MEDICAL NECESSITY: CRIMINAL AND CIVIL ENFORCEMENT

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LEARNING OBJECTIVES

1.
Gain an understanding of what medical necessity is and how it is established.

2.
Review how medical necessity cases are enforced through discussion of laws and case examples.

3.
Discuss compliance measures to address risk associated with medical necessity matters and a framework for responding to potential medical necessity concerns.

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WHAT IS MEDICAL NECESSITY?

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WHAT IS MEDICAL NECESSITY?

- **"Medical necessity" is a fundamental element for both the provision and payment of healthcare**
  - Medicare coverage is limited to items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A).
  - Medicare requires healthcare practitioners and providers to assure that health services ordered for government patients are "provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1).

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WHAT IS MEDICAL NECESSITY?

- AMA (H-320.953) (2016) – Medical necessity is:
  - 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:
    - in accordance with generally accepted standards of medical practice;
    - clinically appropriate in terms of type, frequency, extent, site, and duration; and
    - 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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WHAT IS MEDICAL NECESSITY?

- **Who determines medical necessity?**
  - Treating physician
  - Reviewing physician (e.g., during chart reviews, prior authorizations)
- **What sources guide medical necessity determinations?**
  - Medicare Act and implementing regulations
  - Medicare Benefit Policy Manual defines Medicare-covered services and related requirements
  - National and Local Coverage Determinations offer interpretations and guidance
  - State Regulations and Provider Manuals define state-based coverage and program guidelines

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WHAT IS THE LEGAL FRAMEWORK?

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HOW CAN MEDICAL NECESSITY BE A FALSE CLAIM?

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 medically necessary . . .

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FALSE CLAIMS ACT - 31 U.S.C. §§ 3729-3733

- **False Claim**
  - Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval (31 U.S.C. § 3729(a)(1)(A))
- **False Record or Statement**
  - Knowingly makes, uses, or causes to made or used, a false record or statement material to a false or fraudulent claim (31 U.S.C. § 3729(a)(1)(B))
- **"Reverse" False Claim**
  - Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or
  - Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government (31 U.S.C. § 3729(a)(1)(G))
- **Conspiracy**
  - Conspires to commit any of the above violations (31 U.S.C. § 3729(a)(1)(C))

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FALSE CLAIMS ACT - 31 U.S.C. §§ 3729-3733

- A properly pleaded FCA claim must contain four elements:
  1. A **claim** for payment was **submitted** to the government
  2. The claim (or record or statement material to the claim) was **false**
  3. Defendant **knew or should have known** the claim was false
  4. The claim or statement was **material** to the government's decision to pay

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FALSE CLAIMS ACT - 31 U.S.C. §§ 3729-3733

- Violations are punished by **treble (3x) damages plus mandatory per claim civil penalties**
- Civil penalty inflation adjusted to $13,508 – $27,018 per claim
- Example: Healthcare provider submits 1,000 false claims for which Medicare pays $250,000 total. The provider is potentially liable under the FCA for a maximum of more than $27 million.
  - Damages = $750,000 ($250k x 3) and Penalties = $27,018,000 (1,000 x $27,018)
- Reasonable attorneys' fees and expenses for relator

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CRIMINAL HEALTH CARE FRAUD STATUTE – 18 U.S.C. § 1347

- The Criminal Health Care Fraud Statute, prohibits **knowingly and willfully** executing, or attempting to execute, a **scheme or lie** in connection with the **delivery of, or payment for, health care benefits, items, or services** to either:
  - Defraud any health care benefit program
  - Obtain (by means of **false or fraudulent pretenses, representations**, or promises) any of the money or property owned by, or under the control of, any health care benefit program

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UNITED STATES V. ASERACARE (11TH CIR. 2019)

- Mere difference of opinion between medical experts on an issue about which reasonable minds could differ is insufficient to prove falsity
- Government must show something more than difference of medical opinion concerning prognosis

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UNITED STATES EX REL. POLUKOFF V. ST. MARK'S HOSPITAL (10TH CIR. 2018)

- "It is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA . . ."
- "A doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase."

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UNITED STATES EX REL. DRUDING V. CARE ALTERNATIVES (3D CIR. 2020)

- In the context of certifying terminal illness, "for purposes of FCA falsity, a claim may be 'false' under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements"
- "[A] physician's judgment may be scrutinized and false"
- Reasonableness of medical necessity assessments are "triable issues"

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UNITED STATES EX REL. WINTER V. GARDENS REGIONAL HOSP. AND MED. CTR. (9TH CIR. 2020)

- Opinions "are not, and have never been, completely insulated from scrutiny"
- "Under the plain language of the [FCA], the FCA imposes liability for all 'false or fraudulent claims'—it does not distinguish between 'objective' and 'subjective' falsity or carve out an exception for clinical judgments and opinions"

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WHAT MATTERS CONSTITUTE MEDICAL NECESSITY CASES?

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EXAMPLES OF "MEDICALLY UNNECESSARY" FCA CASES

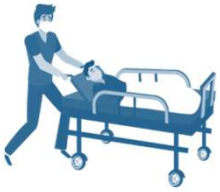
Unnecessary Diagnostics, Screening Tests or Procedures

Unnecessary Devices

Unnecessary or Excessive Services (PT/OT)

Unnecessary Ambulance Transports or Level of Service

Unnecessary SNF, Hospital or Inpatient Rehabilitation Admissions



Unnecessary Home Health or Hospice Services

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UNNECESSARY URINE DRUG TESTING

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PRESS RELEASE

Reference Laboratory, Pain Clinic, and Two Individuals Agree to Pay $41 Million to Resolve Allegations of Unnecessary Urine Drug Testing

Wednesday, April 15, 2020

For Immediate Release
Office of Public Affairs

Logan Laboratories Inc. (Logan Labs), a reference laboratory in Tampa, Florida; Tampa Pain Relief Centers Inc. (Tampa Pain), a pain clinic also based in Tampa Florida, and; two of their former executives, Michael T. Doyle and Christopher Utz Toepke (collectively, Defendants) have agreed to pay a total of $41 million to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid, TRICARE, and other federal health care programs for medically unnecessary Urine Drug Testing (UDT), the Department of Justice announced today. Both Logan Labs and Tampa Pain are subsidiaries of Surgery Partners Inc. Doyle is the former CEO of Surgery Partners and Logan Labs. Toepke is the former Group President for Ancillary Services at Surgery Partners, with oversight of Logan Labs, and a former Vice President at Tampa Pain.

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UNNECESSARY LABORATORY TESTS AND FRAUDULENT BILLING

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PRESS RELEASE

University of Miami to Pay $22 Million to Settle Claims Involving Medically Unnecessary Laboratory Tests and Fraudulent Billing Practices

Monday, May 10, 2021

For Immediate Release
Office of Public Affairs

The University of Miami (UM) has agreed to pay $22 million to resolve allegations that it violated the False Claims Act by ordering medically unnecessary laboratory tests, and submitting false claims through its laboratory and off campus hospital based facilities ("Hospital Facilities").

According to court documents, the United States alleged that UM engaged in three practices that violated the False Claims Act. First, the government alleged that UM knowingly engaged in improper billing relating to its Hospital Facilities. Medicare regulations allow medical systems to convert physician offices into Hospital Facilities provided they satisfy certain requirements. Billing as a Hospital

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IMPROPER BILLING - IMPLANTATION OF CARDIAC DEVICES

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PRESS RELEASE

Nearly 500 Hospitals Pay United States More Than $250 Million to Resolve False Claims Act Allegations Related to Implantation of Cardiac Devices

Friday, October 30, 2015

For Immediate Release
Office of Public Affairs

The Department of Justice has reached 70 settlements involving 457 hospitals in 43 states for more than $250 million related to cardiac devices that were implanted in Medicare patients in violation of Medicare coverage requirements, the Department of Justice announced today.

"While recognizing and respecting physician judgment, the department will hold accountable hospitals and health systems for procedures performed by physicians at their facilities that fail to comply with Medicare billing rules," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "We are confident that the settlements

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UNNECESSARY RESPIRATORY PANELS DURING COVID-19 TESTS

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PRESS RELEASE

Lab Billing Company Settles False Claims Act Allegations Relating to Unnecessary Respiratory Panels Run on Seniors Receiving COVID-19 Tests

Friday, June 16, 2023

For Immediate Release
Office of Public Affairs

VitalAxis Inc., a Maryland-based billing company for diagnostic laboratories, has agreed to pay $300,479.58 to resolve False Claims Act allegations that it caused the submission of false claims to Medicare for medically unnecessary respiratory pathogen panels run on seniors who received COVID-19 tests.

Throughout 2020, VitalAxis performed billing services for a diagnostic laboratory in Atlanta, Georgia that provided COVID-19 testing to residents of senior living communities. For one chain of communities, the laboratory directed VitalAxis to bill Medicare for respiratory pathogen panels purportedly ordered by a physician who had not actually ordered the tests and who was ineligible to treat

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MEDICALLY UNNECESSARY REHABILITATION SERVICES

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PRESS RELEASE

Life Care Centers of America Inc. Agrees to Pay $145 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services

Monday, October 24, 2016

For Immediate Release
Office of Public Affairs

Life Care Centers of America Inc. (Life Care) and its owner, Forrest L. Preston, have agreed to pay $145 million to resolve a government lawsuit alleging that Life Care violated the False Claims Act by knowingly causing skilled nursing facilities (SNFs) to submit false claims to Medicare and TRICARE for rehabilitation therapy services that were not reasonable, necessary or skilled, the Department of Justice announced today. Life Care, based in Cleveland, Tennessee, owns and operates more than 220 skilled nursing facilities across

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FALSE CLAIMS – AMBULANCE TRANSPORTS

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PRESS RELEASE

Ambulance Company to Pay $9 Million to Settle False Claims Act Allegations

Wednesday, March 28, 2018

For Immediate Release
Office of Public Affairs

Medical Transport LLC, a Virginia Beach-based provider of ambulance services, agreed to pay $9 million to resolve allegations that it violated the False Claims Act by submitting false claims for ambulance transports, the Justice Department announced today.

"Those who benefit from federal health care programs must play by the rules," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "The Department of Justice is committed to ensuring that those whose conduct results in improper payments by the federal government will be held accountable."

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MEDICALLY UNNECESSARY SURGICAL PROCEDURES

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PRESS RELEASE

Providence Health & Services Agrees to Pay $22.7 Million to Resolve Liability From Medically Unnecessary Neurosurgery Procedures at Providence St. Mary's Medical Center

Tuesday, April 12, 2022

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For Immediate Release
U.S. Attorney's Office, Eastern District of Washington

Walla Walla, WA – Providence Health & Services Washington (Providence) has agreed to pay $22,690,458 to resolve allegations that it fraudulently billed Medicare, Medicaid, and other federal health care programs for medically unnecessary neurosurgery procedures, announced Vanessa R. Waldref, the United States Attorney for the Eastern District of Washington and Bob Ferguson, the Washington State Attorney General. Today's joint settlement between Providence, the United States, and the State of

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DOJ CIVIL PERSPECTIVE

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CIVIL V. CRIMINAL CONSIDERATIONS

- Parallel Intake/ Referral to Criminal Division
- Preponderance of Evidence v. Beyond a Reasonable Doubt
- Scope of Fraud/Loss to Government
- Patient Harm
- Egregiousness
- Repeat Offender?

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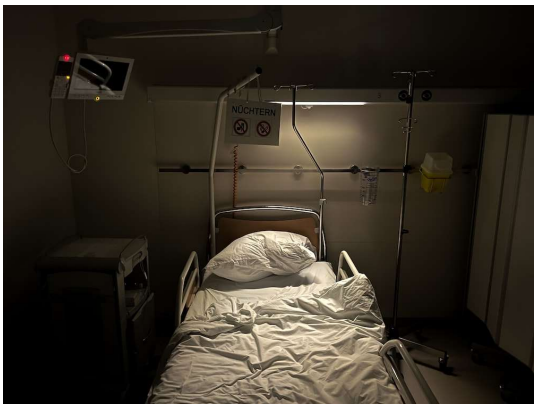
EXAMPLES OF CASES THAT WERE CIVIL AND CRIMINAL

- Drug/urine testing
- Cardiac stents
- Telehealth
- Pain medications/opioids
- DME
- Compound Pharmacies



BUT MOST FCA CASES HAVE POTENTIAL TO BECOME CRIMINAL

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WHAT STEPS CAN COMPLIANCE PROFESSIONALS TAKE TO ADDRESS RISK AND RESPOND TO MEDICAL NECESSITY CONCERNS?

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PRACTICAL TIPS TO MITIGATE RISK

- Establish risk assessments
- Identify potential high risk areas – government reviews, PEPPER reports, internal complaints, utilization review
- Develop policies and procedures providing documentation and other requirements for risk areas
- Provide training to clinical and coding/billing personnel on requirements
- Conduct periodic audits of claims in high risk areas

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PRACTICAL TIPS TO MITIGATE RISK

- Educate physicians and APPs on legal standards of medical necessity
  - Understand difference between medical necessity and clinical judgment
  - Understand payor guidance for documentation needed to support claims
  - Document! Document! Document!
  - Advise on benefits of EMR templates and caution on risks of cut/paste or generic documentations

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IDENTIFYING POTENTIAL ISSUES

- Consider peer review or utilization red flags
  - Patterns of overutilization or outlier status
  - Staff complaints
  - Malpractice cases
- Follow medical staff bylaws
  - Ensure objective assessments
  - Consider external reviews

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ADDRESSING MEDICAL NECESSITY ISSUES

- Adequately scope issue
  - Distinction between lack of documentation to support claim that was billed and procedure/service not being medically necessary
- Consider potential remedial action needed
  - Refund or self-disclosure of claim?
  - Education or corrective action required?

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QUESTIONS?

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