MEDICAL NECESSITY & THE FALSE CLAIMS ACT: AN EVER-MOVING TARGET

HCCA™
Health Care Compliance Association

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OBJECTIVES

- Identify the fraud and abuse laws the Government typically brings medical necessity cases
- Describe the various definitions of medical necessity
- Understand current False Claims Act case law for what must be alleged in order to deem medical necessity of a procedure/service false
- Gain insight through various court decisions regarding the Government's burden in these cases and identify several examples of the different ways in which District Courts have recently addressed medical necessity
- Discuss practical considerations in addressing medical necessity concerns in your organization

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OVERVIEW OF RELEVANT FRAUD & ABUSE LAWS

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FALSE CLAIMS ACT 31 USC 3729-3733

- Involves the presentation of a claim for payment to the federal government that is "known" to be false or fraudulent.
- "Known" means actual knowledge or deliberate indifference to the truth or falsity of the information
- Prohibits
  - presenting (or causing to be presented) a false claim for payment,
  - using or causing to be used a false record or statement for payment,
  - conspiring to defraud the government by having a false claim paid, and
  - using/making a false record/statement to conceal, avoid or lower an obligation to pay money to the government
- No retaliation against anyone who reports such activity in good faith
- *Qui tam* provision

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FALSE CLAIMS ACT 31 USC 3729-3733

- Includes the following:
  - Billing for undocumented services,
  - Billing for **medically unnecessary services** or services that fail to meet professionally recognized standards for care ("worthless services"),
  - Up-coding,
  - Unbundling,
  - Billing for services not actually provided,
  - Failing to refund overpayments made by a federal governmental program,
  - Participating in kickbacks, bribes or rebates in exchange for referrals

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FALSE CLAIMS ACT 31 USC 3729-3733

- False Claims Act Liability
  - Felony
    - Up to five (5) years in prison and substantial criminal fines
  - Civil damage suits may be brought by the federal government or a *Qui Tam* plaintiff on behalf of the government
  - Penalties resulting in 3 times the amount of the overpayment, and
  - Civil Monetary Penalties in the amount of:
    - $5,500 to $11,000 per claim plus attorney's fees (before 8/2016);
    - $10,781 to $21,563 per false claim, between 8/1/16 and 2/3/17; and
    - $10,957 to $21,916 per false claim on or after 2/3/17
    - $11,181 to $22,363 per false claim on or after 1/29/18

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FALSE CLAIMS ACT 31 USC 3729-3733

- Common Theories of False Claims Act liability
  - False Certification
    - Express or Implied
  - Conspiracy
  - Reverse False Claims

- To prevail on a False Claims Act claim, the plaintiff must prove the defendant
  - Made a false statement
  - With scienter
  - That was material;
  - Causing the Government to make a payment

(Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1045 (11th Cir. 2015))

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HEALTH CARE FRAUD 18 U.S.C. §1347

- Defrauding any health care benefit program; or

- Obtaining, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program

- Actual knowledge or specific intent to commit a violation of this statute not required

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HEALTH CARE FRAUD 18 U.S.C. §1347

- To sustain a criminal conviction of Health care Fraud, the Government has to prove
  - the Defendant knowingly devised a scheme or artifice to defraud a healthcare benefit program in connection with the delivery of or payment for benefits, items or services;
  - executed or attempted to execute this scheme or artifice to defraud; and
  - acted with intent to defraud

Government must prove specific intent to defraud

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HEALTH CARE FRAUD 18 U.S.C. §1347

- Penalties
  - Fined or imprisoned not more than ten (10 years, or both
  - If the violation results in serious bodily injury , fined or imprisoned not more than 20 years, or both; and
  - if the violation results in death, fined or imprisoned for any term of years or for life, or both.

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FALSE STATEMENT RELATING TO HEALTH CARE MATTERS 18 U.S.C. §1035

- Whoever, in any matter involving a health care benefit program, knowingly and willfully
  - falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or
  - makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry,
  - in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 5 years, or both.

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MEDICAL NECESSITY

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EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

- SEC. 1862. [42 U.S.C. 1395y] (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—
- (1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

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EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

- no payment may be made under part A or part B for any expenses incurred for items or services—
- not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member

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AMERICAN MEDICAL ASSOCIATION
Definitions of "Screening" and "Medical Necessity" H-320.953 (2016)

- Medical Necessity
  - Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is:
  - (a) in accordance with generally accepted standards of medical practice;
  - (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and
  - (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

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MEDICARE EXCLUSIONS FROM COVERAGE
42 USC 1395y(a)(1)(A)

- Medicare coverage is limited to items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury."
- Health care providers must assure that health services ordered for government patients are "provided economically and only when, and to the extent, medically necessary." 42 USC 1320c-5(a)(1)

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CMS FORM 1500

SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE, TRICARE, FECA AND BLACK LUNG)

In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license #, or SSN) of the primary individual rendering each service is reported in the designated section.For services to be considered "incident to" a physician's professional services, 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills.

5. The services on this form were medical necessary . . .

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SELECT CASE APPLICATION

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PAULUS

- *US v. Paulus:* 2017 WL 908409 – USDC – EDKY
- Criminal case
- Indictment alleged that Dr. Paulus performed unnecessary cardiac procedures, including catheterizations and stent placements, and falsely recorded the existence and extent of lesions observed during the procedure and then submitted the allegedly false and fraudulent claims to health care benefit programs.

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PAULUS

- After twenty-three days of trial and four days of deliberations, Dr. Paulus was convicted of eleven of the sixteen health fraud counts
- Paulus filed 2 Motions for Acquittal: one after the close of the government's case, which the Court deferred, and one after the conviction was returned
- Government had called 11 separate doctors and a number of patients all of whom testified that Paulus' procedures were not medically necessary
- Still, the District Court granted the Motion for Acquittal

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GOVERNMENT'S BURDEN OF PROOF

- Government must prove "specific intent to deceive or defraud" in order to sustain a guilty verdict
  - i.e., that Paulus knowfully and willfully made false statements or representations
- Government's theory:
  - Paulus false recorded the existence and extent of the patient's coronary blockages and inserted stents into patients who didn't need them (without at least 70% stenosis)
- Government must prove beyond a reasonable doubt that Paulus' assessment of the degree of stenosis equated to a false statement and that he made those false statements with fraudulent intent

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REQUIRED PROOF TO ESTABLISH FALSITY

- What is the required proof for establishing falsity?
- "[i]t is fundamental that a false statement is a factual assertion. (Williams v. U.S., 458 US 279 (1982).
- Government must "identify a statement" made by Paulus "which asserts a proposition that it is subject to proof or disproof." (U.S. v. Waechter, 771 F2d 974 (6th Cir. 1985).
- Government claimed reading angiograms is a science; not akin to reading tea leaves
  - Reading angiograms is susceptible to proof of truth or falsity
  - Because inter-observer variability could not account for the stark interpretation differences
  - Paulus inserted stents into patients with less than 70% stenosis and then lied about it in the records

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Inter-Observer Variability

- 2 expert witnesses
- Both acknowledged interpreting stenosis can be a "difficult exercise" resulting in a level of variability between cardiologists; Significant amount of subjectivity and disagreement among cardiologists
- Expert 1
  - "lesions that are between 50-70% are difficult to assess by angiography" and "angiography can be misleading for lesions" classified as "borderline blockages"
  - estimating percentages is an imprecise exercise
  - "Unless you're making a measurement, which most people don't, I think it's a little misleading that it's an actual percentage"
- Trial evidence showed inter-observer variability could account for > 10-20% variability

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PAULUS

- In Acquitting, the Court reasoned:
  - The health care fraud statute is "not intended to penalize a person who exercises a health care treatment choice or makes a medical or health care judgment in good faith simply because there is a difference of opinion regarding the form of diagnosis or treatment."
  - "Therefore, the statutes targeting health care fraud do not criminalize subjective medical opinions where there is room for disagreement between doctors."

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MEDICAL OPINIONS CANNOT BE FALSE

"Expressions of opinion, scientific judgments, or statements as to conclusion about which reasonable minds may differ cannot be false."

"Degree of stenosis is a subjective medical opinion, incapable of confirmation or contradiction"

U.S. v. St. Mark's Hosp., 2017 WL 237615 (D. Utah Jan. 19, 2017), quoting *A Plus Benefits, Inc.*, 139 Fed.Appx. At 983).

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OTHER CASE LAW DISTINGUISHED

McLean

(U.S. v. McLean, 715 F.3d 129 (4th Cir. 2013))

- Pattern of overstating blockage by a wide margin
- Placing unnecessary stents in a large number of patients
- Stark disparity between what was recorded and what angiogram showed
  - > 100 cases involved blockages of 25% or <
  - Interobserver variability 10-20% demonstrated
- Strong circumstantial evidence
  - Statements by McLean that stents unnecessary
  - Evidence of other misrepresentations
- Conviction upheld

Paulus' Motion for Acquittal GRANTED

Patel

(U.S. v. Patel, 485 Fed.Appx. 702 (5th Cir. 2012))

- Uncontested that margin of error with Dr. Patel's visual estimation of blockage was +/- 10%
- Inter-observer variability at moat 10-20%
- Experts observed 0% blockage compared to 60-70% by Dr. Patel
- Circumstantial evidence
  - Peer comparison data
  - Post-investigation conduct
    - Canceled scheduled procedures
    - Revised records of existing findings
  - Patient testimony that they "never complained of chest pain" although such was documented in the records
- Conviction upheld

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PAULUS

- Ultimately the Court stated that the Government failed to prove beyond a reason of a doubt that Paulus "knowingly and willfully exaggerated the extent of his patients' stenosis in their medical records, for the purpose of defrauding a health care benefit program" and therefore granted the Motion for Acquittal

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PAULUS ON APPEAL

- *US v. Paulus;* 894 F.3d 267 (6th Cir, 2018)
- The Sixth Circuit reversed the District Court's Order of Acquittal and reinstated the jury's verdict
- The appellate court held that whether or not a doctor lies about their interpretation of the level of stenosis is a question of fact that a jury can properly weigh and render a decision on.
- The Court noted that the totality of the evidence, which included evidence of Paulus's "astronomical" billing numbers, his enormous salary, and injured patients' testimony, was sufficient for a jury to convict and the District Court erred in substituting its own judgment.

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ST. MARK'S

- *US, ex rel. Polukoff v. ST. MARK'S HOSPITAL; Intermountain Healthcare, Inc.; Intermountain Medical Center; Sherman Sorensen; and Sorensen Cardiovascular Group; Defendants.* 2017 WL 237615, USDC Utah
- Relator brought qui tam on behalf of the Government, alleging that physician was performing medically unnecessary patent foramen ovale (PFO) closure heart procedures and falsely documenting that the procedures were necessary to curtail strokes

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U.S., ex. Rel. POLUKOFF v. ST. MARK'S HOSPITAL (2017 WL 237615 (D. Utah, Jul 9, 2018)

- Whistleblower suit
- Government did not intervene
- Allegations
  - Dr. Sorenson performed unnecessary medical procedures (PFO) and then fraudulently billed Medicare
    - Dr. Sorenson performed PFO closures between 2002 and 2011
    - Performed PFOs with greater frequency than other physicians throughout the country
    - He believed it was best for the patient not to wait until they had a stroke, but who had an elevated risk for stroke
  - The two hospitals also fraudulently billed the government for hospital costs associated with these procedures

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HOSPITAL ACTIVITY

- Intermountain Health Care Internal Guidelines(3/30/2011)
  - Internal guidelines for PFO Developed May be considered for "patients with a single well-documented significant stroke or systemic emboli in a high-risk patient who has been comprehensively evaluated for alternative cause of embolic stroke"
  - Independent neurology exam or other tests to confirm either the occurrence of a stroke or an embolism before performing a PFO closure
  - PFO may only be used to treat migraine headache in a clinical trial setting
- Dr. Sorenson's medical privileges suspended (8/17/2011)
  - Performed procedures that did not adhere to internal guidelines
  - After returning from suspension , continued to perform PFOs that were not in compliance
- IHC took action to permanently suspend Sorenson's privileges (9/2011)
  - Entered into settlement agreement, which Sorenson violated
  - IHC threatened to suspend him and report to NPDB
  - He resigned and went to work exclusively at St. Mark's
- Relator states he discussed Sorenson's suspension with St. Mark's CEO
  - CEO permitted Sorenson to practice and perform PFO closures until his retirement in December 2011

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ST. MARK'S

- The Relator further alleged that Hospital Defendants were aware of the lack of medical necessity of physician's procedures and billed facility services nonetheless.
- Apparently, no LCDs or NCDs existed regarding when a PFO procedure should be performed
- In light of this lack of guidance, Relator, in pleading his case, relied heavily upon recommendations issued by the AHA/ASA for when a PFO closure should be performed

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ST. MARK'S

- The Defendants moved to have the case dismissed, and the District Court granted the Motion, stating:
  - "Medicare does not require compliance with an industry standard as a prerequisite to payment. Thus, requesting payment for [medical procedures] that allegedly did not comply with a particular standard of care does not amount to a 'fraudulent scheme' actionable under the FCA."
  - As such, the Court found the Relator's Complaint improperly equated AHA/ASA standards of care with Medicare's medical necessity requirements and therefore failed to state a claim of fraud
  - The District Court stated that even if the industry standards were not met, "this does not support a claim that Dr. Sorensen's certification that the PFO closures were medically necessary was objectively false"

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ST. MARK'S ON APPEAL

- *US ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir., 2018)
- Tenth Circuit Court of Appeals reversed the District Court.
- The appeals court did not recognize the District Court's distinction between "industry standards" and "Medicare guidelines."
- The Court instead opined that based upon the pleadings, the Complaint properly alleged a claim that the physician claims were legally false because he certified that the procedures were medically necessary when he signed the 1500 form

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ST. MARK'S ON APPEAL

- Express False Certification
  - False certification with a particular statute, regulation or contractual term
- Implied False Certification
  - Whether through the act of submitting the claim, a payee knowingly and falsely implied it was entitled to payment
- Relator brought an "express false certification" case based upon Sorenson's signature on the CMS Form 1500
- National Coverage Determination absent
- *In the absence of an NCD, local contractors may make individual determinations based upon the particular situation*

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MEDICARE PROGRAM INTEGRITY MANUAL

- Contractors may consider a procedure "reasonable and necessary" if it is:
  - Safe and effective
  - Not experimental or investigational
  - Appropriate, including the duration and frequency that is considered appropriate for an item or service, in terms of whether it is:
    - ***Furnished in accordance with accepted standards of medical practice;***
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative

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HOLDING

- A doctor's certification that a procedure is reasonable and necessary is false and actionable under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase
  - Sorenson performed an unusually large volume of PFO procedures (Cleveland Clinic 37 v Sorenson 861)
  - Procedures violated industry standards
  - Procedures violated internal hospital policy
  - Other physicians objected to Sorenson's practice
  - Sorenson knew migraines would not be paid so documented patient's met the AHA/ASA guidance

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ST. MARK'S ON APPEAL

- The 10th Circuit seemed to take the position that medical necessity is to be broadly construed and not simply defined by Medicare guidelines or regulations
- As to the hospital, the pleadings allege that there was enough notice to the hospital that they should have known the procedures were not medically necessary and therefore not reimbursable
  - ("The Cleveland Clinic reported that it had performed 37 PFO closures in 2010; during that same time period [Dr.] Sorensen's billing records indicate that he had performed 861.")
- The Complaint was found to contain enough factual allegations of fraud to allow the case to proceed.

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ASERACARE

- *US v. ASERACARE, INC.*, 938 F.3d 1278 (11th Cir. 2019)
- United States brought civil false claims action against a network of Hospice providers, alleging that Defendants were knowingly providing and subsequently billing for hospice services for patients based upon erroneous clinical judgments that they were terminally ill, when they, in fact were not.
- In order to prove its case, the Government relied, largely in whole, upon opinions from experts that disagreed with the Defendants' clinical judgments that the patients were terminally ill.

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ASERACARE

- After the case had proceeded through discovery, the District Court granted summary judgment in favor of the Defendants
- The District Court opined that because there was only a reasonable disagreement between medical experts as to the accuracy of the conclusion that the patients were terminally ill, with no other evidence to prove the falsity of the assessment, that the Government had failed to unearth the requisite evidence of a false claims act violation

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ASERACARE

- The 11th Circuit agreed and affirmed, stating:
  - "There is no allegation that AseraCare submitted claims that were not, in fact, based on a physician's properly formed clinical judgment, nor is there an allegation that AseraCare failed to abide by each component of the claim requirements.[9] The Government's allegations focus solely on the accuracy of the physician's clinical judgment regarding terminality."
  - "we concur with the district court's post-verdict conclusion that "physicians applying their clinical judgment about a patient's projected life expectancy could disagree, and neither physician [ ] be wrong.""

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ASERACARE

  - "Nothing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient's prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment."
  - "a reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those judgments—or any claims based on them—are false under the FCA."

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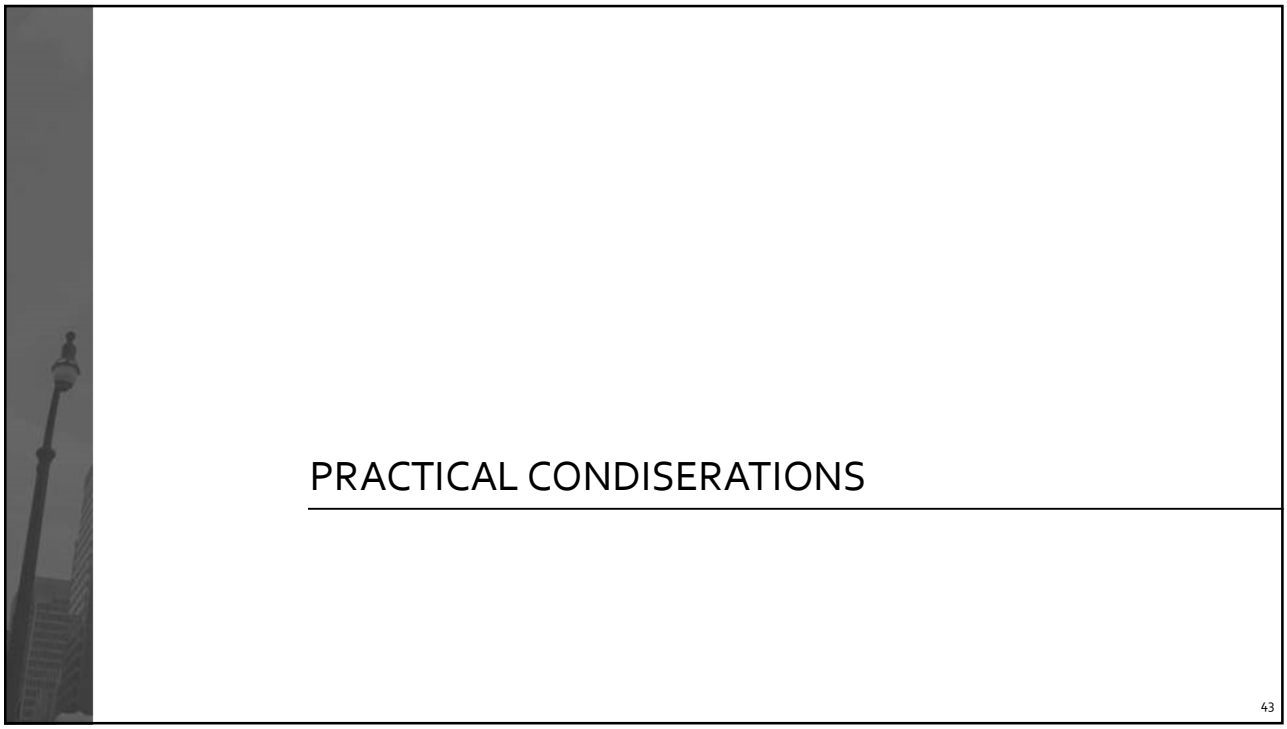

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PRACTICAL CONSIDERATIONS

- Compliance Risk Assessment
- Audit Workplan and Medical Necessity
- Responding to complaints regarding physicians' performance of procedures
- Interface between Compliance and the Medical Staff
- Internal hospital guidelines
  - NCD
  - Industry guidelines
  - Medical standard of care
- Hospital-developed certification forms
- Reliance on the "MAC having paid for it"

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PRACTICAL CONSIDERATIONS

- Example Scenario:
  - Billing department recognizes a cardiologist with unusually high cath lab utilization
    - What do you do first?
    - First steps?
    - When do you involve legal department?
    - Outside counsel?
    - How much do you do in-house vs outside?

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PRACTICAL CONSIDERATIONS

- Example Scenario:
  - Audit finds cloning concerns
    - What do you do next?
    - What collateral concerns would you have?
    - Throughout all of this, what do you do with the doctor?

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PRACTICAL CONSIDERATIONS

- Example Scenario:
  - Collateral issues: Extent of scheme
    - What's the plan of action? What issues do you consider?
  - Scenarios
    - When do you go to the government?

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THANK YOU

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