

# STATISTICAL SAMPLING AND EXTRAPOLATION IN FCA CASES

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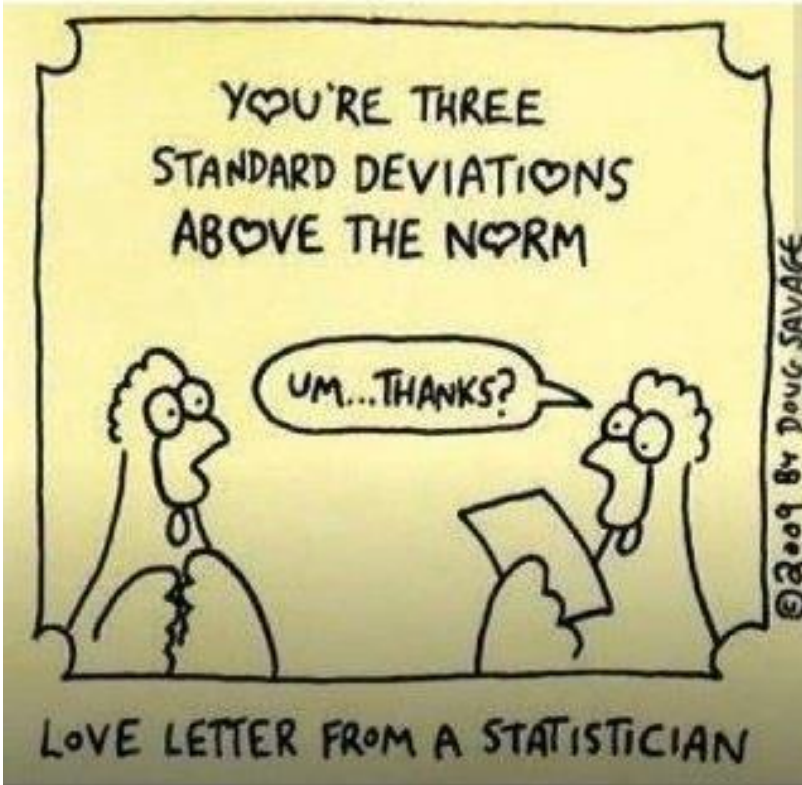
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# QUESTIONS REGARDING THE USE OF STATISTICAL SAMPLING

- Can statistical sampling be used to prove liability (falsity) in FCA cases? (Legal)
- Is the statistical sampling plan reliable? (Factual)



# WHEN IS STATISTICAL SAMPLING NECESSARY AND HOW IS IT HELPFUL?



# WHAT STEPS DOES THE STATISTICAL SAMPLING PROCESS INVOLVE?

## 4 STEP PROCESS

- 1) Define universe of claims.
- 2) Select sample of claims from universe.
- 3) Review of claims to determine number of false claims in sample, error rate, and average overpayment per claim.
- 4) Extrapolate to find:
  - Total # of false claims = (error rate) x (# claims in universe)
  - Total damages = (average overpayment per claim) x (# claims in universe)



**HOW DO YOU DESIGN AN EFFECTIVE  
AND RELIABLE SAMPLING PLAN WHILE  
MANAGING RESOURCE, COST, AND TIME  
CONSTRAINTS?**

# STRATIFICATION

**Stratified random sampling** – sampling method in which the total population is divided into non-overlapping subgroups called strata.



# PRECISION VS ACCURACY



✓ Precision  
✗ Accuracy



✗ Precision  
✓ Accuracy



✗ Precision  
✗ Accuracy



✓ Precision  
✓ Accuracy

# BALANCING ACT

## CONSIDERATIONS WHEN DEVELOPING SAMPLING PLAN

### Sampling methodology concerns

- Precision/Confidence intervals
- Identification of factors to be tested
  - Date, location, CPT code, DRG, ICD-10 code, etc.
- Stratification impacts:
  - Precision of resulting estimates
  - Sample size
  - Which categories of claims will be represented in sample

### Practical concerns

- Sample size
  - Cost – Expert must review each claim
  - Time – Discovery deadlines
- Complexity of sampling plan
  - Judge – *Daubert*
  - Jury

# CONSIDERATIONS WHEN STRATIFYING

## Without date strata

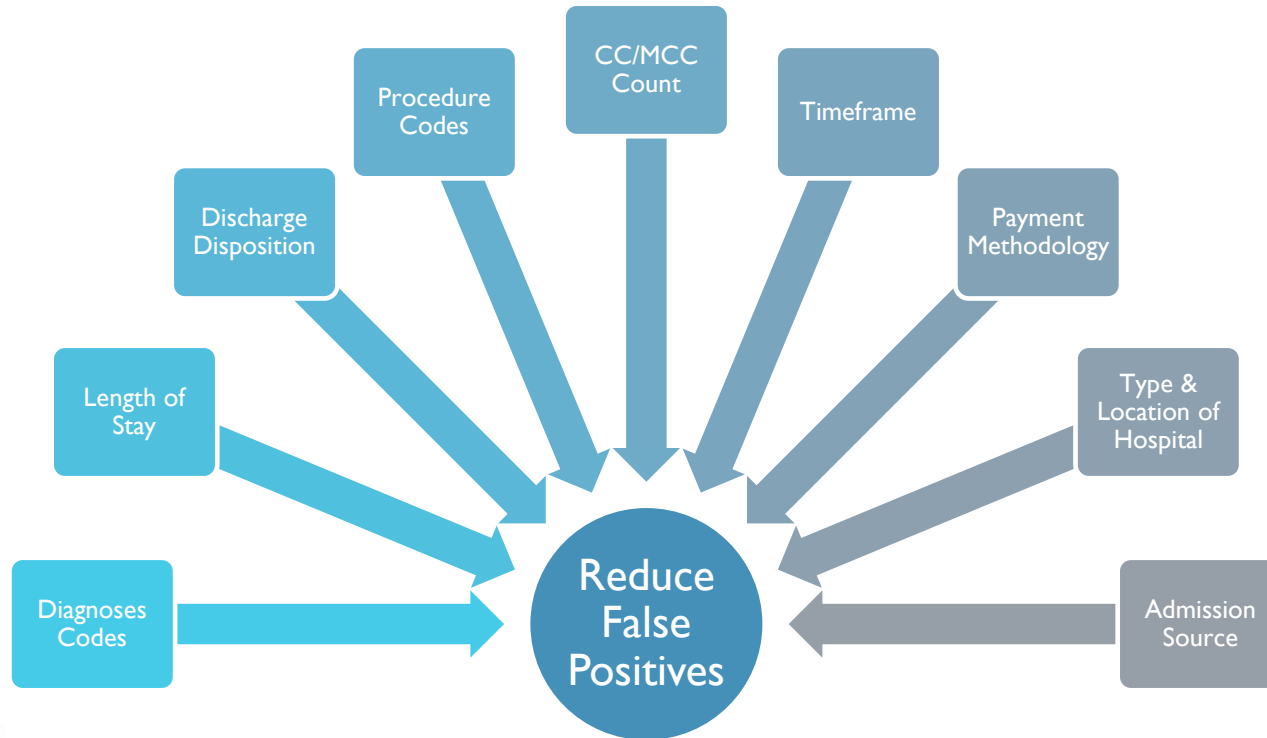
1/1/12 - 12/31/16	# of claims
Stratum 1	30
Stratum 2	30
Stratum 3	30
Stratum 4	30
Stratum 5	30
Stratum 6	30
	<b>180 total claims</b>

## With date strata

1/1/12 - 12/31/14	# of claims	1/1/15 - 12/31/16	# of claims
Stratum 1	30	Stratum 1a	30
Stratum 2	30	Stratum 2a	30
Stratum 3	30	Stratum 3a	30
Stratum 4	30	Stratum 4a	30
Stratum 5	30	Stratum 5a	30
Stratum 6	30	Stratum 6a	30
	180		180
<b>180 + 180 = 360 total claims</b>			

# SME CONSIDERATIONS

## Strategies for a 'tight' universe



# SME CONSIDERATIONS

## Example Allegation: Sepsis Upcoding

- Refine diagnosis range to A41.89 – A41.9 (other specified & unspecified)
  - Why? When a specific bacteria grows in the blood, it is more likely to validate a diagnosis of sepsis.
- Limit length of stay
  - Why? The longer the length of stay, the more likely the patient has a serious illness.
- Consider discharge disposition exclusions
  - Why? A patient who dies or is transferred is more likely to have sepsis.
- Understand the payment
  - COB claims, \$0 paid claims, outliers, adjustment logic

# CASE STUDY

## *DHHS/OIG: MERCY MEDICAL CENTER INCORRECTLY BILLED MEDICARE INPATIENT CLAIMS WITH KWASHIORKOR*

- *Sample: \$3,052,291 – 102 claims*
- *100% error rate*

### *HOWEVER*

*‘For 88 of the inpatient claims, correcting the diagnosis code resulted in no change in the DRG payment. However, for the remaining 14 inpatient claims, the errors resulted in overpayments of \$88,996.’*

**Know your damages opportunity and get rid of the noise.**

<https://oig.hhs.gov/oas/reports/region3/31300033.pdf>

## EXAMPLES OF AREAS WHERE STATISTICAL SAMPLING IS WELL-ESTABLISHED OR CLEARLY AUTHORIZED

- Calculating damages.
- Appeals from administrative agency decisions.
  - Authorized by 42 U.S.C. § 1395ddd(f)(3).
  - But different standard of review.
- Reverse false claims subsection (a)(1)(G) has no false statement or false claim presentment requirement for liability in retaining overpayments.

WHAT DO YOU DO IF YOU AND YOUR EXPERTS HAVE DESIGNED A STATISTICALLY VALID RANDOM SAMPLE THAT IS RELIABLE AND PROPERLY STRATIFIED, BUT THE DEFENDANT FILES A MOTION TO EXCLUDE THE USE OF STATISTICAL SAMPLING TO PROVE LIABILITY BEFORE YOU DRAW YOUR SAMPLE OR DISCLOSE YOUR SAMPLING METHODOLOGY?



# CAN STATISTICAL SAMPLING BE USED TO PROVE LIABILITY UNDER SUBSECTIONS (A)(1)(A) AND (B) OF FCA?

According to Joel D. Hesch & Mia Yugo, *Can Statistical Sampling Be Used to Prove Liability Under the FCA or Does Each Provision of the Statute Require Individual Proofs?*, 41 American Journal of Trial Advocacy 335, 342-52 (2018), the answer is:

- **YES**, because the elements for proving liability under FCA do not require individualized proof of specific claims and the “liability lies in the **fraudulent scheme**, not the individual proofs” for each claim.
- “So long as the allegedly fraudulent claims **arise from the same scheme**, the government need only prove liability for the overall scheme” and need not analyze each invoice or claim.

# CHALLENGES IN MEDICAL NECESSITY CASES

- Defendants argue subjective, independent medical judgments in medical necessity cases preclude use of statistical sampling to prove falsity.
- Relators can overcome this challenge with strong evidence of fraudulent scheme.

## RELATORS' PERSPECTIVE

- Defendants' objections should go to weight and not admissibility of the statistical sampling model.
- Prohibiting statistical sampling would reward large-scale perpetrators of fraud by preventing “the government from logistically being able to bring suit” or try a case when the fraud is too widespread to pursue each individual false claim.

# FAVORABLE RULING ON USE OF STATISTICAL SAMPLING TO PROVE LIABILITY

*United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*,  
114 F. Supp. 3d 549 (E.D. Tenn. 2014)

- “[A]s long as the statistical sample is a valid sample that is representative of the universe of claims, the natural disparity between the claims does not preclude using sampling and extrapolation as evidence...”
- “Given the large number of claims...it is often not practicable to do a claim-by-claim review.”

# CASE CITATIONS

- *U.S. ex rel. Martin et al. v. Life Care Ctrs. of Am. Inc.*, 114 F. Supp. 3d 549, 567 (E.D.Tenn. 2014)
- *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016)
- *U.S. v. AseraCare, Inc.*, 2015 WL 8486874 (N.D. Ala. Nov. 3, 2015)
- *U.S. v. AseraCare, Inc.*, 2014 WL 6879254 (N.D. Ala. Dec. 4, 2014)
- *U.S. ex rel. Michaels v. Agape Senior Community*, 2015 WL 3903675 (D.S.C. June 25, 2015)
- *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833 (N.D.Tex. June 20, 2016)
- *U.S. ex rel. Ruckh v. Genoa Healthcare, LLC*, 2015 WL 1926417 (M.D. Fla. Apr. 28, 2015)
- *U.S. ex rel. Guardiola v. Renown Health*, 2015 WL 5123375 (D. Nev. Sept. 1, 2015)

# IS RELATOR'S SAMPLING AND EXTRAPOLATION PLAN VALID AND RELIABLE?

- Federal Rules of Evidence
- *Daubert*

# STRATEGY CONSIDERATIONS WHEN USING STATISTICAL SAMPLING

- Parties may decide to use a “cooperative approach” to developing the sampling plan.
- Reliability determination could be made prior to close of discovery (or even before sampling is performed) to allow time to correct potential problems with the sampling plan and prevent time and resources from being wasted.

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# THANK YOU!

## FEEL FREE TO CONTACT US WITH ANY QUESTIONS!

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