#### Government Audits, Overpayments and Statistics!

#### GHA Compliance Officers Retreat September 2017

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#### <u>AGENDA</u>

- Extrapolations in Government Audits
  - ZPIC
  - OIG
- Comparison to "60-day" Self-Disclosure
- Implications Under the False Claims Act

### Statistics in Reimbursement Government's View

"The applicability of inferential statistics have [sic] long been recognized by the courts." ... Indeed, as even the public is well aware during election cycles, surveys of a small number of voters can predict the electoral winner.

<u>See United States v. Ukwu,</u> 546 Fed. Appx. 305, 308 (4th Cir. 2013)

### Statistics in Reimbursement Government's View

"[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."

Excerpt from DOJ brief filed in Florida, in 2013

#### Key model predicts big election win for Clinton



A model that has correctly predicted the winner of every U.S. presidential race since Ronald Reagan in 1980 is forecasting a big

Moody's election prediction: Hillary Clinton wins big



Statistical Sampling does not violate due process so long as extrapolation is made from a representative sample and is statistically significant.

Chaves County Home Health Service, Inc. v. Sullivan, 931 F.2d 914 (D.C. Cir. 1991), cert. Denied, 402 U.S. 1091 (1992) (emphasis added)

Medicare contractors may not use extrapolation to determine overpayment amounts. . . unless. . .

- There is a sustained or high level of payment error; or,
- Documented educational intervention has failed to correct the payment error

42 U.S.C. § 1395 ddd (f)(3) - Medicare Modernization Act

**CONSIDER: ZPIC Audits compared to OIG?** 

- Compare ZPIC Audits to OIG Audits?
  - FOIA Request
  - Medical Directors at Medicare Administrative Contractors

The Government's "New Audit Strategy" to "target" providers

# Statistical Sampling Alternate Strategies; ZPIC

#### **Hypothetical**

ZPIC Auditor finds "high" error rate on probe audit

Provider receives ZPIC "education" letter and Provider appeals ZPIC findings

Provider receives FULLY FAVORABLE appeals

ZPIC sends audit letter for probe or extrapolation....

Maxmed Healthcare, Inc. v. Burwell, (W.D. Tx) January 20, 2016

#### **ALJ** rejected extrapolation:

documentation of each step not maintained; low error rate/ data not "normally distributed" precision unacceptable in view of academic references

#### Medicare Appeals Council/ Federal Court:

**Valid** if follow CMS guidelines... then Provider must show invalid; Precision and "normal distribution" arguments rejected

CMS Manual "trumps" academic references

#### <u>Audits</u> CMS Standards in PIM

#### **Medicare Program Integrity Manual – Chapter 8**

Describes "step by step" instructions

- Including need to maintain complete records
- Requires valid methods to be used

### Government Audits Statistical Extrapolation

- Suggestion for Appeals
  - Preserve the argument that cannot replicate per PIM, as appropriate

- Expert opinion at earliest levels of appeal
  - Nearly 700,000 cases backlogged at ALJ

### Government Audits Statistical Extrapolation

Recent administrative decisions:

"We cannot reproduce exactly but . . . it is acceptable"

- However:
  - -Information claims is being pulled from database NOT kept by payor
  - -How to replicate?

## Statistics in Audits Acceptable Error Rate?

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

Government threshold – 5% in the past?

### Statistics in Audits Government Audits

- 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

### HHS OIG Integrity Agreements Acceptable Error Rate

#### Purpose of a Discovery Sample for a CIA Claims Review

The purpose ... is to determine the net financial error rate of the sample...If the net financial error rate equals or exceeds 5%, the results of the Discovery Sample are used to determine the Full Sample size.

### Statistics in Audits Acceptable Error Rate

#### **PRRB** Cases

- Providence Medical Center (1999)
  - Lack of Documentation for sampling method and only 4% error rate: no extrapolation
- St. Francis Hospital (2000)
  - 15% audit threshold error rate without basis to extrapolate

# Statistics in Audits Overpayment Rule

-Identify an issue

Narrow payment window

-Precision/Representative Sampling

–Precision is High

### OlG Audits & Overpayments Mount Sinai Hospital:2012-13

#### April 2017 OIG Report

- OIG Finds Error with 110 of 261 Claims
- Financial Error Rate = 31.49%
- Overpayment = \$1.374 million
- Extrapolated Overpayment Result = \$42 million
- No finding of "Fraud or similar fault"
- OIG Recommends Further Investigation Of Overpayments

### OIG Audits & Overpayments Mount Sinai Hospital:2012-13

#### **Hospital Response:**

- No refund for claims more than 3 years old
  - Even for claims realized coded incorrectly
  - Extrapolation Not Warranted
  - Extrapolation Premature Appeals
  - Extrapolation Methodology Flawed

## OIG Audits & Overpayments Mount Sinai Hospital 2012-13

Multiple strata, to be more precise

Strata of DRG Codes

Inpatient Medical Necessity Claims

Inpatient Rehab Claims

**Outpatient Coding and Device Credits** 

### Statistics in Audits Government Audits

If win on appeal, Showing not VALID

- Document that NO REFUND owed under 60 day rule
- If provider wins on appeal, was an overpayment ever identified?

## False Claims Act Statistical Sampling

#### Hotly Litigated Topic

- Statistics to "prove" intent? Damages? Penalties?
- Relieves Government/Relator of Burden to Prove Elements of FCA Case – Falsity of Each Claim
- U.S. ex rel. Martin v. Life Care Centers of America (Sept. 2014)
- U.S. ex rel. Michaels and Whitesides v. Agape (Dec. 2012)

# False Claims Act Statistical Sampling

#### • U.S. ex rel. Martin v. Life Care Centers of America (Sept. 2014)

#### 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
- District Court allows sampling to prove a defendant's violations of the FCA
- Case Settles for \$145 Million
- Relator's Counsel: "Case paves the way for proving health care fraud in large cases by statistical sampling"

### False Claims Act Use of Statistical Sampling

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

- 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

#### 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 illsuited 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 liabilty" 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)

#### 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).

# "The Valentine's Day Surprise" And the Court Said ...

- We will not review
- Not a pure question of law
- Appeal improvidently granted
- Issue of statistical sampling in FCA cases governed by split opinions in lower Federal district courts
- Aug. 2017 Government Settles Case for \$275,000 (Rejected \$2.5 Million Settlement Offer in 2015)

## False Claims Act Statistical Sampling

#### Sampling/Extrapolation Common In FCA Cases

- Civil Investigative Demand Asks for Large Number of MRs by Patient Name
- Government Attorneys Encourage "Rolling"
   Production

#### Response

- Engage Statistician Early
- Question Assumptions/Methodology
- Verify DOJ Calculations
- Propose Alternative Methodology/Extrapolation

#### **QUESTIONS**

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