence interval, and not the point estimate, there was a 95% probability that the true value was above the lower limit. In order words, the state was protected with a 95% degree of confidence from having to pay an amount greater than the true value of erroneous payments.”

4. Information Retained:

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

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. 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.

5. A Case Example:

First, the PSC defined the universe of claims as all claims that were submitted between August 1 and December 31 . . . In this case, the sampling units were claims related to a particular beneficiary. The PSC created a sampling frame, or listing, of the beneficiaries' Medicare numbers that were associated with the claims in this universe. The PSC determined that there were 254 beneficiaries within the sampling frame, which corresponded to 1,186 claims and 2,972 billed services, for a total paid amount of $26,658.27.

Before the sample was drawn, the PSC determined the sample size by using a formula from the textbook entitled Sampling Techniques by William G. Cochran, 1977. The sample size calculation is detailed in Attachment I to the PSC’s Sampling Methodology. The calculation resulted in a sample size of 20 beneficiaries.

After determining the sample size, the PSC defined five groups or strata according to the total amount paid to the supplier for services rendered to the beneficiary. In this case, the first strata consisted of the smallest dollar amount of claims paid to the provider. Each subsequent strata consisted of increasing dollar amounts with the fifth strata consisting of the highest dollar amount of claims paid. The number of beneficiaries identified for each of the five strata in the defined universe is defined below:
The PSC divided the 20 beneficiaries equally into the five separate groups or strata. In other words, it allocated four beneficiaries to each of the five strata, rather than a number proportional to the number of claims in the universe for each strata. The PSC’s decision to take a uniform number of beneficiaries from each of the strata allowed for more precision in the strata where the dollar impact of the overpayment calculation would be greatest.

A random sample was chosen from each strata using the RAT-STATS program provided by the Office of the Inspector General. RAT-STATS is the primary statistical audit tool used by the Office of Audit Services. It was developed by the Regional Advanced Techniques Staff (RATS) in San Francisco and has been used by the Office of Inspector General since the early 1970s. The random sample resulting from this process consisted of a total of 20 beneficiaries, with 151 claims for 358 services, totaling $32,597.91 paid to the provider.

For each of the 20 beneficiaries in the sample, the PSC reviewed the supporting documentation provided, such as medical records, and evaluated the appropriateness of the claims and services submitted for payment. Based on the review of these materials, the PSC determined an overpayment amount for each claim in the sample and totaled the overpayments by beneficiary for each strata. The total designated overpayment in the sample for all 20 beneficiaries, also referred to as the actual overpayment is $30,388.34.

To determine the estimated overpayment for the entire universe of claims, the PSC first calculated an average overpayment per beneficiary for each stratum by dividing the designated overpayment in each sample group/strata by the number of sampled beneficiaries in each group/strata.

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**Table:**

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<tr>
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<td>Claims in increasing dollar amount</td>
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<th>2</th>
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<tr>
<td>Designated Overpayment in the Sample Group</td>
<td>$1,145.17</td>
<td>$4,324.35</td>
<td>$5,998.38</td>
<td>$8,275.86</td>
<td>$10,644.58</td>
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</table>

Total Overpayment Amount for Sample: $1,145.17 + $4,324.35 + $5,998.28 + $8,275.86 + $10,644.58 = $30,388.34.
This average per stratum was then multiplied by the total number of beneficiaries in each corresponding stratum. The **designated overpayment for the universe** is the sum across the stratum, or $236,203.97. This is also called the **point estimate**.

While the PSC calculated the designated overpayment for the universe of claims, or a point estimate, to be $236,203.97, the Medicare contractor did not demand that point estimate from the supplier, but a lesser amount based on its calculation of an **interval estimate**, or a range of numbers in which it is most plausible that the true overpayment amount is contained (or a range of true possible overpayment amounts in the universe). An interval estimate is reported with a **confidence level** to indicate the level of certainty that the reported interval contains the true overpayment amount.

The PSC calculated a two-sided 95% confidence level, which meant that the PSC was **95% certain that the overpayment amount was within the upper and lower limits**, or between $262,204.43 and $210,203.59, respectively.
<table>
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<th>95% Two-Sided Confidence Interval</th>
<th>Possibility that Overpayment is Less than Lower Bound of Two-Sided Confidence Interval</th>
<th>Possibility that Overpayment is Between Upper and Lower Bounds of Two-Sided Confidence Interval</th>
<th>Possibility that Overpayment is Greater than Upper Bound of Two-Sided Confidence Interval</th>
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<tr>
<td>2 ½%</td>
<td>95%</td>
<td>2 ½%</td>
<td></td>
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</table>

The PSC then reduced the overpayment from $236,203.97 to the lower bound of the 95% confidence interval, or $210,203.59. Stated another way, there is a 97 ½% certainty that the actual overpayment is greater than the $210,203.59 demanded.

### III. Other Applicable Legal Authorities:

#### A. Supplier/Provider Bears Burden of Providing Sufficient Information:

42 U.S.C. § 1395l(e):

“No payment shall be made 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 such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.”

42 C.F.R. § 424.5(a)(6): Sufficient Information:

“The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.”

#### B. Binding Nature of Policies/Rulings:

The following regulatory provisions address the binding nature of statutory and regulatory provisions and CMS Rulings vs. CMS guidelines set forth in manual provisions:

42 C.F.R. § 405.1063:

“All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and the MAC”. 42 C.F.R. § 405.1063(a).

“CMS Rulings are published under the authority of the Administrator, CMS. Consistent with 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS”. 42 C.F.R. § 405.1063(b).
42 C.F.R. § 405.1062(a):

“ALJs and the MAC are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda, and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.”

C. Limitation on and Waiver of Liability:

Section 1879 of the Medicare statute, or 42 U.S.C. § 1395pp, establishes limitation on liability where a determination is made that the services at issue were not ‘reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,’ or where the services in question are determined to be ‘custodial care.’ 42 U.S.C. § 1395pp(a)(1); 42 U.S.C. §§ 1395y(a)(1), (9).

Section 1870(b) of the Act, 42 U.S.C. § 1395gg(b), and the MFMM allows for a rebuttable presumption that providers are ‘without fault’ for overpayments discovered more than three calendar years after the year in which the initial determination was made. MFMM, Ch. 3, Sec. 70.3. A provider shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary’s overpayment determination was made subsequent to the third year following the year in which notice of the payment was sent, although the Secretary can reduce the three-year time period to not less than a year if she finds such reduction is consistent with the purposes of the Medicare statute.

CMS has issued regulations and guidance explaining that a provider can be expected to know that services are excluded from coverage because of CMS notices, including manual issuances, bulletins, or other written guides or directives from contractors. 42 C.F.R. § 411.406(e); see also Medicare Financial Management Manual (“MFMM”), Pub. 110-6, Ch. 3, Sec. 90, Provider’s Liability (provider’s allegations that it was not aware of the Medicare coverage provisions is not a basis for finding it without fault); Medicare Claims Processing Manual (“MCPM”), Pub. 100-04, Ch. 30, Secs. 20, 30, 40.2, 110.2, 120 (waiver of liability not available when a physician is expected to know that certain services are excluded from coverage when local policies have been published).

D. Right to Collect Overpayment:

42 U.S.C. § 1395gg(b) authorizes the Secretary to recoup from a provider or supplier ‘if more than the correct amount has been paid.’

42 C.F.R. § 405.371 allows an intermediary or carrier to offset or recoup, in whole or in part, Medicare payments to providers and suppliers if the intermediary, carrier or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid. See also 42 C.F.R. § 405.373 (Proceeding for Offset or Recoupment); 42 C.F.R. § 405.379 (Limitations to Recoupment).

42 C.F.R. § 405.370 defines recoupment as the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. Offset is defined as the recovery by Medicare of a non-
Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

E. Administrative Appeals Process:

42 C.F.R. Part 405 Subpart I sets forth the administrative review process. A provider or supplier may appeal an ‘initial determination,’ which is defined to include a Medicare Part B overpayment determination, and a determination of liability. 42 U.S.C. § 1395ff(a)(1)(B); 42 C.F.R. §§ 405.924(b)(12), (13).

The first step in the administrative review process is a redetermination, or an independent review of the initial determination. 42 C.F.R. §§ 405.940, 405.948. Following the contractor’s redetermination, a party may request reconsideration by a Qualified Independent Contractor (“QIC”) pursuant to 42 C.F.R. § 405.904. A party that is dissatisfied with a QIC’s reconsideration may then request an ALJ hearing, if the amount remaining in controversy and other requirements for an ALJ hearing are met. 42 C.F.R. § 405.1000. The ALJ must issue a notice of hearing pursuant to 42 C.F.R. §§ 405.1020(c) and 405.1022.

In 2005, CMS amended its regulations to specify the procedures applicable to ALJ hearings of Medicare appeals that explicitly permitted CMS or its contractor, for the first time, to participate in the ALJ proceeding, or be a party to such proceeding where “input from CMS or a contractor will help resolve an issue in a case.” 70 Fed. Reg 11420, 11459 (Interim Final Rule) (Mar. 8, 2005). Participation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but is distinct from full party status, which includes the right to call witnesses, or to cross-examine the witnesses of the appellant or another party to the hearing. Id.; 42 C.F.R. §§ 405.1010, 405.1012.

A party to the ALJ hearing may submit a request for review of the ALJ’s decision by the Medicare Appeals Council (“MAC”) of the Departmental Appeals Board (“DAB”). 42 C.F.R. §§ 405.1100, 405.1102. In addition, the MAC may, on its own motion, review the decision of the ALJ if the decision contains an error of law material to the outcome of the claim and is not supported by the preponderance of evidence in the record pursuant to 42 C.F.R. § 405.1110. CMS or any of its contractors may refer a case to the MAC if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS or its contractor may also request that the MAC take own motion review of a case if CMS or its contractor participated in the appeal at the ALJ level; and in CMS’s view, the ALJ’s decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion. 42 C.F.R. § 405.1110(b).

To the extent authorized by 42 U.S.C. § 1395ff, a party to a MAC decision may obtain judicial review, if the amount remaining in controversy satisfies the requirements of 42 C.F.R. § 405.1006(c). 42 C.F.R. § 405.1136. A party seeking judicial review may file a civil action in accordance with the provisions of 42 U.S.C. § 405(g), which specifies that the Secretary’s findings of fact, if supported by substantial evidence, are conclusive. 42 C.F.R. § 405.1136(f).

F. ALJ Review of Entire Statistical Sample Used by QIC:

42 C.F.R. § 405.1064:
“When an appeal from the QIC involves an overpayment issue and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of the entire statistical sample used by the QIC.”

IV. **Challenges to Statistical Sampling and Extrapolation Methodology:**

A. **Burden of Proof:**

Provider/suppliers have often made general challenges to the statistical sampling and extrapolation. However, to prevail, the provider/supplier must set forth specific arguments that demonstrate that the flaws in the methodology were so significant as to render the overpayment arbitrary and capricious. The MAC has repeatedly acknowledged CMS Ruling 86-1, which states that 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 then goes on to state that ‘the burden then shifts to the provider to take the next step.’ Therefore, the MAC has held that 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.

1. **MAC Decisions:**


   The council agreeing with the ALJ’s finding that the statistical sampling and extrapolation was valid. The sampling study report must show that the sampling variability is not too large. This is shown by attaining a level of estimated relative value error that is under a given tolerance level.


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 calculation based on that methodology. Rather, the test is whether the methodology is statistically valid. Appellant’s challenges to the sample are not based on demonstrable errors in the sample or reference to specific supporting evidence in the record.

Diana Carneal, OTR, D/B/A The Muscle Manager (Appellant) (Beneficiary)
Western Integrity Center (PSC) (Contractor) Claim for Part B Benefits, 2010 WL 7209424, Docket No. M-10-1860 (Nov. 18, 2010):
ALJ erred as a matter of law in finding the PSC’s sampling methodology and overpayment extrapolation invalid in that appellant failed to prove that the methodology employed by the PSC was invalid. CMS’s argument that the ALJ erred by placing the burden on the Medicare contractor to demonstrate that its stratification model did not result in overestimation of the amount owed are “well-founded.”

Border Ambulance Service, LLC (Appellant) (Beneficiaries)
Appellant’s challenges to the sample are not based on demonstrable errors in the sample or reference to specific supporting evidence in the record. Rather, the appellant’s arguments are based upon the testimony of its statistical expert and its cross examination of the PSC’s statistical expert. The appellant’s speculative assertions do not satisfy its burden of proving that the statistical sampling methodology at issue is invalid.

Transyd Enterprises LLC D/B/A Transpro Medical Transport (Appellant) (Beneficiaries)
ALJ erred in finding that extrapolated overpayment was invalid because the PSC failed to establish that its methodology was appropriate to the population of the appellant’s claim, specifically because the PSC did not explain why it had not undertaken stratified sampling. Council agrees with CMS’s argument that ALJ erred in placing the burden of proof on the PSC to explain why it did not use a different sampling methodology.

2. Court Decisions:


B. Due Process:

Beginning with the 1991 D.C. Circuit Court of Appeals decision in Chaves, the argument that statistical sampling and extrapolation constitutes a violation of the provider/supplier’s due process rights have been consistently rejected. DAB and court decisions have held that the government’s interest in ensuring that the Medicare funds are
adequately protected against erroneous payments outweighs the provider/supplier’s interest in an administratively burdensome claim-by-claim review.

1. MAC Decisions:

The appeals process affords Appellants the right to due process because they get the opportunity to review the initial determination, including the validity of the sampling, the use of the sample in the extrapolation.

ALJ erred in finding supplier’s due process rights were violated when ZPIC did not provide timely notice of the results of the audit. Not only is the 60-day notice provision in MPIM inapplicable to the review, but the assertion of a due process violation also assumes the existence of a property interest, and there is no property interest in retaining overpayments. Appellant received sufficient notice of the overpayment and has had ample opportunity to respond through the appeals process. Once sufficient process is afforded to ensure that appellant had a full and fair opportunity to correct contractor or agency error, then due process has been provided.

Appellant asserts broad, but undefined, due process challenge under the 14th Amendment. Council affirms ALJ’s finding that statistical sampling and extrapolation are valid.

Appellant failed to identify any authority for the proposition that it had a due process right or any other right to prior notice of OIG audit methodologies generally, or the OIG’s extrapolation standards in particular. Appellant has not identified any basis for concluding that it was adversely affected or prejudiced by lack of notice about the OIG policy.

2. Court Decisions:

There was no due process violation because Transyd was given the opportunity to challenge the extrapolation and sampling method initially and the Secretary used the same methodology to recalculate the extrapolated overpayment amount.
In addition, Transyd had the opportunity to reopen the matter if there were any mathematical or computation errors. As such, Transyd was not denied due process.

Failure to follow PIM guidelines is not a basis for setting aside a statistical sample or extrapolation: an appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and collected. Moreover, the failure to follow the PIM guidelines does not constitute a per se deprivation of a substantive due process right because the PIM is not a set of mandatory regulations.

Government’s interest in administering the Medicare program or the risk of error outweighs Dr. Bend’s private interest, justifying use of statistical sampling regardless of whether payment is made for chiropractic services or other health care services. Appellant also failed to demonstrate that she was deprived of an opportunity to be heard at a meaningful time and manner due to the insistence of the ALJ to discontinue oral argument and testimony.


Plaintiff argues that sampling was arbitrary, capricious and unreliable because it did not comport with CMS’s guidelines, which establish a minimal due process standard applicable to all carriers who calculate overpayments through the use of statistical sampling and extrapolation. Court finds that while CMS’s guidelines and the expert’s generally accepted principles offer guidance for an acceptable method of statistical sampling in overpayment cases, neither established a legal or constitutional minimum above which the carrier had to operate.

Ratanasen v. State of California, 11 F.3d 1467 (9th Cir. 1993).

Daytona Beach General Hospital, Inc. v. Weinberger, 435 F.Supp. 891, Medicare and Medicaid Guide (CCH) ¶ 28,619 (M.D. Fla. 1977): Sampling method whereby less than ten percent of the total cases were used denied plaintiff due process.

C. Threshold Determination:

Since the enactment of 42 U.S.C. § 1395ddd(f)(3), provider/suppliers have often argued that the Medicare contractor did not make the requisite showing of educational efforts or high payment error prior to extrapolation. The MAC and federal courts have been inconsistent in their treatment of this threshold requirement. While several decisions have noted that this
determination is not subject to judicial or administrative review, others have examined whether such determination was made in any event.

1. MAC Decisions:


Council upholding the ALJ’s finding that the contractor documented a high level of payment error at the outset of its review, which justified the use of extrapolation. The Council did not have the jurisdiction to review this determination.


PSC’s determination that a high or sustained payment error exists is a final determination not subject to administrative review.


ALJ had no authority under Section 1893(f)(3) of the Act to review the Secretary’s (or, by extension, a contractor’s) decision to undertake statistical sampling and extrapolation, based on a sustained or high level of payment error. ALJ erred in considering whether the PSC found a sustained or high level of payment error, and Council does not agree with ALJ’s decision insofar as it seems to suggest that the PSC did not provide the appellant with sufficient notice of its finding that a high error rate existed. Neither Section 1893(f)(3) of the Act nor the MPIM establishes a notice or documentation requirement that a sustained or high level of payment error exists.


Neither the ALJ, nor the Council, may review any aspect of a contractor’s determination that a sustained or high payment error rate exists, which extends to the contractor’s decision to perform extrapolation.


Section 1893(f)(3) of the Act states that determinations of sustained or high payment error rates by the Secretary are not reviewable in the administrative process, but the Council is not precluded from examining the record to
determine whether this determination as in fact made. Council finds that the
record contains sufficient documentation to demonstrate that the Secretary,
through a Medicare contractor, made a determination of a sustained or high level
of payment error, thus permitting the use of extrapolation to determine the
overpayment amount. The fact that the Initial Notice of Overpayment does not
contain a formulaic statement that ‘we have determined a sustained or high level
of payment error’ does not negate the determination documented.

Place for Achieving Total Health (Appellant) (Beneficiary) National
Government Services (Contractor) Claim for Part B Benefits, 2010 WL

John Shimko, DPM D/B/A Lakeside Foot Clinic (Appellant) (Beneficiaries)
CIGNA Government Services (Contractor) Claim for Part B Benefits, 2009 WL
5764286 (Oct. 15, 2009).

Cabarrus Podiatry Clinic (Appellant) (Beneficiaries) Claim for Part B Benefits,
ALJ Appeal No. 1-127356701 (Dec. 14, 2007): MAC holds that neither CMS
nor the contractor made the requisite determination pursuant to Section
1893(f)(3) in the first instance and declines to review the ALJ decision,
reversing the overpayment estimation.

In the Case of Bruce McLeod, D.C. (Appellant) (Beneficiary) Wisconsin
Physician Services Insurance Corp (Contractor) Claim for Part B Benefits, 2013
WL 7135022 Docket No. M-13-204 (January 11, 2013). The determination that
a high level of payment error exists is not in and of itself subject to being
appealed.

2. Court Decisions:

determination of a sustained or high level of payment error is not subject to
administrative or judicial review.”

Court upholds the notion that the Secretary can delegate her authority to
determine that a “sustained or high level of payment error” exists to the
Contractor. This authority is granted pursuant to 42 U.S.C. § 1395kk(a) which
allows the Secretary to subdelegate her functions under the relevant subchapter.

Court finds that the Secretary, by delegation of her authority, made a
determination after examining the data analysis and/or other evidence that there
was a high level of payment error for plaintiff.

Artex Medical v. Sebelius, Civil Action No. 5:10-CV-84-DF (E.D. TX.), Order
of District Court dated April 18, 2011: Section 1893(f) directs that “[t]here shall
be no administrative or judicial review . . . of determinations by the Secretary of sustained or high levels of payment errors.” But even upon review for substantial evidence, the initial determination of a 100 percent error rate, or alternatively, the error rate remaining after ALJ review is sufficient evidence to support the MAC’s finding that the use of extrapolation was a reasonable, implicit finding of a high level of payment error.

D. Sample Size:

Sample size is addressed in CMS manual provisions, and the MAC and federal courts have accepted CMS’s position that while sample size may affect the precision of the overpayment, there are other factors that must be considered, including “real world economic constraints” of the Medicare contractor’s available resources, and the fact that sampling is used “when it is not administratively feasible to review every sampling unit in the target population when determining the sample size to be used.” Applicable decisions have also noted the use of confidence intervals to account for any potential imprecision resulting from a smaller sample size.

1. MAC Decisions:


Stating that, "given MPIM provisions, the fact that AdvanceMed selected a sampling methodology or sample size that another statistician may not prefer, or which may not result in the most precise point estimate, does not provide a basis for invalidating the sampling or the extrapolation as drawn and conducted in this case. These are simply not 'flaws' in the sampling cognizable by the guidelines which render the actual sample drawn invalid."

Further stating, "To hold otherwise would ignore real world constraints imposed by conflicting demands on limited public funds, constraints which CMS chose to incorporate into the statistical sampling guidelines."


Stating that the fact that the contractor selected a sample size that “another statistician may not prefer or which may not result in the most precise point estimate, does not provide a basis for invalidating the sampling or extrapolation as drawn and conducted in this case.” Upheld on appeal to the Third Circuit (2014 WL 542262).
ALJ erred in finding that the sample size of 30 appears to be arbitrary, rather than based on some logical method ensured to result in accuracy.

In the Case of Transyd Enterprises LLC D/B/A Transpro Medical Transport (Appellant) (Beneficiaries) Trailblazer Health Enterprises LLC (Contractor) Claim for Part B Benefits, 2009 WL 5764287 (Sept. 15, 2009):
MPIM does not prescribe a particular sample size.


3. Court Cases:

The Center appealed the ZPIC finding of an overpayment on the basis of the extrapolation from the actual overpayment. The extrapolation included individual beneficiaries that may have had multiple claims for similar services, resulting in a “correlation” that may have skewed the sample. The ZPIC, Wisconsin Physicians Services, conducted a post-payment medical review of chiropractic claims furnished to Medicare beneficiaries. The review used a sampling of 214 claims out of 5,098 services billed. The ZPIC concluded there was a 99.55 percent error rate with an actual overpayment of $11,376.13. Using that data, it then projected a total overpayment of $126,041.31. The Center appealed the alleged overpayment amount arguing a larger sample of claims or samples from a large number of beneficiaries would have resulted in a more accurate result. The ZPIC reaffirmed in a redetermination that used the same statistical sampling method. The ALJ found the sampling method, extrapolation and results were unreliable. The MAC (in a de novo review) found that the method was valid and noted it was required to give substantial deference to manual instructions. The District Court found the ALJ’s method to be thorough and well-reason. But, the Court cited the seminal case on the issue, Chaves, in holding that the sampling method was valid. Schuldt did not present evidence that a different random sample would have yielded a lower rate of denials or a more accurate estimate. The court noted it might have had a different outcome if the review had been de novo.

The court upheld the MAC and ALJ’s decisions that the determination based on a sample of 30 claims was enough to show substantial evidence of overpayment. The PIM does not specify the “precision level” that was required when selecting samples.
Supplier’s expert contends that carrier was obligated to sample a minimum of 320 beneficiaries, but expert did not introduce any empirical findings to support his opinion that the sample size of 30 was too small to be reliable, or that a sample of 320 would have produced an estimated overpayment that was below the lower limit of the 90% confidence level calculated by the carrier. Court stated that plaintiff’s complaint regarding the sampling size is “problematic,” and “if the standard of review was different and a better showing had been made, perhaps I would recommend a different result.” Court was troubled by the “one size fits all” approach insofar as it always employed a sample size of 30 regardless of the size of the sampling universe. However, the court stated that it “must conclude that the ALJ’s decision was not contrary to applicable standards,” as neither the CMS guidelines nor the expert’s generally accepted principles were binding on the carrier or established a due process minimum and precedent has rejected the statistical ‘floor’ argument in relation to sample size.

There is no statistical floor for sample size.

Ratanasen v. State of California, 11 F.3d 1467 (9th Cir. 1993):
There is no statistical floor which auditors must exceed in order to guarantee providers due process. Sample of 3.4% of the population exceeds that of the sample in Michigan Dept of Educ., 875 F.2d 1196 (6th Cir. 1989), where a random, stratified sample of 0.4% was used as a starting point for determining improper expenditures.


E. Precision of Overpayment:

Both the MAC and federal courts have been reluctant to set aside a statistical sampling and extrapolation in response to a supplier/provider’s claim that the overpayment was imprecise in the absence of a showing that the imprecision rendered the overpayment arbitrary and capricious, particularly in those cases wherein the demand amount is the lower limit of a confidence interval.

1. MAC Decisions:

"the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the contractors to assess the overpayment at the lower level of a confidence interval."
The MPIM lists several factors that account for the precision rate of a particular sample including sample size, underlying variation in the population, type of sampling method used and the particular type of estimator used (e.g. simple expansion, ratio estimation).

The fact that the overall precision rate in the stratified statistical sample, as drawn and conducted in this case, is 22.23%, is relevant in relationship to the ‘confidence interval’ in which the estimated overpayment falls, not the validity of the sample drawn and conducted. Appellant provides no argument or factual support for the idea that a lower precision rate would result in a lower overpayment amount demanded (and in fact, would undoubtedly result in a higher overpayment when assessed at the lower confidence level).


Guidance found in MPIM does not require a specific level of sampling precision.

Appellant has not demonstrated that the alleged imprecision in the sample and extrapolation invalidates the sampling or resulting overpayment calculation. This is the burden that an appellant is required to meet when challenging a Medicare audit. Appellant’s position is that a statistical sampling design must result in a highly precise point estimate, and/or otherwise be ‘textbook perfect,’ but the Council does not agree.

Transyd Enterprises LLC D/B/A Transpro Medical Transport (Appellant) (Beneficiaries) Trailblazer Health Enterprises LLC (Contractor) Claim for Part B Benefits, 2009 WL 5764287 (Sept. 15, 2009):
MPIM does not prescribe a particular precision.

2. Court Decisions:

Provider sought judicial review of an overpayment in the amount of $90,628. Overpayment was upheld upon redetermination; QIC also upheld reconsideration that included a forensic analysis of the determination. ALJ held that some of the claims actually satisfied Medicare's coverage requirements (meaning no overpayment was issued) and found the statistical sample used was invalid. "The extrapolation of overpayment to the universal set of claims exceeds the total amount paid to the Appellant by Medicare for said claims" and therefore the sample was not valid. If the sample is not valid; it cannot be extrapolated. Overpayment would need to be calculated on a claim by claim basis. MAC: CMS asserted the ALJ committed an error of law material to the outcome of the claim by invalidating the statistical sample. MAC found the Plaintiff had not satisfied its burden under Ruling 86-1 to demonstrate the statistical sampling method was invalid. MAC found the error was in the PSC's "point estimate" rather than in its sampling methodology – revised actual overpayment should be extrapolated to the universe of claims. MAC agreed with CMS that the error of assessing the estimated overpayment rather than the actual overpayment was moot since some of the sampled claims were properly paid.

District Court Holding: Upheld the MAC's determination; MAC was well within its jurisdictional authority to review the case on its own motion because it concluded the ALJ had committed an error of law. Court held plaintiff failed to meet its burden to demonstrate sampling method was invalid; the MAC "laboriously" explained why the ALJ's determination relied on misapplication of program law and guidelines


Plaintiff’s expert argued that CoV of 11.38% exceeded the 8% tolerance level recommended by other statisticians. Court held that because there is no established standard of precision for this type sampling, the ALJ was correct in concluding that providers like plaintiff must “go further and establish that the degree of imprecision is such that the extrapolation does not reasonably approach the actual overpayment, that is, it is so imprecise as to be arbitrary and capricious.” Also, while CoV was higher than some experts might consider optimal, the carrier compensated for this by adjusting the estimated overpayment downward in a manner favorable to plaintiff. Nothing prevented plaintiff from showing an error in the carrier’s calculations, or demonstrating through his own, more reliable sampling method, an estimated overpayment that was less than the lower limit of the 90% confidence interval calculated by the carrier.

F. Representativeness of Sample:

A common argument is that the sample is not representative of the universe. The MAC and federal courts have not been persuaded by this argument absent a showing that the lack of representation adversely affected the provider/supplier.
1. MAC Decisions:

"… the relevance of the Central Limit Theorem (CLT) in this case, as in many of the overpayment cases before the Council involving statistical sampling, is that it demonstrates that a single sample of an adequate (but finite) size is sufficient to obtain a representative sample even if the overpayments in the sample are not normally distributed."


Presence of ‘outlier claim’ in the sample results in looser precision but does not invalidate the sample, and there was no evidence that the claim was not selected randomly.

Supplier’s expert asserted that the Medicare contractor could have shown that the sample it was used was statistically valid by initiating a ‘comparison of sample and population measure, such as an average amount paid.’ Council notes that the appellant does not argue that the statistical sample was not representative, but rather that the PSC failed to show that the sample was indeed representative.

2. Court Decisions:

Anghel v. Sebelius, 912 F. Suppl. 2d 4 (E.D.N.Y. 2012). Substantial evidence supported the Secretary’s determination that the provider was overpaid. “The random nature of the claims that were chosen was done using an established software program entitled RATSTATS. This methodology demonstrates that the sample was drawn as representative of the universe of claims.”
Supplier’s expert argued that sample was not representative because the average payment in the sample was 70% higher than the payment in the universe. While the Court stated that the expert’s “simple test for the representativeness of this sample is . . . interesting,” plaintiff “does not demonstrate that it dictates a decision that the sample was unrepresentative. Testimony was also contradicted by a data consultant for the Medicare contractor, who found a “close correlation between the respective averages.” Noting that it is for the ALJ and not the court to weigh the evidence and resolve conflicts therein, the court concluded that it was “obliged to conclude that there is substantial evidence to support the ALJ’s conclusions.”

G. Randomness of Sample:

The MAC and federal courts have been responsive to CMS’s argument that the sample was random because it was drawn using the RAT-STATS program developed by the Office of Inspector General.

1. MAC Decisions:

Appellant failed to meet burden of proof in arguing that the two strata samples used were not statistically independent by submitting advanced mathematical calculations in support. Stating that, "As the MPIM 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."

2. Court Decisions:


Software used to generate the random sample was commercially available and known to plaintiff’s expert; there was no testimony that it was an unreliable means for selecting a random sample.
H. Documentation Provided:

The MAC has set aside and/or remanded extrapolations if there is insufficient documentation provided by CMS and/or the contractor that does not allow the provider/supplier to recreate the methodology.

1. MAC Decisions:

The Council remanded the case to the ALJ to fully address the statistical sampling methodology and extrapolation of this case. The record did not contain complete documentation related to statistical sampling and extrapolation prepared or issued by the PSC. The Council instructed the ALJ to take appropriate action necessary to ensure that the record includes complete documentation concerning the statistical sampling and extrapolation.

DAB issued a remand to the ALJ for a new decision with instruction to review all documents or records used by the Appellant’s expert and to include such documents in the record. The ALJ did not proffer to the appellant the actual CD with statistical sampling information that was prepared by the contractor.

DAB cannot review the ALJ’s rulings on sampling and extrapolation methodology because the CDs containing this information are missing and/or inaccessible.

ALJ did not err in setting aside extrapolation of overpayment when CMS or its contractors have not produced documentation necessary to recreate the sampling frame. DAB also finds that contractors had adequate notice that statistical sampling and extrapolation were at issue in this case.

The Council finds ALJ did not err in refusing to order Medicare contractor to disclose documents relating to the qualifications of the contractor’s statistician or the ‘alleged nurse’ who conducted the medical review. ALJ also did not err
in declining to grant request for subpoenas for medical records and witnesses, as issuance of subpoenas is discretionary, and ALJ determined that appellant had not demonstrated that these judicial orders were necessary for the full presentation of the appellant’s case pursuant to 42 C.F.R. §§ 405.1036(f) and 405.1037.

Council notes that none of the records referenced by the Medicare contractor or the QIC pertaining to the statistical sample is in the current record. Council is unable to proceed with its review of the statistical sample based on the current state of the record and remands for supplementary proceedings.

2. Court Decisions:

Anghel v. Sebelius, 921 F. Supp. 2d 4 (E.D.N.Y. 2012). ALJ not required to consider the provider’s expert if the expert’s opinion is based on evidence not in the administrative record.

Supplier’s expert complained of lack of documentation, but the mere failure of the carrier to have all of the documents plaintiff inquired about does not equate to a due process violation, nor is it grounds to invalidate the sampling method of its conclusions. Court also concludes that there was adequate documentation and information available to the plaintiff to test the reliability of the audit, had he chosen to do so. Plaintiff’s expert acknowledged that he never attempted to recreate the audit or otherwise validate or invalidate it through his own methods, and plaintiff failed to demonstrate the lack of any particular documentation that deprived him of a fair opportunity to independently assess the reliability of the sampling method or attack it.

I. Stratification:

Provider/suppliers have often argued that the sample should have been stratified, pointing to CMS manual provisions that state that stratification often results in more precision in the overpayment. However, the fact that stratification may result in more precision has not swayed the MAC and federal courts in most cases absent a showing that stratification would have affected the demand amount.

1. MAC Decisions:

The fact that another sample size or stratification would have been more precise is not considered a “flaw” in the sampling to render it invalid.


Transyd Enterprises LLC D/B/A Transpro Medical Transport (Appellant) (Beneficiaries) Trailblazer Health Enterprises LLC (Contractor) Claim for Part B Benefits, 2009 WL 5764287 (Sept. 15, 2009):
ALJ erred in finding extrapolation invalid in part because of PSC’s failure to explain why it did not undertake stratified sampling, improperly shifting the burden of proof onto the PSC. MPIM does not specify any particular sampling design, but notes that any sample design that results in a probability sample, including simple random sampling, systematic sampling, stratified sampling, or cluster sampling, is appropriate.

CMS objects to ALJ’s decision, which upheld the sampling methodology as valid but directed the contractor to recalculate the overpayment to reflect his favorable coverage determinations, by using two different methodologies and applying the result most favorable to appellant. Given that contractor voluntarily changed methodologies during the appeals process, undoubtedly requiring more work and expense for the appellant and its statistical expert in order to address both methodologies, Council finds it is reasonable to require the contractor to again use both methodologies in implementing this decision. Council states that CMS has no obligation to recalculate using any more than the two methodologies already applied (expansion estimation without stratification, and ratio estimation without stratification).

Appellant fails to explain any basis for concluding that the OIG’s use of a simple sample was methodologically unsound, fails to identify which of the overlapping variables that it lists (such as year, clinic, age, sex) should have been used to stratify the sample, and fails to explain how stratification by any particular variable would be relevant to the purpose of the audit. Appellant offered no basis for concluding that a stratified sample would have resulted in a smaller disallowance. Even if stratification may have resulted in a more precise point estimate and narrower confidence interval, the method for calculating the confidence interval effectively takes into account the lack of stratification. The Board has repeatedly determined that the use of the lower limit of a two-sided
90% confidence interval results in reliable evidence of the amount of unallowable costs charged to federal funds.

2. Court Decisions:

Miniet v. Sebelius, WL 2930746, 10-24127-CIV, 2012 (S.D. Fla. 2012): The Court upheld the decision made by the DAB regarding validity of the stratified sampling methodology. The Court asserted that just because a contractor did not conduct the sampling in the most optimal way did not mean that the methodology was invalid. In order to account for statistically valid overpayment calculation, the contractor used a ninety-five percent confidence interval and reducing its overpayment estimate to the lower bound of the confidence interval.

Pruchniewski v. Leavitt, 2006 WL 2331071, 8:04-CV-2200-T-23TBM (M.D. Fla. Aug. 10, 2006): Selection of five stratum was neither arbitrary nor without justification, was supported by a study by Richard Leavenworth, Ph.D. and CMS’s manual, which permits carriers to use either a simple random sample or a stratified random sample, and approves the use of a stratum of five or six. Court states that “there was again no demonstration by plaintiff that a different stratification would have made a significant difference in the overpayment estimation.”

Ratanasen v. State of California, 11 F.3d 1467 (9th Cir. 1993).

J. Non-Sampling Errors:

1. MAC Decisions:


Appellant argues that PSC’s alleged error in effectuating the ALJ’s decision constitutes a non-sampling error which should invalidate the extrapolation. However, Council rejects argument, stating it is not aware of any authority that would invalidate the extrapolation itself based on alleged contractor error in effectuating a decision. Council also notes that pursuant to 42 C.F.R. § 405.1046(c), the amount of payment determined by the contractor in effectuating the ALJ’s decision is a new initial determination under § 405.924 and that appellant has not sought review of the PSC’s recalculation through the established administrative process.
Council rejects claim that PSC’s failure to have an independent review of the computer program used for the statistical sampling calculations is an error that renders the sampling unreliable. Council also notes that the MPIM specifically identifies the RAT-STATS program as a ‘reputable software statistical package.’

2. Court Decisions:


K. Procedural Issues:

MAC Decisions:

Council rejects CMS’s contention that ALJ did not provide adequate notice of the hearing, as he did not notify the PSC of the hearing and the notice did not specify that the statistical sampling methodology would be an issue at the hearing but finds that ALJ erred in not providing notice of the pre-hearing conference. 42 C.F.R. § 405.1020(c)(1). ALJ also failed to develop a full and fair record, and failed to provide any meaningful analysis or specific reasons for his decision, as required by 42 C.F.R. § 405.1046(b).

Appellant argues that it did not have an opportunity to cross-examine PSC witness, but Council notes that Dr. Landroop did not appear as a “fact witness,” but as a non-party participant to clarify issues for the court, pursuant to 42 C.F.R. § 405.1010(c). MAC also states that there is no absolute right to cross-examination of contractor, non-party participant during a non-adversarial administrative hearing.

Council not persuaded by appellant’s contention that overpayment should be overturned because the contractor has continually failed to accurately set forth the statistical sample or the extrapolated amount and has failed to appear, or otherwise present admissible evidence at any of the hearings concerning the alleged overpayment. CMS’s regulations provide that ALJ may not require CMS or a contractor to enter a case as a party or as a participant. 42 C.F.R. §§ 405.1010, 405.1012. In this case, the ALJ sent a copy of the Notice of Hearing to the contractor. The fact that the contractor did not participate in the hearing is not a basis for reversing the overpayment determination.
None of the Notices or Amended Notice of Hearing was addressed to the Medicare contractor. Remand for further proceedings is required to allow the applicable contractors the opportunity to participate.

Council rejects Appellant’s argument that it was denied a meaningful opportunity for a live (in-person) hearing, noting that 42 C.F.R. § 405.1020(b) does not identify any circumstance in which the ALJ is required to hold an in-person hearing. The regulation establishes that the ALJ may determine that an in-person hearing should be conducted if the video teleconferencing technology is not available or special or extraordinary circumstances exist.

Council finds that additional ALJ action is required on remand because CMS or its contractor was not afforded an opportunity to participate in a hearing and the ALJ did not make a complete record of the evidence pursuant to 42 C.F.R. § 405.1042. File does not contain a notice of hearing. The ALJ’s failure to issue a notice consistent with 42 C.F.R. §§ 405.1020(c) and 405.1022 constitutes a material error of law pursuant to 42 C.F.R. §§ 405.1110(c) and (d).

Council reverses and remand ALJ’s decision wherein ALJ states in the decision that the PSC was not present at the hearing to defend the statistical sampling. Although there appears to be flaws in the sampling methodology to make the sampling invalid, the ALJ finds that it is “barred” from reviewing the determination.

L. Limitation on Liability/Waiver of Recovery:

MAC Decisions:

DAB notes that the Appellant liability cannot be waived because the applicable local coverage determinations were in place at the time of the overpayment. As such, the Appellant could not assert waiver of liability under Section 1870(b) of the Social Security Act.
Council notes that there is a “higher, more exacting standard for obtaining a Section 1870(b) waiver than simply showing that the provider did not intentionally or negligently take action (or inactions) that resulted in the overpayment.” Also, Section 1870(b)’s rebuttal presumption is not based on the date of service but the date of payment, which may be long after the date of service.

Technical denials based on Section 1861(s)(7) of the Act (when CMS denies coverage because transportation by other means is not contraindicated or because the regulatory criteria, such as those relating to destination or nearest appropriate facility, are not met, the denial is classified as a ‘technical denial’), the limitation of liability provisions of Section 1879 of the Act does not apply. Appellant is not entitled to waiver of Medicare’s overpayment recovery pursuant to Section 1870(b) of the Act because a provider participating in the Medicare program is held responsible for knowing the statute, regulations, procedures, and guidelines regarding Medicare coverage, billing and payment. Appellant knew or should have known that the documentation it submitted was inadequate and that the beneficiaries did not otherwise meet the coverage criteria for the ambulance transport services at issue.

Appellant’s argument that it is entitled to waiver of recovery because ‘none of the claims should have been reopened beyond one year’ without merit in that rebuttable presumption that provider is without fault applies to overpayment discovered more than three calendar years after the year in which the initial determination was made. Council also rejects appellant’s argument that it is without fault because an overpayment resulted from an ‘error in calculation by the carrier in calculating reimbursement.’ Appellant states that because it was allowed to bill for the diagnostic tests either separately or as a panel, it was the contractor that erred when it paid the appellant the higher amount for the separately billed tests. Council concurs with ALJ, who explained that to be found without fault, not only must the supplier submit accurate documentation, but the supplier must also promptly bring any overpayment errors to the contractor’s attention. Council also not persuaded by appellant’s contention that it is without fault because it interpreted the coding guidelines in the same way that other Medicare contractors have.

M. MPIM Procedures Not Followed:

MAC Decisions:
ALJ erred in finding that failure of ZPIC to provide notice of the audit reports within 60 days warranted dismissal of any financial liability. Council notes that ALJ relied on the 60 day timeline in the MPIM, which applies to prepayment and postpayment review for MR (Medical Review) purposes. However, this case arose from a statistical sampling review by the Benefit Integrity unit of the ZPIC. The MMPIM does not establish a rigid timeline for completing such a review. Council states that substantial deference is due for substantive policies but that operating instructions “stand on a somewhat different footing.” These instructions are founded in CMS’s management of the performance of its contractors in the day-to-day operations of a claims processing system of immense scope and complexity. The contents of the manual were not written, and were not intended to be used, as a source of legally enforceable obligations, prohibitions or rights by Medicare contractors, providers, suppliers, beneficiaries, or the general public.

Transyd Enterprises LLC D/B/A Transpro Medical Transport (Appellant) (Beneficiaries) Trailblazer Health Enterprises LLC (Contractor) Claim for Part B Benefits, 2009 WL 5764287 (Sept. 15, 2009):
MAC rejects appellant’s argument that PSC’s sampling methodology was invalid because the PSC failed to document that its statisticians possessed at least a master’s degree in statistics or the equivalent, as the ALJ said was required by CMS’s manual provisions. Council stated that even if the credentials of the contractor’s statistician failed to comply with the MPIM, that would not necessarily prove that the methodology was invalid. MAC notes that MPIM states that failure by contractors to follow one or more MPIM requirement 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 projection of the overpayment. Similarly, a contractor’s failure to document that a qualified statistician had reviewed the sampling methodology would not necessarily prove that the methodology was invalid.

N. Other MAC Decisions Where Extrapolations Set Aside:
The following are cases wherein the MAC determined that the provider/supplier met its burden of proof and that the extrapolation should be set aside, or the case remanded to the ALJ for further development.

Council remanded the case to the ALJ because the ALJ’s initial decision did not fully consider the relevant evidence presented by the Appellant. Specifically, the ALJ did not articulate why the Appellant’s expert report was not valid, and as a result, the Council was remanding the case back for a more thorough review by the ALJ.

Council finds that there are two major and related shortcomings in the sample that cannot be corrected at this juncture and that the overpayment demand must be limited to the total sum of the individual overpayment amounts identified in the cases sampled. The first flaw 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 second error is the “uncertainty and inconsistency of the data recorded in two different and unidentified Excel CD files” that the PSC could not explain.

General Medicine, P.C. (Appellant) (Beneficiaries) Palmetto, GBA (Contractor) Claim for Part A Benefits, 2010 WL 7232825, Docket No. M-10-1933 (Nov. 24, 2010): Council found appellant’s case based on unsupported speculation and conjecture. It addresses claim that stratification should have been used, stating that the statistical sampling guidelines do not require stratification of every sample in order to make the sampling valid. As to appellant’s argument that the sample drew claims from only 12 of the 20 facilities included in the frame, the Council states that the appellant has presented no evidence that these eight facilities billed a proportionate share of the total claims in the frame. However, the Council then states that appellant has raised some “valid theoretical objections to the sampling and, on remand, may wish to pursue and establish an actual factual basis for these arguments. The Council states that it “does not find appellant’s statistical consultant’s arguments frivolous, only unproven at this stage and given its burden of proof” and then goes on to state that “[f]or these reasons, the Council vacates the hearing decision and remands this case to an ALJ for further proceedings, including a new decision.” Council directs the ALJ to conduct another hearing, noting that the burden of proving there were flaws in the sample methodology which actually rather than theoretically bore on the overpayment recovery should be placed on the appellant.

Council finds no reason to disturb ALJ’s finding that sample probe review upon which PSC based its overpayment extrapolation was invalid. Pursuant to MPIM, probe reviews cannot be used for extrapolation.

Physicians’ Affiliated Services, Inc., DAB Medicare Appeals Council, Docket No. 000-45-1313 (1997): Extrapolation invalid where carrier failed to document sufficiently the statistical sampling methodology or justify the “universe” used to select the sample.