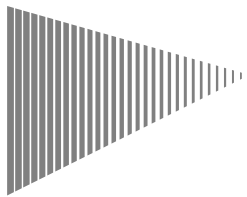


The Updated OIG Self-Disclosure Protocol and Statistical Sampling for Non-Statisticians

October 13, 2015



Health Care Compliance Association
Clinical Practice Compliance Conference

Agenda

- ▶ Enforcement Climate
- ▶ New trends in CIA Requirements
- ▶ Updated Provider Self-Disclosure Protocol
- ▶ Sampling Terms
- ▶ Demonstration of RAT-STATS Statistical Software
- ▶ When the OIG Samples

Recent Headlines

Bloomberg- BNA From [Health Care Daily Report](#) **DOJ Cites 'First of Its Kind' Settlement on Overpayments**

August 5, 2015

By Chris Marr

A home health-care provider agreed to pay \$6.88 million to resolve allegations it failed to refund overpayments from government programs, in what the Department of Justice described as a “first of its kind” [settlement](#) in an Aug. 3 announcement.

Atlanta-based Pediatric Services of America Healthcare and affiliated corporations (PSA) plus PSA's former owner, Portfolio Logic LLC, reached the joint settlement in two separate whistle-blower cases in the U.S. District Courts for Georgia's northern and southern districts, in which the U.S. and multiple states intervened. The U.S. claimed PSA failed to refund overpayments from TRICARE and the Medicaid programs of 20 states including California, Florida, Georgia, Illinois, New York and Texas between 2007 and 2013, according to the settlement agreement.

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United States ex rel. Kane v. Healthfirst **August 19, 2015**

- ▶ The Southern District of New York denied the defendants' motion to dismiss government allegations that the defendants had knowingly and improperly failed to report and return “identified” overpayments from a federal health care program, in violation of an amended “reverse false claims” provision of the civil False Claims Act (FCA).
- ▶ The court held that the federal government (and the relator) sufficiently alleged that, after the health system had been put on notice that some of the payments were likely erroneous, the health system was liable under the FCA for the “intentional or reckless” failure to take steps to report and return Medicaid overpayments in a timely manner.

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[Kusserow on Compliance: Credit balances going to the top of the high risk list](#)

Failing to reconcile credit balances and repaying overpayments has become a new and major threat to providers. Now these acts can be viewed as “reverse false claims” that could easily result in millions of dollars in penalties. The Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) mandated the report and return of overpayments within [...]

Continually Evolving Enforcement Activity

- ▶ OIG continues to enter into CIAs with providers and health systems
- ▶ Recent OIG initiatives
 - ▶ Enhanced use of data analytics to identify outliers
 - ▶ Medicare Compliance Reviews that include claims testing

OIG Medicare Compliance Reviews

- ▶ Over 100 reviews listed on the OIG website
- ▶ Hospitals at risk for noncompliance are identified through data mining and analysis
- ▶ Reviews involve on-site audits by OIG, looking at various “risk areas” for noncompliance with Medicare billing requirements and an evaluation of internal controls
- ▶ Estimates of overpayment are based on sampling and extrapolation
- ▶ First mentioned in a 2012 OIG Work Plan

Risk Areas

- ▶ Inpatient short stays
- ▶ Inpatient same-day discharges and readmissions
- ▶ Inpatient claims with payments greater than \$150,000
- ▶ Inpatient hospital-acquired conditions and present on admission indicator reporting
- ▶ Outpatient claims for intensity modulated radiation therapy planning services
- ▶ Outpatient claims billed with modifier -59
- ▶ Outpatient claims billed during an inpatient stay
- ▶ Outpatient claims for E&M services billed with surgical services
- ▶ Outpatient claims involving manufacturer credits for replaced medical devices
- ▶ Inpatient and outpatient claims paid in excess of charges

**Medicare Compliance Review- October 2014
Hackensack University Medical Center
4/1/2011 through 9/30/12**

Hackensack University Medical Center did not fully comply with Medicare requirements for billing inpatient and outpatient services, resulting in estimated overpayments of at least \$1.7 million over 1½ years.

The Hospital complied with Medicare billing requirements for 138 of the 200 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 62 claims, resulting in overpayments of \$351,580 for the audit period. Specifically, 26 inpatient claims had billing errors, resulting in overpayments of \$248,179, and 36 outpatient claims had billing errors, resulting in overpayments of \$103,401. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

**Medicare Compliance Review- February 2015
University of North Carolina Hospitals
1/1/11 through 9/30/12**

University of North Carolina Hospitals (the Hospital), located in Chapel Hill, NC, complied with Medicare billing requirements for 192 of the 251 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 59 claims, resulting in net overpayments of approximately \$452,000. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$2.4 million for the audit period. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

Medicare Compliance Review - April 2015 Florida Hospital Orlando 1/1/11 through 6/30/12

Florida Hospital Orlando (the Hospital), located in Orlando, Florida, complied with Medicare billing requirements for 121 of the 215 inpatient claims that we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 94 claims, resulting in net overpayments totaling \$494,000. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors. On the basis of our sample results, we estimated that the Hospital received at least \$11.5 million in overpayments from Medicare.

New Trends in CIA Requirements

- ▶ Expanded board requirements
 - ▶ Review and oversight of compliance program quarterly
 - ▶ Annual resolution regarding the effectiveness of the compliance program
 - ▶ Requiring annual certification from President, CEO, COO, CMO that they have received training and understand the terms and requirements of the CIA
- ▶ Increased focus on risk assessment process
 - ▶ Change in sampling approach, targeting high risk areas
 - ▶ Independent Review Organization review of minimum of 100 claims
- ▶ Entity under a CIA may be required to hire an independent monitor

OIG Updated Self Disclosure Protocol (SDP)

- ▶ Originally published on October 30, 1998
- ▶ Updated on April 17, 2013
- ▶ The SDP provides guidance on how to investigate potential fraud, quantify damages, and report the conduct to OIG to resolve the provider's liability under OIG's civil monetary penalty (CMP) authorities.
- ▶ Identified areas where additional guidance would be beneficial to the health care community and would improve the efficient resolution of SDP matters.

<http://oig.hhs.gov/compliance/self-disclosure-info/>

Why Is Disclosure Important?

- ▶ OIG emphasizes dealing with the Federal health care programs with integrity
- ▶ Legal and ethical duty to do so
- ▶ Obligation to take measures to detect and prevent fraudulent and abusive activities
 - ▶ Including implementing specific procedures and mechanisms to investigate and resolve instances of suspected fraud
- ▶ Gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation

Benefits Of Disclosure

- ▶ Good faith disclosure and cooperation with the OIG's review and resolution process are typically indicators of a robust and effective compliance program
- ▶ Individuals and entities that use the SDP and cooperate with the OIG during the SDP process deserve to pay a lower multiplier on single damages
- ▶ Using the SDP may mitigate potential exposure
 - ▶ Overpayments retained may create liabilities under the Civil Monetary Penalties Law and the False Claims Act
- ▶ OIG commits to working with individuals and entities that use the SDP in good faith and cooperate with the OIG's review and resolution process

Conduct Eligible for the SDP

- ▶ Disclosing party must acknowledge that the conduct is a potential violation
- ▶ Disclosing party must explicitly identify the laws that were potentially violated
- ▶ Prior to disclosure, the disclosing party should ensure that the conduct has ended or at least that corrective action will be taken

Required Steps for Self-Disclosing

- ▶ Conduct a review to estimate the improper amount paid
- ▶ Must conduct a review of either
 - ▶ All the claims affected by the disclosed matter or
 - ▶ A statistically valid random sample of the claims that can be projected to the population of claims affected by the matter
- ▶ When using a sample to estimate damages, the disclosing party must use a sample of at least 100 items
- ▶ If a probe sample was used, those claims may be included in the 100-item sample if statistically appropriate

Given the increased likelihood of being reviewed by the government, it is important to understand the governmental sampling process, to ensure that any repayments are calculated accurately.

Sampling Terms and Process



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What is Sampling?

Sampling

- ▶ Evaluating a small representative group of records to determine inferences on the entire population

Benefits of Sampling

- ▶ Reduce costs
 - ▶ Sampling can be extremely cost-effective ,if done correctly
- ▶ Expedite timeline

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Types of Sampling

- ▶ Statistical
 - ▶ Stratified
- ▶ Non-statistical (judgmental)

Stratification

- ▶ Strata are buckets that group records with similar characteristics or expected outcomes
- ▶ Typically have a stratum with largest dollars
 - ▶ Caution: might not be the most influential records in the sample
- ▶ Can stratify on attributes other than dollars
 - ▶ Stratify by:
 - ▶ Region
 - ▶ CPT or Dx Code
 - ▶ Payer
 - ▶ Service line or specialty
 - ▶ Facility

Stratified Sample

- ▶ Dividing the population into homogenous groups (strata) and draw a simple random sample from each group

Stratum Number	Stratum Definition	Population Size	Population Amount	Sample Size	Sample Amount
1	\$0 to \$196.99	27,512	\$ 1,701,227	30	\$ 2,035
2	\$197 to \$543.99	6,536	\$ 2,155,506	30	\$ 10,155
3	\$544 to \$1,214.99	2,793	\$ 2,227,005	30	\$ 24,079
4	\$1,215 to \$2,938.99	1,246	\$ 2,221,397	30	\$ 53,916
5	\$2,939 to \$19,999.99	363	\$ 1,920,153	30	\$ 149,796
6	\$20,000 and above	15	\$ 461,526	15	\$ 461,526
Total		38,465	\$ 10,686,814	165	\$ 701,508

Other Stratifications

- ▶ All claims paid by Medicare as primary payer
- ▶ All CPT codes in the range of 99201 though 99499
- ▶ Example by region

Stratum Number	Stratum Definition	Population Size	Sample Size
1	Northeast Region	54 Offices	20
2	Southeast Region	42 Offices	20
3	Western Region	63 Offices	20
4	Central Region	47 Offices	20
Total		206	100

Statistical Sampling vs. Non-statistical or Judgmental Sampling

Statistical Sampling	Non-statistical Sampling
Every record in the sampling population has a known, nonzero chance of selection	Sample selection may be subjective; some items may have zero chance of selection (i.e. reviewing top 80%)
A statistical sample is representative of the sampling population	Might not be representative
Estimation precision can be prescribed beforehand and quantified afterwards	Estimation precision cannot be scientifically quantified
More readily accepted by regulators	Less acceptable but still OK with some

Terminology

- ▶ Population and sample
 - ▶ **Population** is what you want to know something about
 - ▶ **Sampling population** is what you sample from and make estimates about
 - ▶ **Sample** is the subset of the population that you have randomly selected
- ▶ **Point estimate** is the statistical estimate of an amount or percentage
- ▶ **Precision** measures the noise in the estimate – how much it would change if a different sample were selected
- ▶ **Confidence interval** is a precision measure; it is a range around the estimate. If we sample repeatedly and construct confidence intervals for each sample, a specified percentage (90% or 95%) of the intervals will contain the true population value.
- ▶ **Lower bound** is the lower limit of the confidence interval.
- ▶ *OIG requires a 90% confidence level and a 25% precision*

Example from a current CIA

- ▶ Overpayment: The amount of money the Company has received in excess of the amount due and payable under any Federal health care program requirements.
- ▶ Paid Claim: A claim submitted by the Company and for which the Company has received reimbursement from the Medicare or Medicaid programs.
- ▶ Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
- ▶ Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

Assumptions Affecting Sample Size and Precision

- ▶ If designing for a specific precision, assumptions about the population impact sample size
- ▶ Let's say 80% of the population dollars are **expected** to be in error.
 - ▶ A smaller sample size will be needed to reach precision than if only 30% of the dollars were expected to be in error
 - ▶ You don't have to look as hard to find erroneous claims

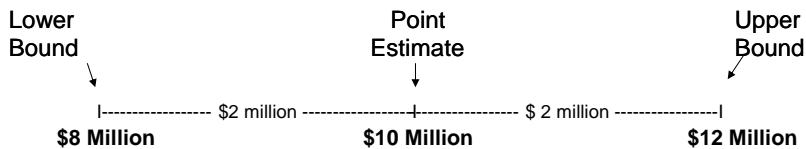
Example: It's reported that a physician is consistently using an erroneous CPT Code

Relative Precision

- ▶ Relative precision is measure of accuracy of the estimate
 - ▶ Smaller relative precision is better
 - ▶ Relative precision can be improved by increasing the sample size or by refining the population to include only those items that have a good chance of qualifying
 - ▶ It is the factor that is added to and subtracted from the estimate to create the confidence interval divided by the estimate

Confidence and Precision

Suppose an estimated value is:
\$10M plus or minus \$2M



Confidence Level: i.e., 90% or 95%

Absolute Precision: \$2 million - aka: *margin of error* or *sampling error*

Relative Precision: $\$2 \text{ million} / \$10 \text{ million} = 20\%$

Lower Bound: $\$10 - \$2 = \$8 \text{ million}$

Upper Bound: $\$10 + \$2 = \$12 \text{ million}$

Point Estimate: \$10 million

**Consideration of lower bound
impacts sample size decisions**

Requirements for Self Disclosure



Page 31 1 January 2014 Presentation title

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Requirements for Self Disclosure

- ▶ Conduct an internal investigation
- ▶ Submit the disclosure as outlined in the SDP

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Key Elements of a Sampling Plan and Report

- ▶ Sampling Unit – Define what was sampled (i.e. paid claims, billed claims or patient days).
- ▶ Sampling Frame – Define the population from which the sample was selected.
- ▶ Sample Size – Must be at least 100 for Medicare.
- ▶ Source of Random Numbers – Recommend RAT-STATS, but can use other sources (ACL or Excel).
- ▶ Method of Sample Selection– Was the population sorted first? Were random numbers assigned to the whole population?
- ▶ Sample Design – OIG guidelines recommend simple random sampling, but other designs are permitted. Details should be included in the report.
- ▶ Missing documentation – Must be treated as an error.
- ▶ **KEY: Document the exact process used**

When the OIG Samples



OIG approach

- ▶ Targeting healthcare providers who look different from others in their practice areas.
- ▶ Using stratified random samples of provider billings.
- ▶ Extrapolating sample results to the whole sampling population.
- ▶ May use sample to identify areas for more intensive review, to identify targets, or as evidence for search warrants.
- ▶ If no evidence of fraud in the sample, can shift resources to other efforts.
- ▶ The OIG may seek agreement to sampling methodology. This may allow the Company to suggest modifications.

When the OIG samples (working with the OIG)

- ▶ Involve a statistician to review the OIG sampling plan and possibly suggest options to reduce the burden.
- ▶ Some options might include starting with a probe sample to see whether it is worth continuing or randomly splitting the sample and checking after the first half is reviewed.
- ▶ Another option might be to drop small value claims.
- ▶ A statistician may be able to suggest a better stratification which can lead to a smaller sample.
- ▶ If you do not agree to the OIG's methodology, document your disagreement and rationale. The OIG may still proceed with their methodology, it but you will retain options to disagree later.

When EY samples

- ▶ Sample design – simple random samples are less efficient than stratified samples because they are larger
 - ▶ We assign random numbers to the whole population, sort by the random numbers to put the population in random order and then select the desired number of sample units.
 - ▶ Some random number generators require a starting value. We usually use something like the total dollar amount in the population. Save the random numbers.
 - ▶ Sample selection can be done in a number of ways. We sort the population by invoice number or dollar amount and then assign population numbers from 1 to the total number of units in the population. This is so the random selection can be replicated.
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Using RAT-STATS Statistical Software



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What is RAT-STATS?

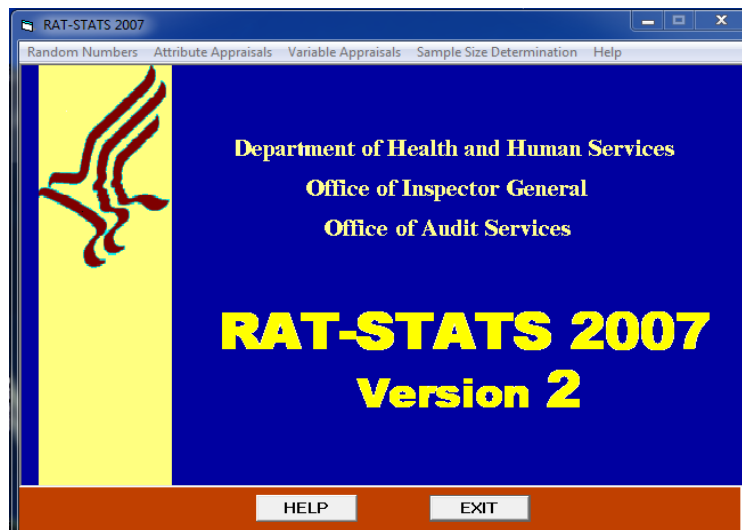
- ▶ Primary statistical tool for the OIG's Office of Audit Services
 - ▶ Created by the OIG in the late 70's
- ▶ Assists the user in selecting random samples and estimating improper payments
- ▶ OIG does not require the use of RAT-STATS. However, an active CIA contains this language....

Selection of Locations for Review. The IRO shall utilize RAT-STATS to select a random sample of 12 percent of the Company's locations.

- ▶ Many providers download the software in their efforts to fulfill the claims review requirements for corporate integrity agreements or provider self-disclosure protocol.

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To Download, visit <http://oig.hhs.gov/compliance/rat-stats/>
Website has a user guide and companion manual but the OIG does not provide technical support.

Sampling Summary

- ▶ It is vitally important to sample thoughtfully, because the sample can impact the outcome
- ▶ Sampling can be a helpful method to internally scope possible problems.
- ▶ A smaller sample can be used in the beginning and can then be expanded if a self-disclosure makes sense.
- ▶ Sampling is an important tool for quality assurance and can identify weaknesses before they become problems.

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Thank you!

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