Medicare’s Use of Statistical Sampling to Determine Overpayments

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Broad Topics:

Why
When
How
Administrative/Judicial Appeal
Arguments Raised and Outcomes
Recommendations
THE WHY

WHY DOES CMS USE STATISTICAL SAMPLING AND EXTRAPOLATION?

To Determine Overpayments . . .

• Determine overpayment in a manner that minimizes government’s administrative burden.
  – CMS Ruling 86-1.
  – 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 recoupment if a determination is made that a provider/supplier to whom payments are to be made has been overpaid.
In An Administratively Feasible Manner

Most current estimate. . .
• Approximately 1 million physicians billing the Medicare program.

Authority

CAN CMS USE STATISTICAL SAMPLING AND EXTRAPOLATION - - IS IT PERMISSIBLE?
Seminal Case Allowing Statistical Sampling in Medicare Context

Chaves County Home Health Servs. v. Sullivan, 931 F.2d 914 (D.C. Cir. 1991):

• The Court 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.

THE WHEN

WHEN CAN CMS USE STATISTICAL SAMPLING AND EXTRAPOLATION?
Prerequisites to Using Statistical Extrapolation

42 U.S.C. § 1395ddd(f)(3) (Section 1893(f)(3))
• A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset or otherwise unless the Secretary determines that --
  – There is a sustained or high level of payment error; or
  – Documented educational intervention has failed to correct the payment error.

Guidance

• CMS Program Integrity Manual Chapter 8: http://www.cms.gov/manuals:
  – High level of payment error:
    • Error rate determination
    • Probe samples
    • Data analysis
    • Provider/Supplier history
    • Information from law enforcement investigations
    • Allegations of wrongdoing by current or former employees of provider or supplier
    • Audits or evaluations by OIG.
Threshold Determination Not Subject to 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
- 42 C.F.R. § 405.926(p)
- PIM, Ch. 8.4.1.2.

THE HOW

HOW DOES CMS PERFORM STATISTICAL SAMPLING AND EXTRAPOLATION?
Conducting the Statistical Sampling and Extrapolation

• No generally accepted principles of statistical sampling
  – Michael King, 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.’
  – Alpine Home Care, 2011 WL 3668254 (Jan. 12, 2011)

CMS Guidelines

• PIM Chapter 8:
  – Provides instructions to follow to ensure that a statistically valid sampling is drawn and that statistically valid methods are used to project an overpayment; but
  – Failure by contractor to follow one or more requirement does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment
Basic Requirements

- Must follow a procedure that results in a probability sample:
  - 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;
  - Each sampling unit in each distinct possible sample must have a known probability of selection.

A Probability Sampling is Always Valid

- 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.
Execution - - Major Steps

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 (the actual overpayment);
6) Estimating the overpayment for the defined universe and determining the demand amount.

Terms

– **Sampling Unit:** 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.

– **Sampling Frame:** the listing of all the possible sampling units from which the sample is selected.
And More Terms . . .

- **Sample design**: 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 sampling* involves classifying the sampling units in the frame into non-overlapping groups, or strata. 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.
  - *Cluster sampling* involves drawing a random sample of clusters and reviewing either all units or a sample of units selected from each of the sample of 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.

Case Example: Universe, Sampling Unit, Sampling Frame

- The PSC defined the **universe of claims** as all claims that were submitted between **August 1 and December 31, 2004** by Dr. No.
- 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 **$266,658.27**.
Case Example: Stratified Sample

- The PSC defined five groups or strata according to the total amount paid to the supplier for services rendered to the beneficiary.
- 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.

<table>
<thead>
<tr>
<th>STRATA /GROUP</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claims in increasing dollar amount</td>
<td>Smallest dollar amount</td>
<td>Increasing dollar amount</td>
<td>Increasing dollar amount</td>
<td>Increasing dollar amount</td>
<td>Increasing dollar amount</td>
</tr>
<tr>
<td>Number of benes in universe</td>
<td>134</td>
<td>44</td>
<td>32</td>
<td>25</td>
<td>19</td>
</tr>
<tr>
<td>Total: 254 benes</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

21
Case Example: Sample Size

- The PSC determined the sample size by using a formula from the textbook *Sampling Techniques* by William G. Cochran, 1977.
- Sample size calculation resulted in 20 beneficiaries.

A Word About Sample Size . . .

- PIM Ch. 8.4.4.3.
- The size of the sample will have a direct bearing on the precision of the estimated overpayment but it is not the only factor that influences precision. Other factors: the underlying variation in the target population, the particular sampling method used, the particular form of estimator used.
- It is neither possible nor desirable to specify a minimum sample size that applies to all situations.
- Real-world economic constraints shall be taken into account. Contractor shall consider their available resources.
- A challenge to the validity of the sample that the particular sample size is too small to yield meaningful results is without merit as it fails to take into account all of the other factors that are involved in the sample design.
Case Example: Equal Distribution Among Strata

- 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.

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Case Example: The Five Strata

<table>
<thead>
<tr>
<th>STRATA/GROUP</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Sampled Benes in the Strata/Group</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Total: 20 benes</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
Case Example: Precision in Stratification

• 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.

Case Example: Randomization

• A random sample was chosen from each strata using the RAT-STATS program provided by the Office of the Inspector General.
• 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.
Case Example: 
Actual Overpayment

- 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.

<table>
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<tr>
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<th>5</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</tbody>
</table>

Total Overpayment Amount for Sample: 
$1,145.17 + $4,324.35 + $5,998.38 + $8,275.86 + $10,644.58 = $30,338.34

Total Amount Paid: $32,597.91
93.2% Error Rate
Case Example: Average Overpayment Per Bene

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

### Case Example: Average Overpayment Per Bene

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<td>$8,275.86</td>
<td>$10,644.58</td>
</tr>
<tr>
<td>Divided by:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Sample Beneficiaries in Group</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Equals:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Overpayment for Bene</td>
<td>$286.29</td>
<td>$1,081.09</td>
<td>$1,499.60</td>
<td>$2,068.97</td>
<td>$2,661.15</td>
</tr>
</tbody>
</table>
**Case Example: Point Estimate**

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

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<tr>
<td>Multiplied by:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>134</td>
<td>44</td>
<td>32</td>
<td>25</td>
<td>19</td>
</tr>
<tr>
<td>Equals:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated Extrapolated Overpayment in Each Group</td>
<td>$38,363.20</td>
<td>$47,567.85</td>
<td>$47,987.04</td>
<td>$51,724.13</td>
<td>$50,561.76</td>
</tr>
</tbody>
</table>

**Designated Overpayment or Point Estimate:**

$38,363.20 + $47,567.85 + $47,987.04 + $51,724.13 + $50,561.76 = $236,203.97.

Recall: Total Amount Paid for Universe: $266,658.27
**Case Example: Interval Estimate**

- While the PSC calculated the designated overpayment for the universe of claims (or point estimate), the Medicare contractor did not demand that point estimate from the supplier.
- PSC demanded a lesser amount based on its calculation of an **interval estimate**.
- Interval Estimate is a range of numbers in which it is most plausible that the true overpayment amount is contained. Usually consists of an upper limit/bound and a lower limit/bound.
- An interval estimate is reported with a **confidence level** to indicate the level of certainty that the reported interval contains the true overpayment amount.

**90% Confidence Interval**

- **Means . . .**
  - 90% confidence that the actual overpayment lies somewhere between the lower and upper limits of the interval; or a 10% probability that the true value of the error rate falls outside the confidence interval.
  - Stated another way, 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.
CMS Policy: Confidence Interval

- Policy of demanding the lower limit of the interval estimate was developed by CMS to account for any imprecision in the extrapolation in a manner that benefits the provider. PIM, Ch. 8.
- The greater the imprecision, the wider the confidence interval. The smaller the imprecision (or greater the precision), the narrower the confidence interval.
- It leads to a demand amount for recovery that is “very likely less than the true amount of the overpayment.”

Case Example: 95% Confidence Interval

- PSC calculated a two-sided 95% confidence interval, which meant that the PSC was 95% certain that the overpayment amount was within the upper and lower limits; or 5% likelihood that overpayment outside the interval;
- 2 1/5% likelihood that true overpayment higher than upper limit/bound of interval and 2 1/5% likelihood that true overpayment smaller than lower limit/bound.
Case Example:  
95% Confidence Interval

<table>
<thead>
<tr>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>2 ½%</td>
<td>95%</td>
<td>2 ½%</td>
</tr>
</tbody>
</table>

Case Example: 
Two-Sided 95% Confidence Interval

- Upper and Lower Limits/Bounds of 95% Confidence Interval: $262,204.43 and $210,203.59.
  - Recall Point Estimate: $236,203.97.
  - Demand Amount: $210,203.59.
Notice of the Overpayment

- PIM states that overpayment demand letter should include information about the review and statistical sampling that was followed:
- Information about sampling methodology:
  - Description of universe, frame, sample design;
  - Definition of sampling unit;
  - Sample selection procedures, numbers and definitions of strata and size of sample;
  - Time period under review;
  - Sample results, including overpayment estimation methodology and calculated sampling error as estimated from sample results;
  - The amount of the actual overpayment from each of the claims reviewed.

What Is The Provider/Supplier To Do?

- Administrative Appeals Process:
  42 C.F.R. Part 405 Subpart I:
  Initial Determinations: Medicare overpayment determination and determination of liability
Administrative Appeal:
Step 1

• Redetermination: 42 C.F.R. §§ 405.940, 948:
  – Contractor independent review of the initial determination.

Administrative Appeal:
Step 2

• Reconsideration by a Qualified Independent Contractor ("QIC"): 42 C.F.R. § 405.904.
Administrative Appeal: Step 3

- ALJ Hearing. 42 C.F.R. § 405.1000.
- In 2005, CMS amended its regulations to explicitly permit CMS or its contractor to participate 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).
- The ALJ may not draw any adverse inferences if CMS or a contractor declines to participate or invoke party status. 42 C.F.R. §§ 405.1010(f), 405.1012(d).

The Appeal - - Step 4

- Medicare Appeals Council
- A party to the ALJ hearing may submit a request for review of the ALJ’s decision by the Medicare Appeals Council of the Departmental Appeals Board ("MAC"). 42 C.F.R. §§ 405.1100, 405.1102.
- 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 the evidence in the record pursuant to 42 C.F.R. § 405.1110.
Administrative Appeal: Step 4

- CMS or its contractor may 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 the 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).
- 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. Id.

Judicial Appeal

- Judicial Review.
- 42 C.F.R. § 405.1006(c)
- 42 U.S.C. § 405(g)
  – Secretary’s findings of fact, if supported by substantial evidence, are conclusive.
Burden of Proof

• “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 . ..” 42 C.F.R. § 405.1063(b).

• 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 a basis for recoupment. The burden then shifts to the provider.

Burden of Proof
What Does It Look Like?


• 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.
Specific Challenges:
Due Process


• 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 PIM 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.

Due Process: Federal Court Decisions


• 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.


• Appellant 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.
Specific Challenges:
Threshold Determination Not Made


• 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;

• Council does not agree with ALJ’s decision 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 PIM establishes a notice or documentation requirement that a sustained or high level of payment error exists.

Threshold Determination
But see . . .


• 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.
Threshold Determination: Federal Courts’ View

• 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.

Specific Challenges: Sample Size

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):
• PIM acknowledges that sample size affects precision but does not prescribe a particular sample size and states that challenge to size not sufficient to demonstrate that sampling was invalid as there are many factors that affect precision.

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.
Sample Size: Some Reluctance . . .


- 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.

Specific Challenges: More on Precision


- Overall precision rate in the stratified statistical sample of 22.23% is relevant 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 PIM 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.
Precision:
Federal Court decisions

- 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.

Specific Challenges:
Sample Not Representative

*Place for Achieving Total Health (Appellant) (Beneficiary)
- 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.
Representativeness: Federal Court


- 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.”

Specific Challenges: Lack of Documentation


- 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.


- 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.


- 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. §§ 405.1030(f) and 405.1037.
Lack of Documentation: Federal Court


• 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 concludes that there was adequate documentation and information available to the plaintiff to permit him 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.

Specific Challenges: Should Have Stratified

• PIM on Stratification:

• “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.” Ch. 8.4.11.1.
Specific Challenges: Should Have Stratified

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.
• PIM 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.

• 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 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.

Stratification: Federal Court

• Selection of five stratum was neither arbitrary nor without justification, was supported by a study 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.”
Specific Challenges: Procedural Issues


- 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 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.

Specific Challenges: Procedural Issues


- 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 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).
Specific Challenges: Waiver of Liability

Liability can be waived pursuant to 42 U.S.C. § 1395pp if provider determined to be without fault.


- 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.”


- 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.

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Specific Challenges: Failure to Follow PIM


- Council stated that even if the credentials of the contractor’s statistician failed to comply with the PIM, that would not necessarily prove that the methodology was invalid.
- MAC notes that PIM states that failure by contractors to follow one or more PIM 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.


- ALJ erred in finding that failure of ZPIC to provide notice of the audit reports within 60 days warranted dismissal of any financial liability. The PIM 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.

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Other MAC Decisions Where Extrapolations Set Aside


- Council finds that there are two major and related shortcomings in the sample. 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.

And More. . .


- 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”
- “For 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 appellant bears burden of proving there were flaws in the sample methodology which actually (rather than theoretically) bore on the overpayment.
Recommendations

• Adhere to all appeal deadlines;
• Make sure you have all documentation needed to recreate sampling methodology;
• Keep in mind the burden of proof - - conclusory allegations are insufficient.
• Make sure your expert demonstrates how the lack of precision, representativeness, etc. prejudices to provider.