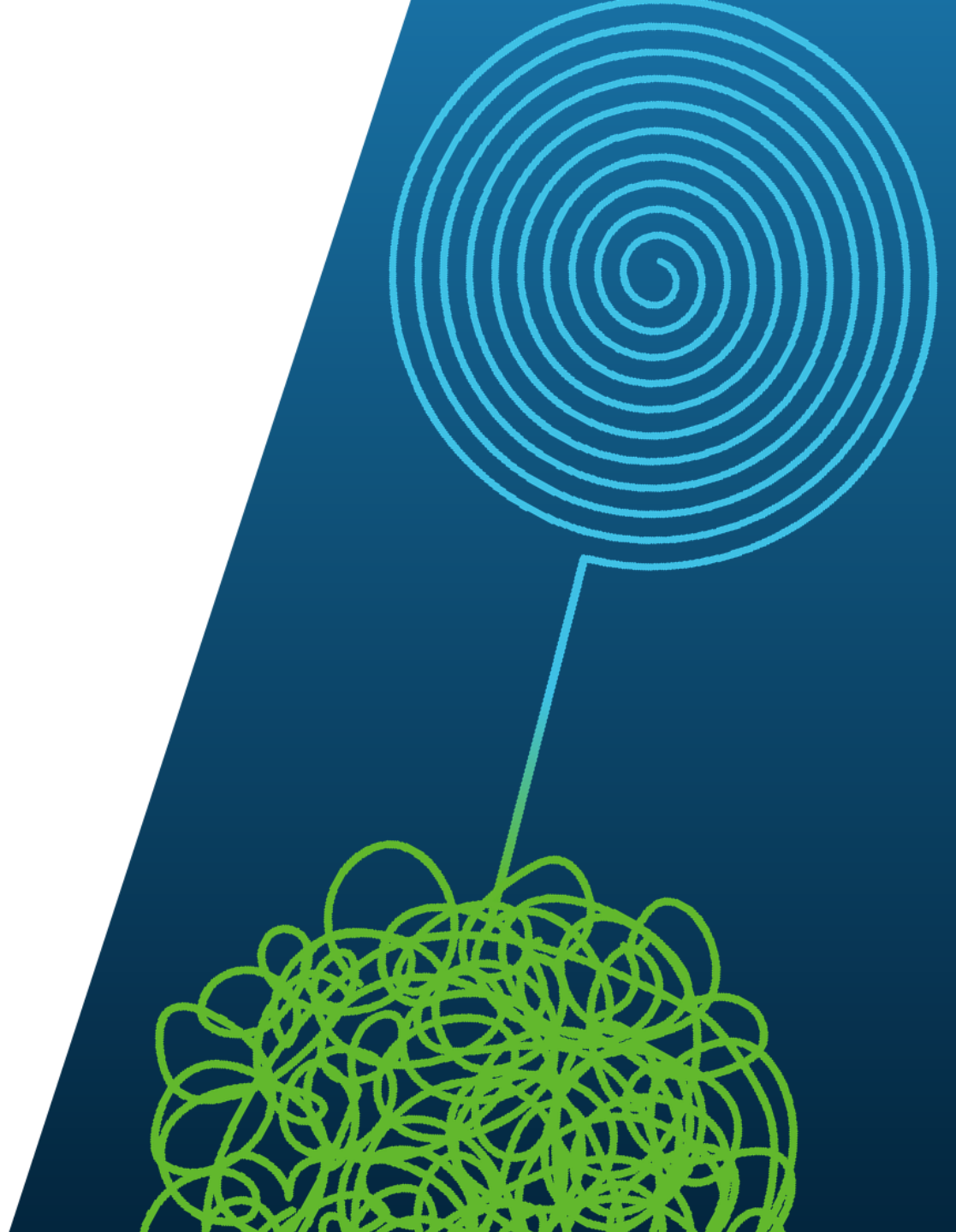
Healthcare Regulatory Roundup #108

How to Mitigate Risk While Auditing for Revenue Integrity:

Sample Design, Interpreting Results, and Navigating Compliance Next Steps

February 4, 2026



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Introductions



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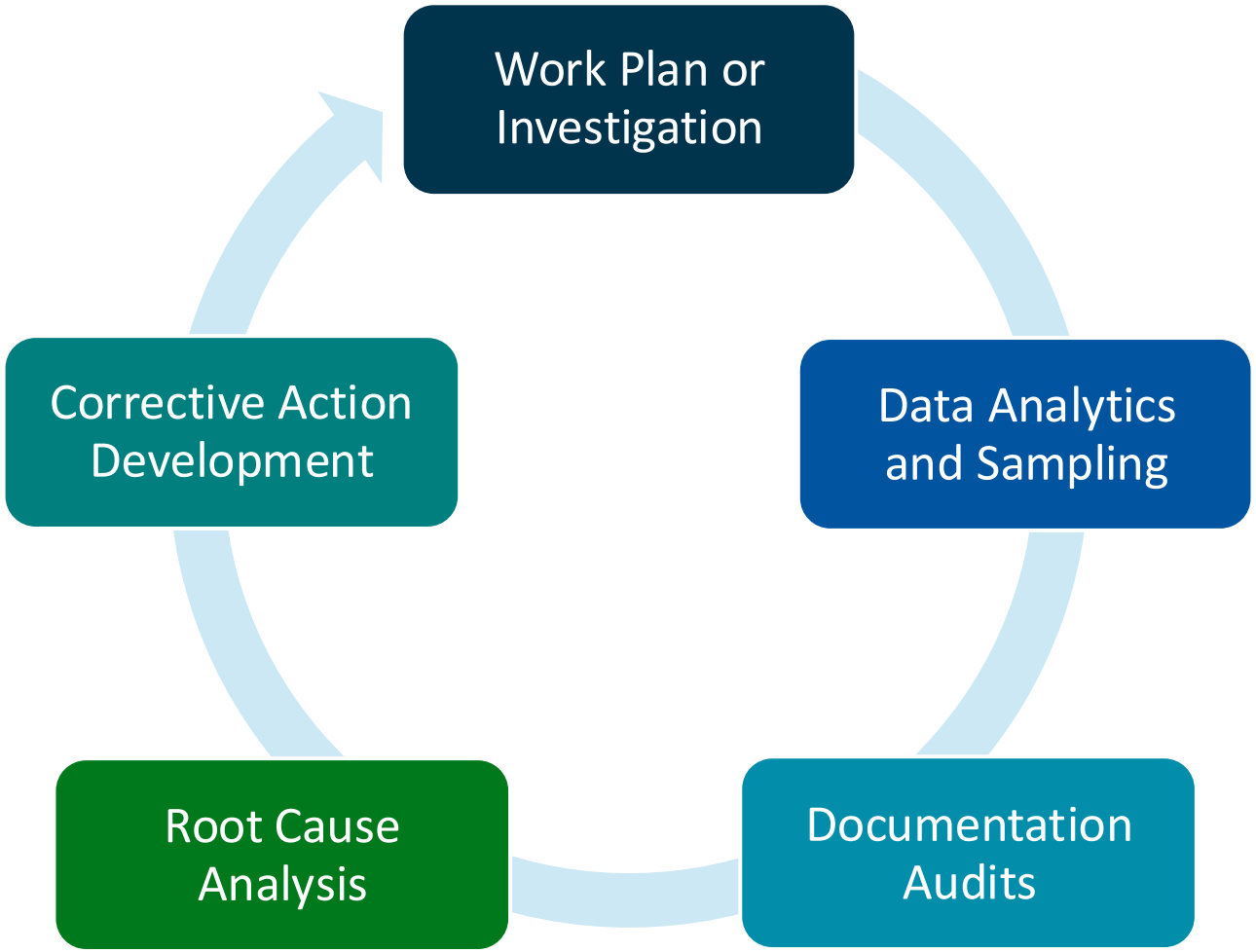
Today's Agenda

1. The Auditing and Monitoring Cycle
2. Overview of Statistical Sampling for Non-Statisticians
3. The 60-Day Rule

1. The Auditing and Monitoring Cycle

Cycle of Coding Auditing



“Good Faith Investigation” – Reasonable Diligence

- Define review purpose and key questions
- Draft audit description and determine scope (documents, codes, time period)
- Identify impacted departments and estimate required hours/capacity
- Preserve all notes and materials; maintain confidentiality throughout
- Document discussions, analysis, and rationale clearly and consistently
- Engage stakeholders to clarify processes and refine audit scope
- Assess variability across locations, providers, or facility types
- Confirm applicable regulatory and legal requirements

Data Analysis and Risk Assessment – Internal vs. External Data

Internal Data

- **Benchmark and review:**
  - E/M Bell Curves
  - Procedures (high use of at-risk procedures)
  - Modifiers based on percentage frequency
    - Consider what codes are being edited
  - wRVUs (productivity) across a department

External Data

- **Publicly reported data**
  - Highest utilizers of codes or modifiers are targets for audits
- **OIG, CMS, CERT, RAC enforcement on similar issues**
- **Recent CIAs relevant to issue**
- **Comparative Billing Reports (CBRs)**
  - See national and state results

Data Requests

- Determine what data is needed to be requested from Analyst
  - Include all data needed by Medicare for refunding on the front end if possible (HICN, etc. – see refund form)
- Cleaning data and understanding it
  - What type of file was received?
    - Transaction? Payment?
  - What do each of the column headers mean?
  - Does the data include any elements that should not be included in the audit?
    - Secondary payers?
  - Remove zero paid claims, unless the study is for another purpose
  - Remove duplicate payments, but confirm that the report is not duplicating total payments across all transaction lines

Data Requests (*cont.*)

Is the data missing elements needed?

- Modifiers
- Rendering vs. billing provider
- Payer
- Payment
- Location of service or POS

Validation of data

- Do additional filters need to be applied or is the data over filtered?
- Does the data make sense compared to what you thought you would see per interviews?
- Is there a frequency report that could be run to validate the count?
- Is the date range correct?

Data analytics from other systems

- E/M Bell Curves

Documenting Data and Sampling

1. Name of each data file

2. Parameters of the original data or any data requested

3. Removal of non-applicable data:
   - What are the characteristics and count of the data removed?
   - **Best practice:** show waterfall of claims

4. Sampling Unit and how it was identified

5. Sampling Frame: Sorting method and how the data was randomized

   Tip: *address bias, do not sort by name or DOS*

6. Limiting Criteria: Rationale for narrowing the data and the scope at each step in the process

   Tip: *This is the information needed in the methodology report*

Sampling



- Probe audits
- Audits for refunding/SVRS
- Categories:
  - Physician/facility
  - Service type
  - Location
  - Coder

Probe Audit

- Not statistically valid
- Can be cherry-picked
- Avoid claims with guidelines which are highly subjective – may be determined after review
- Avoid services that have a very small volume
- Identify high-risk areas for review (enforcement, volume, and payment)
- However, if a low error rate threshold established, consider random sampling to allow for an appropriate balance of the correct and incorrect claims
- Identify universe – intended to be used for Expanded Audit
- ***BUT*** probe is intended to be learned from and will help confirm the appropriate universe of claims and help eliminate claims (or other units) with no issues

Probe Audit (*cont.*)

- Goal is to be **narrowly targeted**
  - Decreases scope creep
  - Decreases opportunity to overstate dollars in error
- Universe and Sampling Frame
  - Consider:
    - Certain services, providers, codes
    - Timeframe when the activity that led to the error started or 6 years, and stopped
    - Payer: to be confirmed by Compliance and Legal

- **Tips and risks for probe auditing:**
  - The goal is to identify a high and sustained error rate
  - PIM used to state 50%, which is a coin toss, statistically, 70, 80, 90% provides a more accurate outcome
  - Statistically significant: typically, 30 – 50 sampling units

Documentation Audits

- Review of medical record relevant to the unit of measure defined in sample
  - Date of service, encounter, code, patient course of treatment
- Make separate or margin notes on other issues seen that may require further analysis, but assess and record findings for in-scope review uniquely
- Quantify the claims error rate and the financial error rate

EHR Use in Audit

- Ask department for location of placement of certain documents if not readily found
- Confirm whether templates, set-up of the workflow, charge capture, auto-generated documentation, or billing set-up is part of the root cause of the error



Confirm Criteria/Elements to Audit in Scope

Correct medical record	Date of service	Place of service
CPT, HCPCS, ICD-10-CM, Revenue Code assignment	Modifier	Documentation support for codes billed
Medical necessity per LCD/NCD/MUE	ABN, if applicable	Insurance paid as per data

Audit Report Spreadsheet

- Use approved audit tool for recording applicable claims data and audit findings
  - Claims detail with code submitted
  - Audited code and reason for any deficiencies
    - Use the same language for the same issue every time
  - Insurance primary payments
  - Estimated correct payment
  - Calculated error rate
  - Note: upload results to audit tracking tool and verbally communicate findings to Compliance Officer
  - Tip: mark all documents DRAFT until confirmed by appropriate stakeholders (Manager, Director, Compliance Officer), and only mark as final once calculation of errors have been approved
  - Preliminary observations are sent to stakeholders with only relevant observations shared with each stakeholder.
    - Exception: If expanded audit is warranted, verbally communicate observations

What Is the Error Rate Telling Us?

Claims error rate vs. financial error rate

Concentration of errors in universe

Compare sample and errors to universe of claims

How subjective are the results?

What operational processes are associated with the error?

Moving to Next Steps

Probe exceeding threshold may require an Expanded Audit

Claims in probe which were found to be in error should be refunded within 60 days of calculation

If moving forward to expanded audit, remove probe claims from the review

Expanded Audit

- Statistically-valid random sample
  - Use of RAT-STATS or similar program
  - Statistical methodology requires an anticipated rate of occurrence
  - Therefore, a probe sample is recommended to establish that rate for each Expanded Sample

2. Overview of Statistical Sampling for Non-Statisticians

Statistical Sampling Methodology

- Expect decision whether to do extrapolation to be scrutinized closely.
  - "After finding a single overpaid claim, we believe it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim."
- Sampling and extrapolation methodology must be explained in disclosure (if used).
- Sources of guidance:
  - OIG Self Disclosure Protocol
  - CMS Program Integrity Manual, Ch. 8.4, Use of Statistical Sampling for Overpayment Estimation
  - Outside statistical expert

Medicare Program Integrity Manual (MPIM)

8.4.1.4 - Determining When Statistical Sampling May Be Used

(Rev. 12127; Issued: 07-21-23; Effective: 08-21-23; Implementation: 08-21-23)

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 compared to similar service providers;
- 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);
- 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.

https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c08.pdf

MPIM: 8.4.1.3 - Steps for Conducting Statistical Sampling (Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

- The major steps in conducting statistical sampling are:
  1. Identifying the provider/supplier
  2. Identifying the period to be reviewed
  3. Defining the universe (target population) and the sampling unit, and constructing the sampling frame
  4. Assessing the distribution of the paid amounts in the sampling frame to determine the sampling design
     - It is very likely that the distribution of the overpayments will not be normal. However, there are many sampling methodologies (for example, use of the Central Limit Theorem) that may be used to accommodate non-normal distributions.
     - The statistician should state the assumptions being made about the distribution and explain the sampling methodology selected as a result of that distribution.

MPIM: 8.4.1.3 - Steps for Conducting Statistical Sampling (Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23) (*cont.*)

5. Performing the appropriate assessment(s) to determine whether the sample size is appropriate for the statistical analyses used, and identifying, relative to the sample size used, the corresponding confidence interval
6. Designing the sampling plan and selecting the sample from the sampling frame
7. Examining each of the sampling units and determining if there was an overpayment or an underpayment
8. Estimating the overpayment:
    - When an overpayment has been determined to exist, the contractor shall follow applicable instructions for notification and collection of the overpayment, unless otherwise directed by CMS.
    - For each step, the contractor shall provide complete and clear documentation sufficient to explain the action(s) taken in the step and to replicate, if needed, the statistical sampling.

8.4.2 - Probability Sampling (Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23)

- Regardless of the method of sample selection used, the contractor shall follow a procedure that results in a probability sample
- For a procedure to be classified as probability sampling, the following two features must apply: It must be possible, in principle, to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe
- Although only one sample will be selected, each distinct sample of the set has a known probability of selection
- It is not necessary to actually carry out the enumeration or calculate the probabilities
  - All that is required is that one could, in principle, write down the samples, the sampling units contained therein, and the relevant probabilities; and…

8.4.2 - Probability Sampling (Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23) (*cont.*)

- Each sampling unit in each distinct possible sample must have a known probability of selection.
- In the case of statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection:
  - The selection probabilities do not have to be equal, but they should all be greater than zero.
  - In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.

8.4.2 - Probability Sampling (Rev. 11962; Issued: 04-21-23; Effective: 05-22-23; Implementation: 05-22-23) (*cont.*)

- Once a procedure and design that satisfies these above properties has been selected, execution of the probability sampling may occur.
- If a particular probability sampling design is properly executed, i.e., defining the universe, the sampling 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 or that the resulting estimates are "not statistically valid" cannot legitimately be made.
  - In other words, a probability sample and its results are always "valid." However, because of differences in the choice of a design, the level of available resources, and the method of estimation, some procedures lead to higher precision (smaller confidence intervals) than other methods.
  - A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment.

Probability Sample Requirements

- Independent observations
  - Dependency: Multiple dates of service for the same patient
- Normally distributed
- Continuous data
- Ability to be sampled (non-zero)
- Representative
  - Does the sample represent the same percentages as the Frame
- Random selection from a random table (unbiased)

Statistical Sampling Design Process

- Known overpayment
  - Incidence of error in the probe
- Define the Universe
  - Must be numerical not verbal
- Limiting criteria
  - Define **who**, **what**, **time period**, and **how** overpayment will be measured
- Define the Frame
- Define the Sampling Unit
- Simple or stratified sampling?
  - Stratified sampling should be outsourced

Determining Sample Size for Full Sample

- Use of RAT-STATS
- Attribute vs. variable sampling:
  - Attribute sampling: Answers the question with a yes or no only
  - Variable sampling: Used to determine the average overpayment based on normal distributed data
- Rate of Occurrence
- Confidence Level: 90%
- Precision: 10%
- Frame size (number of units being sampled from)
- Sample size determined by RAT-STATS

Extrapolation

- **Appraisal performed in RATSTATs for studies claims**
  - Attribute or Variable, confirm accuracy
  - Can use error rate for other payers
- Repay claims found in error if no extrapolation is performed



3. The 60-Day Rule

Finalized Changes – Medicare Parts A and B

- In 2025, CMS finalized knowledge standard from False Claims Act
  - Overpayment has been identified when "a provider or supplier has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment"
- Finalized 42 CFR § 401.305(b)(3)
  - "a suspension of the applicable requirements for 180 days, to conduct a timely, good faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment"
- No longer ties identification to quantification
- No reference to credible evidence
- 6-year lookback maintained

60-Day Rule Changes Simplified

Through December 31, 2024

Day 1 of 180: Provider has credible evidence

Days 1 – 180: Allowance for investigation and quantification

Day 1 of 60: Overpayment identified as of date of quantification of overpayment

Days 1 – 60: Timeframe to refund overpayment

Requirements Effective January 1, 2025

- Day 1 of 60: Overpayment identified when person has knowledge of overpayment or acts in reckless disregard or deliberate ignorance
- Days 1 – 180: Suspension for up to 180 days allows for investigation and quantification; investigation period stops 60-day clock
- Days remaining in 60-day period: Restart of 60-day clock; timeframe to refund overpayment

Corrective Action

- The auditor should confirm the appropriate stakeholders with the Manager (e.g., Compliance or Director of Revenue Compliance) prior to action planning
- The relevant department (e.g., Coding Director, Clinic Manager) to create the corrective action plan and is approved by Compliance



Root Cause Analysis



Revise processes



Implement internal controls



Provide applicable staff training



Follow-up audit: recommend developing a policy for the number of failed reviews that result in disciplinary action to ensure no favoritism is perceived

- Incorporate the Corrective Action Plan into final report

Final Report



- Provided to stakeholders as appropriate
  - Include responsible party (e.g., Manager) in submission for oversight of implementation of corrective action
  - Results include root cause analysis
- Lack of adherence or change subject to disciplinary action

Ripple Effect

- Actions and events that result in payment errors can impact the **accuracy of physician compensation**, the **cost report**, and **implicate Stark and other federal and state statutes**.
- **Ensure all stakeholders consider all implications of the error.**



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Healthcare Regulatory Roundup #109:
Top 10 Compliance Risks

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