



OIG Mandated Six Year Look Back Audits

Use of Statistical Sampling and Extrapolation

Recent Updates and Perspectives

Drivers of Efficient and Diligent Analysis

HCCA – Compliance Institute

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Objectives

- Help compliance professionals better understand extrapolation as it pertains to payment analyses to calculate voluntary repayments
- Debunk common myths related to advantages of extrapolation
- Understand situations to use or not use extrapolation, including example case studies and best practices to avoid operational delays and challenges
- Understand OIG and MAC expectations



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Introductions and Perspectives

- From legal counsel:
 - Chad Eckhardt, Attorney at Law, Frost Brown Todd LLC
- From an auditor / consultant / health plan / payor:
 - James Rose, Managing Director, SunHawk Consulting LLC



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Agenda

- Determination of an Overpayment Matter
- Use of Statistical Sampling and Extrapolation
- Recent Updates and Perspectives
- Drivers of Efficient and Diligent Analysis

Note: Definitions and examples simplified to allow for ease of presentation and use by non-statisticians



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When Do I Have an Overpayment?

- First considerations
- Confirming a need to dig deeper
- How to conduct a preliminary analysis while maintaining appropriate options
- When to ask for external support



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Legal Authorities

- False Claims - 31 U.S.C. 3729(a)(1) (Published, 1863; amended 1986)
 - Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval
- Overpayment Obligations - 42 U.S.C. 1320a-7k(d) (Section 6402 of ACA, 2013)
 - “Any overpayment retained by a person after the deadline for reporting and returning the overpayment...is an obligation for purposes of section 3729 of such [Title 31]”
- Overpayment Regulations - 42 C.F.R. 401.301 et. seq. (Published, 2016)



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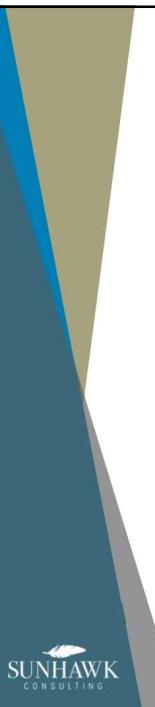


Overpayment Regulations

1. Obligation to Report and Return. Medicare requires that a person who has received an overpayment from Medicare to report and return the overpayment. (42 C.F.R. 401.305(a)).
2. Obligation to Investigate Potential Overpayments. A person must exercise reasonable diligence in investigating whether it has received an overpayment and quantify the amount of such overpayment. (42 C.F.R. 401.305(b)).



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Overpayment Regulations – con't

- Investigation Details. Absent extraordinary circumstances, the DHHS suggests that **six (6) months is a reasonable** amount of time for a person to investigate whether it has received an overpayment. (81 Fed. Reg. 7654, 7662, Feb. 12, 2016)
- Timeline. Any overpayment identified during must be reported and returned within **sixty (60) days** of such identification. (42 C.F.R. 401.305(b)(1)(i)).
- Lookback period. An overpayment must be reported and returned if a person identifies with **within 6 years** of the date of the overpayment was received.



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When to Self-Disclose?

- Know of an actual violation of requirements
 - Medical Necessity Requirements
 - Billing Requirements
- Know of a potential violation of medical necessity requirements in which resolution is desired
 - Closing of a Transaction
 - Under Corporate Integrity Agreement
 - Reduce Risk Portfolio



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Use of Statistical Sampling and Extrapolation



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Extrapolation 101

- Extrapolation explained:
 - Creating a value estimate describing a large population without actually testing the entire population.
 - (The dollar value of errors in the population of 100,000 items is estimated to be \$10,000 +/- \$1,000 with 90% confidence
 - based on our sample of 100 items.)
 - Why extrapolation:
 - More efficient than testing the entire population.
 - In terms of expense
 - In terms of time



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Extrapolation 101

- Extrapolation process:
 - Understand the value estimate you wish to describe.
(The overpayment amount – versus the total paid or total that should have been paid – the distinction is important.)
 - Understand the facts and circumstances related to the transactions you plan to evaluate.
 - Determine the sample size you need based on the level of confidence and precision you wish to address.
 - Develop a probe sample as appropriate and evaluate any assumptions regarding the data under review.
 - Estimate the error in the population. Explain your estimate in the context of your statistics!



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Extrapolation 101

- Variable vs Attribute Sampling

VARIABLE SAMPLING	Variable sampling is used when estimating something that can be quantified (that is, the measurement is on either the interval or ratio scale such as height or dollar value). This measurement is known as a variable.	Dollar Amount (A range of values)
ATTRIBUTE SAMPLING	Attribute sampling is used when determining what percentage or proportion of the population has the characteristic we are interested in. Either the sampling unit has the characteristic, or it does not.	Number of Errors (Yes or No)

- Attribute sampling can be used when the dollar error is always the same (\$50 error or no error).
- Examples in our presentation today focus on dealing with variable errors.



Using Statistical Sampling, GAO, May 1992

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Extrapolation 101

- Statistics terms you need to know:
 - **Sampling Frame:** The population we will evaluate.
 - **Sampling Unit:** The description of the individual “item or characteristic” under review – claim, claim line, beneficiary.
 - **Sample Size:** The number of sampling units needed to evaluate the sampling frame.
 - **Probe Sample:** Initial sample from the sampling frame used to estimate error rates and standard deviation of the characteristic under review, useful for optimizing the sample size. May be used in the full sample if drawn from the first set of items in random number assignment. Generally, 30 to 50 items.



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Extrapolation 101

- Statistics terms you need to know:
 - **Confidence:** The confidence (80%, 90%, 95%) associated with the ability of the corresponding interval to contain the true mean or universe total. Higher is better. (*Generally, HHS OIG Advises using a 90% Confidence Level.*)
 - **Precision Percentage:** The result of dividing the precision amount by the point estimate and stating the result as a percentage. Lower is better. (*Generally, HHS OIG advises to strive for a 25% precision when developing sample sizes. Actual results from the audit of samples will vary and need to be evaluated based on the circumstances.*)



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Extrapolation 101

- **Example conclusion regarding a population:**
 - With 90% confidence the overpayment is between \$50,419 and \$67,411 with a precision of 14.42%.
 - The point estimate would be \$58,915 and the lower and upper boundaries above calculated as follows:
 - Precision of 14.42% x Point Estimate of \$58,915 = \$8,496
 - \$58,915 less \$8,496 = \$50,419
 - \$58,915 plus \$8,496 = \$67,411



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Extrapolation 101

- The relationship between Confidence and Precision:
 - Assuming everything else is held constant – as the desired confidence level increases – say 90% to 95% - the precision will be less – 14% to say 30% - resulting in a larger interval.
 - With 90% confidence the overpayment is between \$50,419 and \$67,411 with a precision of 14.42%.
 - With 95% confidence the overpayment is between \$76,589 and \$41,240 with a precision of 30%.



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Extrapolation 101

- The relationship between Error Rate and Sample Size:
 - Assuming a universe of 1000 items and standard deviation of 100 the following was produced by RAT-STATS for 90% confidence and 25% precision:
 - 1% error rate estimate requires sample of 906
 - 5% error rate estimate requires sample of 654
 - 25% error rate estimate requires sample of 256
 - 75% error rate estimate requires sample of 79



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Extrapolation 101

- The impact of **Standard Deviation** on **Sample Size**:
 - Assuming a universe of 1000 items and estimated error rate of 25% the following was produced by RAT-STATS for 90% confidence and 25% precision:
 - Standard deviation of 50 requires sample of 155
 - Standard deviation of 100 requires sample of 256
 - Standard deviation of 150 requires sample of 379
 - **Standard Deviation:** A measurement of the variation or homogeneity of the sample items about the average value (mean).
 - *A smaller standard deviation allows for smaller sample sizes and greater precision (smaller precision percentage).*



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Extrapolation 101

- **Simple Random** vs **Stratification** vs **Cluster Sampling**
 - **Simple Random:** All items have an equal chance of being sampled and are selected from one overall “batch”
 - **Stratification:** All items have a chance of being selected, but they are sorted into different “strata” and each strata may have different weightings regarding the number of items to be selected
 - **Cluster:** All items are sorted into clusters and only certain clusters are randomly selected for review. The items with the selected clusters are randomly sampled.



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Authoritative References

- OIG – Provider Self Disclosure Protocol
- OIG – RAT-STATS – Statistical Software
- MAC Overpayment Websites
- HHS OIG – *Statistical Sampling: A Toolkit for MFCUs*
- CMS – Medicare Program; Reporting and Returning Overpayment – Federal Register
- Just Ask! – Your Statistician, Consultant, Counsel, Compliance Officer, OIG Email RATSTATS@oig.hhs.gov



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Repayment and Extrapolation Standards

- Decisions on overpayment amount
 - When do I not need to make a repayment?
 - When should I make a repayment?
 - If I am making a repayment, do I use the lower bound or mid-point?



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Reporting Options

- CMS – Self-Referral Disclosure Protocol (“SRDP”)
 - Stark law violations only – Likely not applicable to most incidents
- MAC - Overpayment Report and Return
 - Technical billing violations
- OIG – OIG Provider Self Disclosure Protocol (“OIG-SDP”)
 - Anti-Kickback, Civil Monetary Penalties, Stark Law
- Department of Justice (“DOJ”)
 - Conduct may create liability beyond the authority of just CMS or just the OIG



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Repayment and Extrapolation Standards

- Refunding Federal Health Care Program Overpayments
 - Extrapolation permitted
 - Must describe the statistically valid sampling and extrapolation methodology
 - Must retain audit and refund documentation in the event that a Medicare contractor or the OIG audits claims that the provider or supplier believes have been previously refunded



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Repayment and Extrapolation Standards

- CMS “will not recover an overpayment twice,” but does not intend to exempt from subsequent audit by CMS, a CMS contractor or the OIG any claims that form the basis for a returned overpayment
- No materiality threshold and cannot offset underpayments against overpayments for purposes of calculating a net financial error rate, which then is used to determinate whether a sample review must be expanded to a larger review



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Repayment and Extrapolation Standards

- MAC Standards
 - Require the methodology to be disclosed – example from a MAC voluntary submission form: “If specific patient/Health Insurance Claim Number (HICN)/claim number/claim amount data not available for all claims due to statistical sampling, please indicate methodology and formula used to determine amount and reason for overpayment.”



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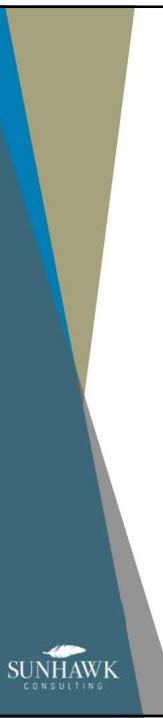
Repayment and Extrapolation Standards

- OIG Self-Disclosure Protocol
 - When using a sample to estimate damages, the disclosing party must use a sample of at least 100 items and use the mean point estimate to calculate damages. If a probe sample was used, those claims may be included in the 100-item sample if statistically appropriate.
 - The SDP does not require a minimum precision level for the review of claims so long as sample size 100
 - Note, in its Corporate Integrity Agreements, OIG recognizes a materiality threshold by permitting the offset of underpayments to overpayments for purposes of calculating a net financial error rate, which then is used to determinate whether a sample review must be expanded to a larger review. Offsets are not a part of the self-disclosure protocol.



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Recent Updates and Perspectives



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OIG Self-Disclosure Protocol Examples

- 08-19-2020:

- After they self-disclosed conduct to OIG, St. Vincent Hospital (SVH) and MetroWest Medical Center (MetroWest), Massachusetts, agreed to pay \$41,495.36 for allegedly violating the Civil Monetary Penalties Law.
- OIG alleged that SVH and MetroWest, through a contractor, employed an individual that they knew or should have known was excluded from participation in Federal health care programs.

How might extrapolation apply to this example?



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OIG Self-Disclosure Protocol Examples

- 08-11-2020:

- After it self-disclosed conduct to OIG, VHS San Antonio Partners, LLC, d/b/a St. Luke's Baptist Hospital (St. Luke's), Texas, agreed to pay \$232,200 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks.
- OIG alleged that St. Luke's paid remuneration to two physicians in the form of a disproportionate amount of compensated orthopedic surgery emergency on-call coverage.

How might extrapolation apply to this example?



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OIG Self-Disclosure Protocol Examples

- 08-27-2019:
 - After they self-disclosed conduct to OIG, Wellmont Health System and its wholly owned subsidiaries Wellmont Medical Associates and WPS Providers, Inc. (collectively, "Wellmont") and Medical Education Assistance Corporation (MEAC), Tennessee, agreed to pay \$851,061 for allegedly violating the Civil Monetary Penalties Law.
 - OIG alleged that Wellmont and MEAC submitted false or fraudulent claims for the professional services of a trauma surgeon that did not comply with teaching physician requirements because the medical record did not support that he was personally present during the key portion of the procedure or service.

How might extrapolation apply to this example?



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False Claims Act - Consequences

- False Claims Act
 - \$11,000 - \$23,000 per claim penalty
 - Treble (3X) damages
 - For example: Imaging center runs 100 x-rays ordered by a physician who did not have a medically necessary reason for ordering them
 - OP reimbursement of \$229 per test
 - + (\$22,900 for overpayment x 3) = \$68,700
 - + (\$11,000 for penalty x 100) = \$1,100,000
 - = TOTAL \$1,168,700
- Repayment of Government's cost in bringing the action
- Exclusion from Federal Programs or Corporate Integrity Agreement



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Qui Tam Action - Whistleblower

- Whistleblowers can bring an action on behalf of the Federal Government
- Filed under seal so the Federal Government can review and decide to intervene
- Typically, if successful, whistleblower is awarded 15% - 30% of Government's recovery
 - Huge financial incentive
 - Typically stems from disgruntled, prior employee
- Lawsuit precludes self-disclosure as an option
- Cost of defense if the Government intervenes is high



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False Claims Act – Statute of Limitations

Cochise Consultancy Inc. v. United States, ex rel. Hunt (2019)

- Two limitations periods. (31 U. S. C. §3731(b)).
- The first period requires that the action be brought within 6 years after the statutory violation occurred.
- The second period requires that the action be brought within 3 years after the United States official charged with the responsibility to act knew or should have known the relevant facts, but not more than 10 years after the violation.
- Whichever period provides the later date serves as the limitations period



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Other Considerations

- What reimbursement model are you operating under?
 - Critical Assess Hospital (CAH) vs Prospective Payment System (PPS)
- How are beneficiary co-payments and deductibles accounted for?
- If a risk adjustment matter, what issues may be involved?



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Other Considerations

- Can the extrapolation take underpayments into consideration?
 - Claims refunds?
 - Extrapolation refunds?
 - MAC submission
 - OIG self-disclosure



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Other Considerations – Legal Support?

- During initial audit
 - Attorney-Client Privilege may attach to results
 - Attorney review may limit “knowledge of...”
- When determining how to report
 - Advise regarding pros and cons per legal principles
 - Obtain anonymous direction
- When making a report
 - Advise regarding settlement options



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Drivers of Efficient and Diligent Analysis



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Top 3 Extrapolation Myths

- Extrapolation is always more efficient than full review
- Sample stratification can be used to reduce overpayments
- Must always use original sample size estimate or OIG minimum of 100 claims



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Top 3 Extrapolation Myths

- Extrapolation is always more efficient than full review
 - May be easier to review actual claims
 - Just as time consuming to gather and analyze the data for sampling
 - Data analysis may be just as valid as chart review
 - Consider interviews and other process reviews to assist in defining scope of issue



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Top 3 Extrapolation Myths

- Sample stratification can be used to reduce overpayments
- The sampling approach should be selected to be most efficient at addressing the objective of the study.

Example Appraisals Using the Same Data	Point Estimate	Lower Boundary	Precision	Sample Size Medicare	Sample Size Non- Medicare
Large Simple Random	\$113,803	\$49,998	56%	93	7
Large Stratified	\$113,816	\$50,527	56%	93	7
Small Simple Random	\$116,031	(\$6,972)	106%	30	7
Small Stratified	\$121,660	(\$14,648)	112%	30	7



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Top 3 Extrapolation Myths

- Must always use original sample size estimate or OIG self-disclosure protocol minimum of 100 claims
 - Probe samples help understand the data
 - Once evaluated, a smaller sample may be sufficient
 - Once evaluated, a smaller sample may indicate that the economics of your initial sample size estimate are not feasible
 - The OIG self-disclosure process may not apply



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Recommendations for Efficient Extrapolation

- Carefully evaluate the scope of the review
 - Is the issue systemic or isolated?
 - Is the issue payor specific or across all payors? Secondary payors?
 - Is the issue related to a specific individual or individuals?
 - Is the issue related to an office, location, system, employee type, charge type, patient type?
 - Where in the flow of transactions did the issue occur – reception, billing, data entry, data transformation, data transmittal?
 - What data retrieval, chart collection, audit tasks will be overly burdensome?
 - What is your reimbursement model – fee-for-service, value based, risk adjustment, cost reimbursement, prospective payment system?



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Recommendations for Efficient Extrapolation

- Educate data gatherers regarding goals and objectives of data extraction
 - Ensure the data elements needed for ultimate reporting are obtained
 - Ensure the data elements needed to transform the data into the sampling frame are obtained
 - Ensure the data elements needed to pull the transactions are obtained



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Recommendations for Efficient Extrapolation

- Communicate internally regarding the process
 - Multiple departments may be needed in the data gathering and data analysis process – include them early on



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Recommendations for Efficient Extrapolation

- Determine the confidence and precision intervals early on
 - What type of issue are you dealing with?
 - Will self-disclosure to OIG be considered?
 - Is this simply a MAC repayment?
 - Are there non-governmental repayments involved?



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Recommendations for Efficient Extrapolation

- Document all decisions with rationale
 - There are different approaches to addressing any issue.
 - Document why you chose the path you took.
 - Note consideration of different approaches.
 - Provide context as needed regarding your decision.



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Recommendations for Efficient Extrapolation

- Include your consultants, statistician, legal counsel, compliance officer early in the process.
 - Prior to concluding on the nature of the error.
 - Prior to deciding on the type of sampling to perform (simple random, stratified, cluster...).
 - Prior to pulling any data to use in the sampling process.
 - Prior to performing any file audits (beyond those few necessary to confirm a concern).



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Summary Considerations

- General guidance, specific facts and circumstances may be valid reasons to adjust your approach.

Concept	OIG Self-Disclosure	MAC
Minimum sample size	100	Not Specified
Confidence interval/precision	Not Specified	Not Specified
Consideration of underpayments	No	Yes
OTHER?		



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Summary

- The most efficient approach may not be the most obvious.
- Be sure to fully understand the coding and billing process in order to fully anticipate the data that needs to be extracted for the review.
- Ensure your data staff, consultant, compliance lead are on the same page regarding the project objectives before pulling any data.
- Involve your statistician / consultant early in the process.
- Involve your compliance / legal counsel early in the process to access the nature of the issue, the type of disclosure, and repayment that needs to be made.



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Questions?

- Chad Eckhardt, Attorney at Law, Frost Brown Todd, LLC
- James Rose, Managing Director, SunHawk Consulting LLC

