Medicare and Medicaid Audit Overpayments: Challenging Statistical Sampling and Extrapolation

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Introduction to Legal Issues in Statistical Sampling and Extrapolation



What Is Sampling?

Sampling is taking a subset of the claims in a Medicare/Medicaid provider's universe of claims for the purpose of auditing them for potential disallowance.

How is the sample of claims chosen? Usually via computer software which generates pseudorandom numbers using a seed. This is a replicable process.

The sample must be randomly selected to be valid.

However, not all random samples result in a valid sample.





What Is Extrapolation (or Projection)?

Extrapolation takes the results of an audited sample of claims and projects the total dollar amount of the overpayment from the sample over the universe of the provider's paid claims.

The audited sample has a known amount of dollars in error and that amount is projected to the claims universe for a global repayment amount with a given level of confidence, which is necessary since this is merely an estimation of the global overpayments.





HCFA REVENUE RULING 86-1

1986 a ruling was issued by Health Care Financing Administration (HCFA, the precursor to CMS).

Entitled "Use of statistical sampling to project overpayments to Medicare providers and suppliers" it stands for the proposition that:

"HCFA and its Medicare contractors may use statistical sampling to project overpayments to providers and suppliers when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible."





C.F.R. Regulatory Basis for Statistical Sampling for Overpayment Estimation

US HHS "may introduce the results of a statistical sampling study as evidence of the number of violations . . . or the factors considered in determining the amount of [a] civil money penalty. Such statistical sampling study, *if based upon an appropriate sampling and computed by valid statistical methods*, constitutes prima facie evidence. [T]he burden . . . shifts to the [Provider] to produce evidence reasonably calculated to rebut the findings of the statistical sampling study."

~ Excerpt from 45 C.F.R. § 160.536(a)-(b) (emphasis added).

State Medicaid programs generally use a similar approach.





When May Extrapolation be Used?

42 U.S.C. 1395ddd(f)(3) provides that:

Limitation on use of extrapolation

A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—

(A) there is a sustained or high level of payment error; or

(B) documented educational intervention has failed to correct the payment error.

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





Medicare and the MPIM

What is the Medicare Program Integrity Manual?

Why does it matter?

There is one relatively recent change in the 2019 MPIM that may favorably impact an audit :

 Extrapolation issues-sustained or high level of error (more than 50% of sample claims in error)





MPIM: Determining When Statistical Sampling May be Used

8.4.1.4 – Determining When Statistical Sampling May be Used (Rev. 828; Issued: 09-28-18; Effective: 01-02-19; Implementation: 01-02-19).

The contractor shall use statistical sampling when it has been determined that *a sustained or high level of payment error exists*. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error. For purposes of extrapolation, *a sustained or high level of payment error* shall be determined to exist through a variety of means, including, but not limited to:

- high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review);

- provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices);





MPIM: Determining When Statistical Sampling May be Used (cont'd.)

- CMS approval provided in connection to a payment suspension;
- information from law enforcement investigations;
- allegations of wrongdoing by current or former employees of a provider/supplier; and/or
- audits or evaluations conducted by the OIG. (Emphasis supplied).





States and Medicaid Statistical Sampling: A Toolkit for MFCUs (and others as well)

- Guidance for the various state Medicaid Fraud Control Units
- Published September 2018
- Useful guidance with examples
- Lays out the process that should be followed
- Recommended reading





States and Non-MFCU Medicaid Statistical Sampling

Unlike the Medicare program, which uses the MPIM, the Medicaid program nationally (except for the MFCUs) has no universal guidance outlining the rules of the process to be used.

Your state may have simple rules, detailed rules, or no rules at all.

The burden of proof is typically on the provider to challenge the statistical sampling and extrapolation.

In such settings, the State's methodology is presumed valid unless and until the provider proves otherwise.





The Role of the Expert: Why You Should Always Have One

A statistical consultant is essential to understanding how the audit was conducted and whether the results are statistically valid.

• Laypersons generally cannot understand these concepts absent training.

The expert will review both the audit process used and the results in your particular case.

The expert is the key person who will be able to properly answer important questions pertaining to the audit.

- An expert is critical when responding to the audit and at the subsequent hearing.
- Raise issues as early as possible in the proceedings.





The Role of the Expert: Asking the Important Questions

- Is the audit process used by the auditors properly designed?
- Is this process suitable and/or appropriate for use in this audit of my client?
- How was the sample size chosen? Was that selection proper?
- Was the sample tested?
- Is the sample size adequate (large enough) to obtain the confidence interval?
- Do you have a probability sample?
- Did the auditors properly document the audit?





The Role of the Expert: Asking *More* of the Important Questions

Is the software program used for random number generation certified or otherwise widely accepted for this purpose? Is it proprietary?

Was the software program used in the manner it was designed to work?

- When in doubt, have an expert look at the program's source code.
- Can't get the source code? Argue violation of due process.
- Need actual code run and results.
- Was adequate documentation for replication provided?

Remember, an audit using extrapolation is a scientific hypothesis which must be able to be replicated (reproduced) with the same outcome.





The Role of the Expert: Asking *Even More* of the Important Questions

Can the results be replicated by the provider?

- If not, there is a serious problem.
- Retaining the seed is a critical factor.
- Was the computer program/code used to generate random numbers provided?
- Is the frame sorted in the same order that it was in at the time the random numbers were used to pick the sample?
- Was stratification used?
- Check the extrapolation calculations themselves.





Right Idea, Wrong Answer







Dewey Wins the Election!!



What happened? Bad sample...





What is Required for Statistical Validity?

- Properly defined (in writing), maintained and provided: universe, frame, sampling unit.
- Must be possible to calculate the number of samples of the given size in a frame of the given size.
- Each member of the sample must have an equal probability of selection.
- Sample must be random.
- Sample must be free from bias (representative).
- Sample must be of adequate size.
- Audit must accurately measure the variables of interest.
- Must have replicable results.
- Normally distributed overpayment data for parametric statistics to work.
- Accurate estimation of overpayment by using the correct formula for estimation.





Defenses Beyond the Scope of the Webinar

Not covered here are the following defenses to audits and individual claim determinations:

authority to audit;

scope of audit;

waiver of liability;

provider without fault;

individual claim defense;

clinical aspects of claim;

compliance with documentation rules (NCDs/LCDs); and

medical necessity.





Who Has the Burden of Proof?

This rests on the provider, who must demonstrate that the sampling and extrapolation is invalid.

The presumption is that the contractor conducted the audit in a valid manner.

Burden can be high.

At the ALJ hearing level there is no right to cross-examination of the contractor's witnesses.

Your direct case must be as strong as possible.





How Probability Statistics Work and When They Don't

PART TWO

Feed Some Tidbits to a Fortune Teller – the Outcome Can be as Good as a Political Poll







An Expert's Success Depends on How Well the Statistical Issues in the Case are Presented

Issues may include:

- inconsistency in audit definition;
- documentation not produced;
- demonstrably sloppy execution;
- false assertions of probability sample;
- no 90% confidence level; and/or
- inaccurate overpayment determination.





Documentation: The Devil is in the Details

Revenue Ruling 86-1, the C.F.R. and the US Code determine that sampling may be used.

The assumption is made that the statistical results are valid, hence it is up to the appellant to demonstrate that the process is invalid.

- Every step of the audit process has to be documented and provided in order to show where the audit failed.
- Replication is the gold standard of scientific knowledge.

Invalid results are not an accurate measurement of overpayment.

Sloppy execution, breaking mathematical rules of statistics and defending the statistically indefensible plague these audits. These problems cannot be proven without documentation.





Statistical Review Requires That You Look Behind the Curtain















(Individual claim: must be within frame)

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Corrupted Frame = Bad Sample







Descriptions Must Be Statistical

Define the universe – descriptions must be numerical not just verbal.

• Field of descriptive statistics

Were the universe, frame and sample frame correctly described?

Verification of audit data often identifies:

- multiple conflicting audit definitions;
- more than one universe;
- different frames;
- no probability sample;
- faulty calculation of extrapolation results; and/or
- inaccurate reporting of overpayment amounts.





Operational Definitions

An operational definition is a clearly defined description of some characteristic. It should be specific and describe not only what you are measuring but how. An operational definition needs to be agreed upon by the other parties using it as you want everyone defining, measuring, and interpreting things the same way.

A good operational definition should:

- be clear, specific, definable, measurable and unambiguous;
- specify the device for measuring the factor;
- specify the units of measurement and time frame;
- describe the measurement method; and
- include the decision criteria.

Outcome: definition is specific, practical, and everyone defines and measures the same thing the same way; there is confidence in what the definition means, which eliminates opinion from the discussion.



Operational Definition Success: the 2-Midnight Rule

The 2-midnight rule was developed because, in practice, the assessment of Medical Necessity of hospital admission was widely disparate and dependent on which rater made the decision. The decision of Medical Necessity in these situations had not been operationally defined nor had raters been trained on the definition. CMS came up with an operational definition that was time based (if the patient was in the hospital for 2 midnights) then hospital admissions could reasonably be considered inpatient admissions.

Prior to the 2-midnight rule, decision accuracy of Medical Necessity decisions was less than chance (50:50, or a guess). The issue was further complicated by auditors denying all of the dollars associated with the claim rather than assessing the outpatient dollar amount. Contractors reviewing at higher levels of review asserted the hospital could rebill at the outpatient rate. Problem: claims under review cannot be rebilled. When these cases go on 6, 8, 10 years the hospital is denied legitimate payment.

A clear operational definition can solve many coding decision problems.





Inter-rater Reliability Failure Example

There were the 3,642 claim lines for the 48 beneficiaries in the sample.

All claim lines were denied by ZPIC at the initial level.

At redetermination, the decision was all claim lines were denied.

At reconsideration, 2,560 claim lines (70.3%) were allowed.

At reopening, 2,766 (75.9%) were allowed.

When the four levels of decision were compared with one another, there was total agreement for only 876 (24.1%) of the claim lines. The 24.1% in agreement (23.9% partial agreements) left only **0.2% in total agreement by** all 4 of the reviewing entities.

Less than a quarter 1% of the sample decision level service lines had total agreement over all 4 of the reviewers. This audit demonstrates a systemic problem with assessment of payment denials at the decision line level.





Quality Assurance MPIM Operational Definition

MPIM Section 4.7.4 – Medical Review for Program Integrity Purposes, Section D – Quality Assurance, item (4) provides directions for UPICs to ensure that the variable of interest is accurately measured. Section D is partly quoted here:

4. The UPIC shall <u>develop a system to address how it will monitor and maintain accuracy in decision making</u> (inter-reviewer reliability) as referenced in chapter 3 of the PIM.

The UPIC shall establish a Quality Improvement (QI) process that verifies the accuracy of MR [Medical Review] decision made by licensed health care professionals.

UPICs shall include inter-rater reliability and/or peer review assessments in their QI process and shall report these results as directed by CMS. (Emphasis added.)

To date there is no evidence that these requirements and reports have not been met.





Probability Statistics Are Different From Arithmetic

The probability space of a frame:

1) it must be possible to calculate the number of samples of a given size that can be taken from a frame of a given size; and

2) we must know the likelihood of selection of each sampling unit.

- Simple sample must have equal probability of selection.
- Stratified sample must have a simple sample in each stratum.







-----_____ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ ____ _____ ___ _____ (2, 3, 4, 5, 6) (1, 12, 23, 34, 45) (1, 2, 3, 4, 5) (1, 11, 21, 31, 41) (8, 23, 46, 73, 90)



(1, 2, 3, 4, X)




How Many Samples Taken 5 at a Time Are in a Frame of 100?

Combinations: N!/(r! [N-r]!)

- In words: frame factorial/sample factorial (frame minus sample factorial)
- In numbers: 100!/(5!95!)

Samples of 5 from 100 75,287,520

Samples of 5 from 9971,523,144Samples of 5 from 10179,208,745





Different Number of Sample Sizes in Frame of 100

 $_{n}C_{r} = n!/(r! \times (n-r)!)$

Combinations = frame size factorial divided by sample size factorial times frame size factorial minus sample size factorial.

Combinations = 100!/(5!x95!).

If the sample size is 5 100! /(5! x 95!) there are 75,287,520 (two commas).

If the sample size is 2 $100!/(2! \times 98!)$ there are 4,950 combinations.

If the sample size is 10 100!/(10! x 90!) there are 17,310,309,456,440 (four commas).





Frame of 100 Oranges







Sample of 5 Oranges







Solution to the Apple Problem

- Go to the frame of 100 and only use oranges (remove all apples):
 - will change frame size and sample size;
 - must choose new sample based on frame.
- Redefine the frame to include apples and oranges:
 - remember it then must include all the apples; but
 - do you care about apples?
- Move frame to cover other information in the 10,000 claim universe;
 - what do you want to measure from the universe?





Distributions are the Measurement Yardstick of Statistics

Shape of the data under the curve,

Representative sample (small and accurate picture of overpayments in the frame),

You've just seen how many samples of 5 there are in 100 and you can imagine how many samples of 150 there would be in a frame of 2,000.

However, not every sample is a good one.

If sample does not match the frame in size and shape then the overpayment average cannot be a good estimator.





Possible Samples That Can Be Randomly Drawn From the Frame







Representative Sample



Good sample



Bad sample







One and Only One Sample Chosen

90% confidence means 1 in 10 samples will be faulty.

- The distribution of the means of all possible samples would combine to give a theoretical mathematical model for that frame.
- There must be a probability sample to make a proper extrapolation.





"Normal" Distribution







What's the Big Deal About the Normal Distribution?

The Normal Distribution allows substantial mathematical power for using sample as estimators.

• The distribution is bell-shaped.

- It is a continuous, symmetrical distribution that is standardized over all types of data:
 - the mean, median and mode are all the same number;
 - one standard deviation accounts for 68.3% of the data;
 - two standard deviations account for 95.43% of the data;
 - three standard deviations account for 99.7% of the data; and
 - outliers are more that 3 standard deviations.

The Normal Distribution allows for the use of the Central Limit Theorem ("CLT").

• CLT provides the statistical grounding for point estimates and confidence levels.





Confidence Levels on Normal Distribution







Confidence Levels

Highway median (mean or point estimate). Yellow line 99% confidence, dotted line 95% confidence, solid white line 90% confidence. Beyond the lines there is no valid confidence level.







Illustration Not Based on Actual Data







Non Normal Mean and \$0 Overpayment





Probability of Selection

The formulae for equal probability of selection is fairly straightforward:

 $P(A) = \frac{\# sample claims}{\# frame claims}$

Requires independent observations and sampling without replacement.

The probability of selection for stratified samples gets complicated very quickly.







Stratified Probability of Selection P(SA) + P(SB) + P(SC) + P(SD) + P(SE) + P(SF)

Probability of Selection in a Stratified Frame of 300

For 6 strata P(A) + P(B) + P(C) + P(D) + P(E) + P(F) Additive

Stratified set by number of claims in stratum in jar of 300:

- *p* blue (15 in 300)
- + *p* green (30 in 300)
- + *p* white (20 in 300)
- + *p* purple (100 in 300)
- + *p* orange (135 in 300)
- + *p* black (0 in 300)





Unequal Probability of Selection

Strata can't overlap.

Every member of the population being studied must be identified and classified into one, and only one, stratum.

When there is overlapping, there is no longer independence of strata and no longer equal probability of selection: those who are in multiple strata are more likely to be chosen.

The probability for the **two** strata then is $P(A \cup B) = P(A)+P(B)-P(A \cap B)$.

For **three** strata the probability is $P(A \cup B) = P(A)+P(B)-P(A \cap B)$ and $P(A \cup C) = P(A)+P(B) + P(C)-(P(A \cap B) + P(A \cap C) + (B \cap C))$.

Then it must be repeated for every other stratum.





If Overlap Between Two Strata A and B



Probability of the overlap is the intersection of the two strata: $(A \cap B)$. The probability for the two strata then is $P(A \cup B) = P(A) + P(B) - P(A \cap B)$.

... it gets more and more complicated as the number of overlapping strata increases.





Common OIG Stratification

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Strat	Target	# sample Claims	Payments	Dollar range
Strat A	Equipment	6	130,000	8,084 50 662
				50,002
Strat B	Inpatient code	30	656,5000	76,800
	High \$			12,956
Strat C	Inpatient code	30	1,730,000	3,100
	Low \$			12,957
Strat D	Outpatient code	30	3,425,000	13,000
	High \$			71,200
Strat E	Outpatient code	30	1,900,000	3,000
	Low \$			71,2001

Range of all frame payments is 3,000 to 76,000 All strata overlap - numerically bad stratification



Accurate Measurement of Overpayment

Did extrapolation meet the mathematical criteria of the chosen statistic?

If there are point estimates and confidence levels:

normally distributed sample overpayment averages;

adequate sample size to support chosen confidence levels;

representative sample;

probability sample; and

based on error rates > 50% (amount paid positively correlated with overpayment).

If statistic not based on normal distribution is it valid and properly executed?

Are findings correctly and accurately reported?





Declared Confidence Levels







RAT-STATS Overpayment Estimation

Formulae:

Point estimate = (mean overpayment)frame size

Confidence Level:

Point estimate
$$\pm \alpha \frac{\text{chosen confidence}}{2} \cdot \text{sample sd} \cdot \sqrt{\frac{\text{frame size}(\text{frame size} - \text{sample size})}{\text{sample size}}}$$





Faulty Findings Frequently Found

No 95% or 90% confidence as declared by auditor.

Negative overpayment calculations (CMS owes provider).

Overpayment calculation greater than the amount paid.

Demanding lower confidence level dollar amount when 90% confidence level is not attained.

Any calculation done on a corrupted frame and/or sample.

Affirmatively, a misleading wrong interpretation of calculation.





The Calculator Expects Overpayments To Be:

Probability sample

- Possible to calculate the number of samples of a given size in frame of a given size
- Known probability of selection
- Proper execution of methodology
- Proper randomization
- Use correct formulae
- Accurate estimate of the overpayment

Parametric Statistic

- Random sample
- Independent observations
- Normally distributed (sample averages)
- Representative

Adequate Sample Size







RAT-STATS

Department of Health and Human Services Office of Inspector General Office of Audit Services

RANDOM NUMBERS





Data File Format Audited Values Examined and Au Examined and Au	Examined and Difference Values	
Data File C:\Users\mrchr\DXXXXXXXXXXXXXXXXXXIa OP Spreadsheet Sheet1 Difference Cell A1 Termative Confidence Interval Calculated Using the Empirical Likelihood Image: Confidence Values Audited Values Examined Values	Frame Description File C:\Users\mrchr\Dextextextextextextextextextextextextexte	Data Excel File Preview Row # A B C 1 48.03 23 31806 2 48.03 25 12316 3 55.18 7 458 4 22.46 Frame Excel File Preview Row # A B C 1 48.03 23 31806 2 48.03 25 12316 3 55.18 7 458 4 22.46
e Output Options:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	vel must be lower.



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Stratified Variable Appraisal Report								
Name of Audit/	Review: Padda							
Name of D	of Data File: C:\Users\mrchr\Desktop\PADDA\RAT STAT\Padda OP for RAT-STATS 8-19							
Name of Frame Description File: C:\Users\mrchr\Desktop\PADDA\RAT STAT\Padda OP for RAT-STATS 8-19								
Name of Out	put File: C:\Users\mrc	hr\Desktop\PADDA\F	AT STAT Padda RAT S	TAT (v2019) Resu	View			
Name of Ex	cel File:	XXXXXXXXXXXXXXXXX	XXXXXXXXXX		View			
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							
View Data: 🔿 Overall	Stratum Selection 1	Number of Strata	3					
Difference Values Data Fi	le Summary							
	Summary for D	ifference Values						
Mean 5	6.05 Standard Deviation	on 25.08	Standard Error(Mean)	5.23				
Skewness -	0.15 Kurtos	sis 3.16	Standard Error(Total)	166,276				
Frame Size 31	,806 Sample Si	ze 23	Point Estimate	1,782,837				
Standard RAT-STATS Confidence Interval								
	80% Confidence Level	90% Confidence Level	95% Confidence Level					
Lower Limit	1,563,147	1,497,317	1,438,002					
Upper Limit	2,002,527	2,068,357	2,127,672					
Percision Amount	219,690	285,520	344,835					
Percision Percent	12.32%	16.01%	19.34%					
t-Value Used	1.321236741613	1.717144374380	2.073873067904					
Alternative Confidence Interval Calculated Using the Empirical Likelihood Approach								
	70.00% Confidence Level	Target Chi-Square	Obtained Chi-Square					
Lower Limit	1,610,374.06	1.074194	1.074233					
Upper Limit	1,951,994.22	1.074194	1.074213					
Point Estimate	1,782,836.93							
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Levels of Medicare Audit Review







Levels of Review

Audit

UPIC (formerly ZPIC) and OIG initiate most appeals.

Responsible for design, execution, documentation and reporting of audit.

Redetermination (MAC)

Done by different MAC personnel than audit. Frequently do not obtain statistical files or review them, yet will declare the audit valid and the findings at a specified level of confidence. If statistics not reviewed here, provider required to go to QIC.

Reconsideration (QIC)

QIC (Qualified Independent Contractor) reconsideration generally have statistical review. It is important to know who did the review and what documents were reviewed. This role has changed over time.





Levels of Review (cont'd.)

Next steps:

ALJ Hearing

ALJs appear to be accepting of the reported information from the three levels whether it is correct or not.

Big hurdle to demonstrate that the three levels of review are indeed wrong when the extrapolations are invalid and are inaccurate in the calculation of overpayment statistics.

Medicare Appeals Council (MAC)

United States District Court

Circuit Court of Appeals

SCOTUS





Case Law Summary Discussion

PART THREE

Case Law Summary Discussion

Common arguments made by providers include sample size not large enough, but in and of itself, sample size inadequacy arguments are not likely to persuade the Administrative Law Judge UNLESS:

- You can demonstrate a severe lack of accuracy and/or precision such that a more precise analysis would have established materially different conclusions.
- You may have to audit your universe yourselves to demonstrate this.

Other areas of potential attack:

- randomness of sample;
- representativeness;
- bias; and
- insufficient documentation of all aspects of the audit process.





"I'll pause for a moment so you can let this information sink in."





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