

# Latest Trends in Medical Necessity Reviews, Statistical Sampling, and Extrapolation

## Compliance Officers' Roundtable Retreat September 5, 2018

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# **AGENDA**

- **Case Update: What is Medical Necessity and When Is it A Compliance Issue?**
- **Trends in Auditing and Issues in Statistical Sampling/ Extrapolation for Reimbursement**
  - New Audits
  - Using Statistics to help Identify Potential Overpayments

# **What is Medical Necessity**

- **Government payors will only pay for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."**

**45 U.S.C. § 1395y(a)(1)(A).**

# **Who Decides What is Reasonable and Necessary?**

- **CMS: National Coverage Determinations (NCDs)**
- **Medicare Contractors: Local Coverage Determinations (LCDs)**
- **The relevant medical standard of care, as defined by published practice guidelines, advice of medical consultants, expert testimony, accepted standards of medical practice, and/or the medical circumstances of the individual case.**

# **Medical Necessity in False Claims Act Cases**

- ***United States v. AseraCare, Inc.*, 176 F. Supp.3d 1282 (N.D. Ala. 2016).**
- ***United States of America ex rel Gerald Polukoff v. St. Marks Hospital, Intermountain Healthcare, Inc., et al.*, 895 F.3d 730 (10th Cir. 2018).**
- ***United States of America v. Richard E. Paulus, M.D.*, 894 F.3d 267 (6th Cir. 2018).**

# U.S. v. Paulus: Government's Case:

## • **Outlier**

- In 2006-2008, Paulus inserted stents in 22%, 29%, and 31% of his Medicare patients. The average for the peer group was 4%.

## • **Liar**

- "Paulus repeatedly and systematically saw one thing on the angiogram and consciously wrote down another, and then used that misinformation to perform and bill unnecessary procedures."
- 9 doctors testified on behalf of the government. They reviewed Paulus' angiograms and often saw no blockage or only mild blockage where Paulus had recorded a severe blockage.

## • **Greed**

- Administrators kept daily tabs on the volume of procedures:
  - When volume spiked: "Oh yeah," "Now we're talking," and "Cha-ching."
  - On a day when Paulus was out: "Paulus can never leave again!!!!!!"
- Paulus' average annual salary: over \$2.5 million. His compensation was tied to the number of procedures he performed.

# Potential Overpayment Analysis

## *Government Methods*

"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.**

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.”**

**Excerpt from DOJ brief filed in Florida, in 2013**



# Statistical Extrapoliation

## *Documentation*

Must disclose all pertinent documentation to permit replication

## Freedom of Information Act Requests

- Too "burdensome"
- You cannot have PHI
- Too expensive?

# Statistical Extrapolations

## *Trends?*

### Family Rehab: 5th Circuit

- Recoupment stopped by Temporary Restraining Order (TRO) when case at ALJ

### Adams EMS:

- Texas District Court grants TRO to stay recoupment

\* Not a way to avoid refunds – just payment delays

# Medical Necessity Reviews

## *Inpatient Orders*

### 2019 IPPS **Proposed** Rule:

Signature Not Required on inpatient order  
as condition of payment

- Previously, consider entire medical record per  
DAB – MAC

Remember: Caring Hearts v. Burwell, No. 14-  
3243 (10th Circuit) (May 2018)

# Medical Necessity Reviews

## *Focus Areas*

### Intensity-modulated radiation therapy (IMRT)"

- "planning" billed separately (if not on same day)
- LCDs "vague" on timing
- CMS installing new edit

# Government Reviews

## *Quality of Care*

- DRG coding system: 1983
  - Accuracy based on **coding** accuracy.
    - Coders did not question the clinical validity of diagnoses documented by the physician
    - If Official Coding Guidelines satisfied by physician records, coding correct

# Medical Necessity Reviews

## *Quality of Care*

### **Quality:**

How well providers comply with "best practices" according to evidence-based medicine and scientific literature

- e.g., use of antibiotics before surgery" ...

# Government Reviews

## *Quality of Care*

- **DRG** accuracy now involves additional components including:
  - Patient Status - Medical Necessity
  - Clinical Validation – Clinical Integrity
- Birth of Physician Documentation (PDI)
- Evolution of PDI to CDI...and ...
- However, coding principles remain valid!

# Clinical Validation

- Clinical Validation: 2011 Recovery Audit Contractor (RAC) Statement of Work :
  - ...a process **separate** from DRG validation.
  - *Clinical validation involves a clinical review of the case to see **whether or not the patient truly possesses the conditions that were documented.***
  - *Clinical validation is beyond the scope of DRG (coding) validation, and the skills of a certified coder. **This type of review can only be performed by a clinician or maybe performed by a clinician with approved coding credentials.***



# Government Reviews

## *Quality of Care?*

Hospital: Acute Tubular Necrosis (ATN)  
(MCC)

Auditor: Acute Kidney Injury (AKI) (CC)

- no biopsy performed as "required" per scientific literature
- urinalysis findings not consistent

Appeal:

# Government Reviews

## *UPIC Activity*

- UPIC Performs Audit of Medicare Claims
- New UPIC Review:
  - **Medicaid** Claims !
    - What are Medicaid standards?
      - Prepayment review/ prior authorizations being audited
    - *Early education of auditors critical*

# Potential Overpayment Analysis

## *The Potential "Problem"*

- ***Government Audit Findings***
  - 60 Day Rule: Credible Allegation of an Overpayment is a Government Audit Finding
  - Legally, **DUTY TO INVESTIGATE**

# Potential Overpayment Analysis

## *The Potential "Problem"*

- Compliance Conclusion:

Your research shows **MAYBE**

- Failure to satisfy a coverage "requirement"

# Potential Overpayment Analysis

## *The Potential "Problem"*

- Compliance Conclusion: **MAYBE**
    - HYPOTHETICAL
      - National Coverage Determination (NCD)
        - Legal Requirements for payment, with one not satisfied
- ... legal considerations post Escobar

# Potential Overpayment Analysis

## *The Legal Issues*

- Universal Health Services, Inc. v. United States ex rel Escobar, 136 U.S. 1989 (2016)
  - When defendant submits claims for payment to Medicare, there is "implied certification" that conditions for payment satisfied
  - To be liable under False Claims Act, the "error" or false representation must be **material** to payment

# Potential Overpayment Analysis

## *The Legal Issues*

Escobar: Materiality standard

Not all violations of standards are "False Claims"

**Example:** Government knew of issue and paid regardless

D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016)

Note: **Evolving** Case Law!

# Potential Overpayment Analysis

## *The Legal Issues*

Escobar: Materiality standard

Condition of Participation, not payment?

Related to Quality of Service, not whether service performed/medically necessary?

**Medical Necessity**



# Potential Overpayment Analysis

## *Preliminary Conclusion*

Escobar: Materiality standard

Hypothetically, you reach preliminary conclusion:

There **may** have been an overpayment....

# Statistics in Overpayment Analysis

## *Preliminary Conclusion*

### **Possible Overpayment**

#### **Start and Stop Date?**

- Fact finding
  - Government audit/ internal audit?
  - Adoption of new workflow/ EMR?
  - Change in NCD/LCD?
  - Change in staff?

# Potential Overpayment Analysis

## *Preliminary Conclusion*

### **Possible Overpayment**

#### **Start and Stop Date: Probe Review**

- Claims pulled at random by reviewer
  - internal or external?
- No "magic" number – 40-50?
- Methodic time periods

# Potential Overpayment Analysis

## *Conclusion*

**Probe Audit Finds No Errors**

### **Document investigation and Conclusion**

Satisfy legal duty to investigate under 60-Day Rule!

\*\* Consider focused education on potential issue, inclusion in future audits

# Potential Overpayment Analysis

## *SVRS Sampling*

- Define Precision to Set Sample Size
- Defined Range of Payments

Not the same as OIG Hospital Compliance Audits!

**See**, OIG Questions and Answers for CIAs

# Potential Overpayment Analysis

## *Acceptable Error Rate?*

What is error rate?

– 1 out of 20?

– **\$5 out of \$10,000**

Government threshold – 5% in the past?

See, OIG FAQ: CIA Claims Review

# Discussion

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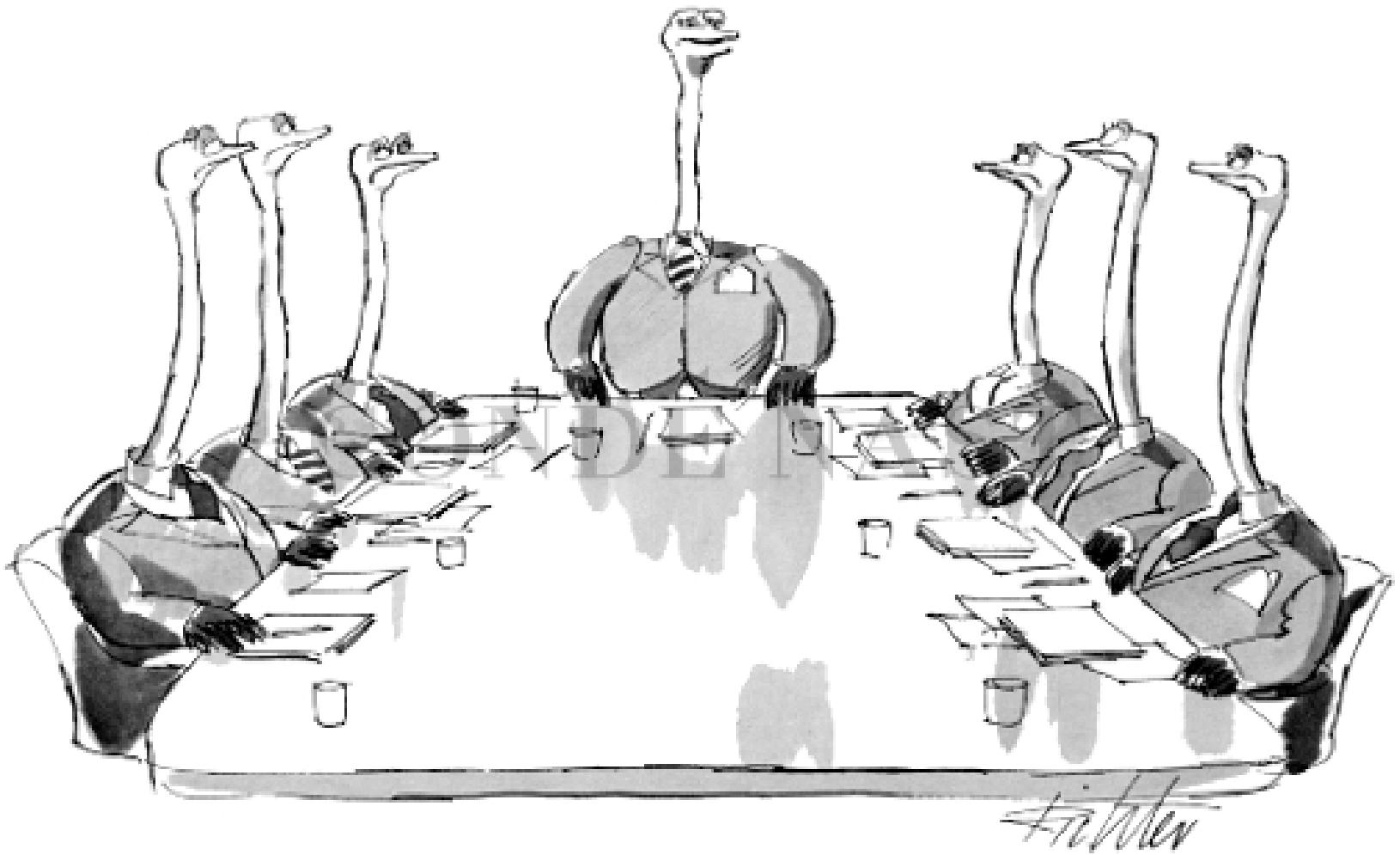
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*"The motion has been made and seconded that we stick our heads in the sand."*