

"Random" is Not Necessarily "Valid": Managing and Defending Against Statistics in Audits and FCA Claims

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Key model predicts big election win for Clinton

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MOODY'S MODEL PREDICTS BIG ELECTION WIN FOR CLINTON

FOX NEWS POLL: Clinton leads Trump by 10 points, both seen as flawed presidential candidates

HILLARY CLINTON WILL WIN ELECTION BY A LANDSLIDE, ACCORDING TO MOODY'S HIGHLY RELIABLE ELECTION MODEL

U.S. Presidential Popular Vote			
100% OF PRECINCTS REPORTING			
Hillary Clinton (D)	41,765,317	42%	
Donald Trump (R)	40,124,439	40%	
Gary Johnson (I)	8,205,481	8%	
Others	5,148,624	5%	
All States (I)	4,811,773	5%	

U.S. Presidential Electoral (270 needed)			
100% OF PRECINCTS REPORTING			
Hillary Clinton (D)	343	42%	
Donald Trump (R)	195	40%	
Gary Johnson (I)	0	8%	
Others	0	5%	
All States (I)	0	5%	

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Excerpt from DOJ brief filed in Florida, in 2013

"The applicability of inferential statistics have [sic] long been recognized by the courts." In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019-20 (5th Cir. 1997). Indeed, as even the public is well aware during election cycles, surveys of a small number of voters can predict the electoral winner. See United States v. Ukwu, 546 Fed. Appx. 305, 308 (4th Cir. 2013) ("[I]n many elections, a sample of 1,000 Americans can show, with enough certainty to satisfy the preponderance of the evidence standard, what is likely to happen in an election involving over 100 million voters.") (upholding the use of statistical sampling to prove amount of loss in tax fraud case)."

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Statistics in Audits

Trends

- "Routine" Government Audits
DEFAULT to statistical extrapolation
- Use of Statistics in False Claims Act Cases
 - Errors show "reckless disregard" or intent

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Statistics in Audits *Inferential Statistics*

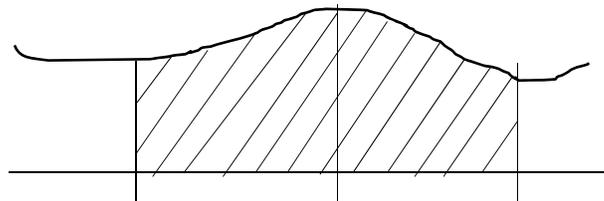
Definition -

- **Sample** items
- To determine **what the population** might look like
- Example: Pull 20 coins **at random** from the "box"
 - All coins sampled are quarters
- What do you know about the population based on those quarters?

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Statistics in Audits

Why does representativeness matter?



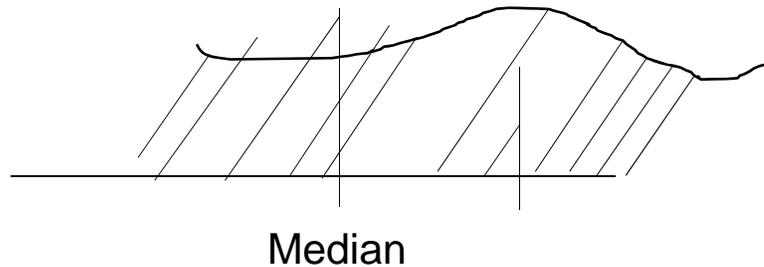
Median Coverage

Normal distribution ... of sampled items?

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Statistics in Audits

Why does representativeness matter?



Skewed distribution? **BIAS?**

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Statistics In Audits

Precision and Error Rates

- Precision
 - Coefficient of Variation
 - Reliability
 - Can the 90% Confidence Interval "correct" for very imprecise data?
 - **NO**

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Statistics in Audits *Inferential Statistics*

Wisdom in conducting a “probe” audit

- Why?
- To be sure have a good understanding of the population and study design
- We don’t always know how many quarters versus nickels are in the box!

UNFORTUNATELY, the government often ignores this

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OIG Audits *Hospital Compliance Reviews*

We identified **multiple strata**, to be more **precise**
Strata of DRG Codes?

Range: Underpayments to Overpayments
From underpaid 20K to overpaid 150k

How Precise?

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Government Audits

Reviews

We identified **multiple strata**, to be more **precise**

Strata of CPT codes?

More likely to be precise? How variable are payments?

Claim **lines** sampled?

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OIG Audits

Hospital Compliance Reviews

OIG Auditors:

We identified **multiple strata**, to be more **precise**

What is the sampling unit?

A **claim per OIG**

A **beneficiary's** claim is really a **CLUSTER** of Claims which is less precise

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Audits

CMS Standards in PIM

Medicare Program Integrity Manual – Chapter 8

Describes “step by step” instructions

- Including need to maintain records

CAVEAT- Government auditors ignore **VALIDITY** requirement, state that if it’s random, it is VALID

Government argument: If “miss” a step, ok, as long as outcome reasonable

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OIG Audits

Hospital Compliance Reviews

OIG Auditors:

“We pulled a sample of claims for January 1, 2012 to December 31, 2014 and extrapolate medical necessity denials across the population ...”

Your Answer: _____

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OIG Audits

Hospital Compliance Reviews

- **What happened October 1, 2013 for medical necessity?**

THE RULES FOR MEDICAL NECESSITY CHANGED!

- The law said NO claims could be reviewed for MN until after “probe and educate”
- **OIG ANSWER:** We’ll pull charts for patients up until October 1, 2013 and sample, extrapolate across universe

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OIG Audits

Hospital Compliance Reviews

- **OIG ANSWER:** We’ll pull charts for patients up until October 1, 2013 and sample, extrapolate across universe

- **WRONG:** If you extrapolate “across” that date, you are making medical necessity denials, right?
–But legally, you cannot make medical necessity denials unless completed probe and educate!

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Applicable Standards

- Case Law: Caring Homes Personal Home Services, Inc. v. Burwell. (10th Cir.)
(Decided May 31, 2016)

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Statistics in Audits

Government Audit

- What is error rate?
1 out of 20?
\$5 out of \$10,000

Government threshold 5% in
Settlements!

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Statistics in Audits

Government Audit

- Corporate Integrity Agreements
from HHS-OIG= 5%
- CMS Medicare Managed Care Manual,
Chapter 7, § 120.2, 5
 - CMS requires accurate data
 - **If plan submits 5% or greater
duplicates (errors), not accurate**

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HHS OIG Integrity Agreements

What is the purpose of a Discovery Sample for a CIA Claims Review?

The purpose of conducting a Discovery Sample as part of the Claims Review is to determine the net financial error rate of the sample that is selected. **If the net financial error rate**

equals or exceeds 5%, the results of the Discovery Sample are used to determine the Full Sample size.

The Full Sample size is based on an estimate of the variability of the overpayment amount in the population from which the sample was drawn. The results of the Discovery Sample allow the reviewer to estimate how many sample units need to be reviewed in order to estimate the overpayment in the population within certain confidence and precision levels (e.g., generally, a 90% confidence and 25% precision level).

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Standards in Audits

Error Rate

PRRB Cases

- Providence Medical Center (1999)
 - Sampled bad debts
 - JUDGMENTAL sampling
 - Lack of Documentation for sampling method
 - 4% error rate
- St. Francis Hospital (2000)
 - 15% audit threshold error rate without basis to extrapolate

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Statistics in Audits

Government Audit

Medicare Modernization Act

- **NO** statistical extrapolation unless
SUSTAINED/HIGH ERROR RATE
 - What if no “sustained” error rate?
 - Unsuccessful legal challenges

TALK TO YOUR LEGISLATORS!

Should not have ANY SVRS – recall ZPIC audits/ letters?

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Statistics in Audits
Government Audit

Even IF you win on appeal, remember to

**DOCUMENT Why NOT RETAINING AN
OVERPAYMENT!**

The new CMS Overpayment Rule is
independent of appeal wins!

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Statistics in Audits



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False Claims Act *Statistical Sampling*

- ***U.S. ex rel. Martin v. Life Care Centers of America*** (Sept. 2014)
- Statistics to “prove” intent? Damages?
- **The “Problem”:**
 - Life Care operates over 200 SNFs; billed 68% of its Medicare rehabilitation stays using the Ultra High category (national average of 35%)
 - 54,000 patients admitted assigned to Ultra High level rehabilitation; over 154,000 submitted claims

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False Claims Act *Statistical Sampling*

- ***U.S. ex rel. Martin v. Life Care Centers of America*** (Sept. 2014)
- Statistics to “prove” intent? Damages?
- **The Problem: Is there really a Problem?**
 - Could Life Care operate SNFs located adjacent to rehab hospitals? Have patients needing more rehab?
 - Each patient individually considered? Is it false claim?
 - What about reversal rate when auditors “denials” appealed?

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False Claims Act *Use of Statistical Sampling*

U.S. ex rel. Michaels and Whitesides v. Agape (Dec. 2012)

- Rock Hill Division of District of South Carolina
- Statistical Problem (per the Court) – each claim asserted involved question of medical necessity for hospice services to SNF resident
- By Order of 6/25/15, certified to Fourth Circuit – the issue of whether the Relator can use statistical sampling to prove both liability and damages
- Oral argument held 10/26/16

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Agape Fourth Circuit Brief Highlights

Relator's FCA claims cannot be proved by statistical sampling.

- Statistical evidence is poorly adapted to proving the falsity and knowledge elements of FCA liability generally, and it is particularly ill-suited for use in a case that, like this one, involves an exercise of clinical judgments – whether a patient is terminal—that is highly individualized, context-specific, and uncertain.
 - While "clinical medical judgments are not automatically excluded from liability" under the FCA, courts agree that "FCA liability must be based on an objectively verifiable fact." *United States ex rel. Landis v. Hospice Care of Kansas, LLC*, 2010 WL 5067614, at *4(D. Kan. Dec. 7, 2010)

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Agape Fourth Circuit Brief Highlights

The factors relevant to a patient's eligibility for hospice care are multifaceted, complex, and highly individualized. Indeed, the applicable regulations explicitly forbid the use of "check boxes or standard language used for all patients" in hospice-eligibility certifications. 42 C.F.R. §418.22(b)(3)(iv).

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Agape Fourth Circuit Brief Highlights

Courts have consistently rejected attempts to use statistical sampling to prove liability in fraud cases.

- Relators seek to rely on aggregate data – as opposed to direct proof – to establish that Agape patients were falsely certified to be eligible for hospice care. Although Relators and the Government repeatedly insist that courts routinely accept statistical evidence to prove liability, a review of relevant decisions makes clear that this is not so. To the contrary, courts have consistently rebuffed attempts to use extrapolated data to prove liability in fraud cases.

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Agape Fourth Circuit Brief Highlights

Sampling and extrapolation are most often used to quantify damages when liability is conceded or indisputable – circumstances not present in this case.

- The cases the Relators cite to are critically different from this case, however, in that none of them involved the use of statistical sampling to prove *liability for fraud, i.e., the knowing* submission of a false claim for payment.

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Agape Fourth Circuit Brief Highlights

Recoupment v. FCA Claims

- Recoupment is a far different animal than an FCA case. Recoupment is an administrative proceeding initiated by the claims processor, in which overpayments are recovered through the reduction of future Medicare reimbursements. It is, in essence, a contractual set-off. Unlike the FCA, a recoupment proceeding is not concerned with scienter, and the burden of proof is on the payee to prove entitlement to the amounts paid. Further, recovery in a recoupment proceeding is limited to the actual amount of overpayment, plus interest. The FCA exposes defendants to trebled damages and a fine of at least \$5,000 per claim.

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Agape Fourth Circuit Brief Highlights

The use of statistical sampling and extrapolation in recoupment actions is specifically authorized by statute, provided there is evidence of “a sustained or high level of payment error.” 42 U.S.C. § 1395ddd(f)(3).

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Agape Fourth Circuit Brief Highlights

Statistical Sampling cannot be used to prove scienter in an FCA case.

- It simply is not possible to prove the *knowing* submission of false claims through aggregate proof. “Welding different [statistical] inferences together cannot substitute for direct proof[.]” *Hockett*, 498 F. Supp. 2d at 66. The Relators must, for each claim, adduce evidence of falsity and scienter – and aggregate data cannot prove the falsity or scienter of an individual claim.

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SavaSeniorCare Amicus Brief Highlights

The Reasonable Exercise of Professional Judgment Is Essential

- The entire Medicare program depends on the reasonable exercise of professional judgment focused on the unique, individual needs of each Medicare beneficiary.

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SavaSeniorCare Amicus Brief Highlights

The FCA Does Not Authorize Trial by Formula, Which the Supreme Court Has Rejected Under Analogous Circumstances

- As this Court has explained, the “conduct alleged [in an FCA case] must represent an objective falsehood.” *United State ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008).
 - In this case, Relators lament that “[d]ue to the sheer volume of [payment] claims at issue, trying this case would be cost-prohibitive and would result in a trial of monumental proportions spanning over a year... .” Relators’ Br. at 10 (internal quotation marks omitted). However, it is Relators who made the voluntary decision to seek the maximum bounty possible by alleging that Agape submitted thousands of false payment claims involving thousands of Medicare beneficiaries and dozens of health-care facilities about which Relators have no personal knowledge.

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SavaSeniorCare Amicus Brief Highlights

The Court Should Reject the Adverse-Consequences Arguments Made by Relators and the Government

- Relators suggest that unless this Court condones the use of statistical sampling and extrapolation to establish liability and damages in FCA cases based on medical necessity, fraud will go unpunished and undeterred.
- The concerns expressed by the Government do not outweigh a defendant's fundamental right to insist that relators and the Government present proof as to each element of each FCA cause of action seeking relief that is essentially punitive in nature.

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American Healthcare Association Amicus Brief Highlights

Allowing Sampling to Prove FCA Liability Would Impermissibly Shift and Distort the Burden of Proof the Statute Imposes on *Qui Tam* Relators and the Government

- The focus of the burden is on the specific false claims alleged because they are the "*sine qua non*" of an FCA violation. *Sanderson v. HCA – The Healthcare Co.*, 447 F.3d 873, 878 (6th Cir. 2006)(citation omitted). Thus, relators must prove, "at an individualized transactional level," that actual claims were submitted.
 - Falsity requires proof of "an objective falsehood" a "difference of opinion" or statements "about which reasonable minds may differ cannot be false."
- If sampling could be used to prove FCA liability for a mass of unspecified claims in cases like this one, that would shift the burden of proof to defendants to have to *disprove* the elements of FCA liability for each unspecified claim.

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American Healthcare Association *Amicus* Brief Highlights

Allowing Sampling to Prove FCA Liability Would Magnify the Threat to Health Care Providers of the Statute's Draconian Penalties and the Enormous Pressure to Settle Meritless Claims.

- If Relators are permitted to use their suggested “Trial by Formula” approach to proving FCA liability – an approach relators and the government are invoking with increasing frequency against health care providers nationwide – that will amplify, by many orders of magnitude, the serious threat of massive FCA liability and additional adverse consequences that those providers already face.
- Allowing the use of sampling to prove FCA liability – and the exponential multiplying of damages and penalties it entails – will only intensify providers’ already substantial incentives “to settle otherwise unmeritorious suits to avoid rising financial ruin.”

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QUESTIONS?

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