Strategic Management
Next Generation Compliance

RAT-STATS and Sampling:
Strategies for
Auditing and Government Enforcement Activity

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Statistical Audits & Enforcement

- Extrapolation and Sampling are Hot Topics
- Attention to extrapolation and sampling mostly in the context of Medicare fee-for-service and MIP
  - Recovery Audit Contractors (RACs)
  - Zone Program Integrity Contractors/ Program Safeguard Contractors (ZPICs/PSCs) and Benefit Integrity Units
  - Review MICs/Audit MICs (Medicare Integrity Contractors)
- General sampling and audit concepts, however, apply to any entity, including Managed Care Plans
- Many Audit Objectives, such as:
  - Claim based audit and overpayment
  - Enrollment application or eligibility status audit
  - Marketing compliance and targeted verification
  - Patient or member satisfaction audits
  - Arrangements review for conflict of Interest
  - LEIE screening compliance

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Strategies Using Sampling and RAT-STATS

- **Self-Assessment Audits**
  - Use as part of an effective Compliance Program with an pro-active Auditing and Monitoring element
  - Use to prevent recovery audits and enforcement activity aimed at your facility
- **Self Disclosures to OIG and CMS Contractor**
  - Overpayment projection must follow standards accepted by contractor or OIG
- **Government Enforcement Activity**
  - Fair Play/Transparency
  - Efficient Enforcement for all parties
  - Redetermination/Appeal Strategies
    - First line of defense
    - Verify and assess, and re-assess exposure
  - Assess secondary exposure

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Enforcement Environment

- **HEAT: A renewed commitment to expanded data sharing and improved information sharing procedures between HHS and the DOJ**
  - With the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT), fighting Medicare fraud has become a Cabinet-level priority for both DOJ and HHS.
    - Use of new state-of-the-art technology to fight fraud
    - Increased funding to help strengthen HHS's ability to monitor Medicare Parts C & D (Medicare Advantage and Prescription Drug benefit) compliance and enforcement
    - Expand DME enforcement
- **New Contractors & Sophistication turn up the heat**:
  - MAC, RAC, PSC/ZPIC, MIC
  - Increased use of data mining for *automated* reviews and pattern analysis that may lead to *complex* reviews
    - Hospitals, physician practices, nursing homes/SNF, DMEs, are receiving demand letters, etc
    - Medical Necessity/Chart Reviews
    - If Statistically Valid Random Sample, projection possible

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RAT-STATS & Enforcement

- **Attention to extrapolation now in fee-for-service Medicare & MICs but certain principles apply to any auditing and investigation based on sampling**
- **Statistical Tool of Choice: RAT-STATS**
  - Contractors & MMA 935 Audits
    - Sets forth guidelines for PSC/ ZPIC BI units and contractor MR units guidelines for statistical sampling when it has been determined that sustained high level of payment error exists (see, CMS Medicare Program Integrity Manual, Chapter 3)
    - Requires probability sampling
  - OIG Self-Disclosure Protocol (SDP) for Providers
  - Disclosures by providers to MAC
  - RAT-STATS is used and recommended for use in sampling and projection
- Be aware of it!
- Note: SAS, SPSS also reputable packages

RAT-STATS & Enforcement

- **Limitation on Use of Extrapolation Pursuant to Section 935 of MMA:**
  (1) 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.[70]*

- **CMS guidelines for statistical extrapolations are set forth in the Medicare Program Integrity Manual**

- **(CMS Pub. 100-08, Chapter 3, §§ 3.10.1 through 3.10.11.2).**
- **Challenges to Statistics**
  - If an extrapolation is flawed, it may be successfully challenged, bringing the total dollars at issue to the "actual" alleged overpayment, and not the extrapolated alleged overpayment!!!
  - **This is true for Medicare/Medicaid and any other payor or plan**

What is RAT-STATS?

- **Features and Background**
  - Free Statistical Software from HHS OIG
  - Statistical Sampling Tool
  - Statistical Estimation Tool
  - Created by the HHS OIG and recommended for
    - Self Disclosure Protocol
    - Disclosure to a CMS Contractor
    - MMA 935 Claim Accounts Receivable Audits
  - Pros and Cons
    - Free & Approved
    - Sampling Replicable
    - Sample Amendment Possible
    - Estimation Complex
    - Statistical expertise
    - Version Issues

Basics of Sampling -Samples

- **Samples- types and sizes**:
  - Sample, Random Sample, Probability Sample
  - Statistically Valid Random Sample (SVRS)
  - Attribute Sampling
  - Variable Sampling (dollar sampling)
  - Simple random sample and stratified sample
  - OIG: Probe Sample (30), Discovery Sample (50), Full Sample (?)
  - CMS: "Probe Reviews" probe sample (20-40) & post-payment sample for systemic problems 100+

- **SVRS**:
  - Must be replicable to be verifiable
  - Random numbers (software or tables) ->RAT-STATS

Basics of Sampling - Validity

- **Statistical Validity and Size - Unrelated**
  - CMS Medicare guidelines (CMS Pub.100-08 Chapter 3 Section 10.2):
  - *If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid."*
  - *A feature of the probability sample is that the level of uncertainty can be incorporated into the estimate of overpayment...*

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Error Rates - Differences

- Error Rate – Occurrence Rate
- Financial Error Rate – Overpayment Rate
  - If Financial Error Rate > 5% in Discovery Sample, then Full Sample and System Review
  - OIG in CIAs: 5%
- Example
  - Net of under payments

Universe	Sample	Sample Payment	Sample Overpayment	Claims with Error	Error Rate	Financial Error Rate
1000	50	10,000	4500	15	30%	45%
1000	50	10,000	450	15	30%	4.5%

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Basics of Projection/Estimation

- **Extrapolation Issues**
  - Variable and Attribute Appraisal
  - Point Estimate and Bounds/Limits
  - Confidence Interval
    - One Sided and Two Sided (RAT-STATS)
  - HHS Standards
    - OIG in SDP: Point Estimate with 90% Confidence/ 25% Precision -Two Sided
    - CMS: Lower Limit of 90% Confidence Interval - One Sided (better for target, lower than Point estimate)

Sampling Strategies for Auditing

- **Objective Issues**
- What is your prime audit objective
  - 1) Is a criterion met: Yes/No questions?
  - 2) How much money is paid/received in error?
- The main objective will dictate appropriate type of sampling and error rates to use and report
- For SDP/Recovery Audits/Re-determination it is mostly the second objective

Sampling Strategies for Auditing

- Define your objective (dollars/occurrence) and integrate preliminary knowledge
- Select and document universe assembly
  - Scope and implied exposure issues, don't make it worse!
- Document sampling process, including random numbers
- Determine your sample unit
  - Entire claim, line item, patient name, patient account MRN, member name, facility
- Determine sampling size using statistical method appropriate for objective
- Start with a Discovery Sample or Probe Sample
- Check if Discovery Sample can serve as Full Sample
- Stratify only if there is a gain in efficiency of estimation, keep it simple
- Watch discrepancy between low *financial error* rate and high error rate!
- Use probe samples in routine auditing & monitoring
- If external auditor is engaged, ask for proposed methodology and if phased approach is possible

Sampling Strategies for Disclosure

- Get help from legal counsel and statistical expert
- Watch scope and exposure, there is inherent risk
- Begin with a Discovery Sample
- Beware of the Spare
- Design Full Sample to comply 90% confidence & 25% precision level requirements
- Document every step
  - Written Sampling Plan
  - Universe, Sample, Random Numbers
  - Software used, estimator used if manual
  - Estimation output from software such as RAT-STATS, SAS, SPSS etc
  - Mind resource and time estimates and qualifications of personnel
- Ask yourself, can this be replicated exactly?

Enforcement /Response

- **MMA and Medicare Guidance Clarify Limitations**
- The MMA sets limits regarding when statistical extrapolation may be used. Medicare manuals establish guidelines for CMS to follow when performing an audit based upon a statistical sample. If an extrapolation is flawed, it may be successfully challenged, bringing the total dollars at issue to the "actual" alleged overpayment, and not the extrapolated alleged overpayment.
- Pursuant to Section 935 of the MMA:
  - *(1) 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.*
  - CMS guidelines for statistical extrapolations are set forth in the Medicare Program Integrity Manual (CMS Pub. 100-08, Chapter 3, §§ 3.10.1 through 3.10.11.2).
- An invalid sample would make a projection a "flawed" extrapolation.   How do we know the sample is valid? We can verify! Replication, replication, replication. This is true for any contractor, audit, investigation!

Enforcement /Response

- **When Demand Letter/Recovery Audit or Other Government Audit or Investigation Happens – What About Statistics:**
  - Have a coordinated response strategy involving all applicable departments and document and track all responses back to government
  - If sampling is involved, it is most important that the sample is **valid** in order for it to support any estimation or projection.
  - All too often, this aspect of verification is set aside in the early phases of the defense strategy and immediate focus becomes re-analyzing the claims for medical necessity or compliance with other documentation and coverage, or eligibility requirements.
  - Maybe looking into the statistics and estimation methods is outside the provider's or plan's and attorney's immediate comfort zone and expertise, and hence initially given lower priority.
  - Maybe a strategic mistake. ***A simple rule to remember is that if a sample is not valid, any projection is invalid and hence not owed with good reason.***
  - Lack of confirming a valid sample is the easiest and fastest step toward rebuttal and appeal. Stop recoupment.

Enforcement /Response

- **When Demand Letter/Recovery Audit or Other Government Audit or Investigation Happens – What About Statistics:**
- Both Statistical and Medical Documentation/Eligibility Requirements Matter
- Request for Information:
  - Transparency of what underlies any findings and request can be expected – goes to fairness
  - Ask for clarification and documentation to understand what underlies what is being requested
  - Sampling Plan and Audit Objective
  - Sampling Frame
  - Sampling Unit
  - Universe
  - Random Numbers
  - Sample Selection Process/Software used with exact specifications
  - Period of Review
  - Estimator for Overpayment, Estimate and Confidence Interval Information
- Conduct a Verification Audit to Replicate the Result – 3 Steps:
  - A professionally documented report by the government auditor should make this straightforward.
  1. Verify the Validity of the Sample
  2. Verify the Validity of the Criteria Applied against regulations/coverage and eligibility criteria (sample unit by sample unit)
  3. Verify the Estimate "as is" and "revised", if disagreement.

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Things to Consider -Summary

1. Don't assume statistical portion of the government audit is necessarily correct and justifies the recovery amount.
2. Request sampling plan to ensure the government contractor had a sampling plan when designing the sample.
3. Request random numbers and information on random number generator used.
4. Ensure the random sample numbers can be regenerated and matched with the selected claims, i.e., the sample used was a valid probability sample.
5. Ensure the claims universe is properly assembled and consistent with the sampling frame.
6. Verify the confidence interval, point estimate and upper and lower bounds of the overpayment estimate can be confirmed using RAT-STATS estimation.
7. Verify that the lower limit estimate of 90% confidence level was calculated and can be confirmed using appropriate statistical formula for variable sampling.
8. Assess whether lower limit is the basis of the recovery amount demanded, and if not aim for this, instead of the point estimate, in any settlement negotiations.
9. If the sample is found invalid for reasons of lacking documentation or evidence of mismatches and inconsistencies, consider drawing your own statistical sample to self-assess and get a sense of what the underlying claims overpayment risk really is.
10. If the government's sample is found valid and confirmed, examine claim by claim.
11. Reanalyze claim by claim using an independent auditor with appropriate credentials and credibility. If the overpayment analysis on a sample claim-by-claim analysis refutes the government auditor's sample results, re-estimate using RAT-STATS for the point estimate and appropriate statistical formula for the lower limit.
12. Ensure that any response to a demand letter/overpayment resolution that is based on sampling incorporates statistical aspects and expertise.

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