Intro to Healthcare Compliance

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Roadmap for Today

1. Legal implications pertaining to billing
2. Patient privacy and access to information
3. Other legal issues

Current Environment

- Healthcare is one of the most regulated industries
  - Legal action by the U.S. Department of Justice (DOJ)
  - Largest part of GDP
- Congress has increased funding for enforcement
- Government investigations occur often
  - Creation of new investigation units
  - Duty to self-report
  - Increase in penalties

Enforcement Actions

- **Focuses:**
  - **Specific types of behavior**
    - Hospital-physician arrangements
    - Patient assistance programs
  - **Specific industries**
    - Home health
    - Laboratories
    - Pharmacy benefit managers (PBMs)
  - **State and Federal**

Regulation Refresher

Fraud and Abuse Laws

- Healthcare providers are subject to special limitations in business arrangements
- Certain marketing practices, investments, and contracts, which are standard in many other industries, are not permitted in healthcare, especially when the arrangements involve reimbursement from government health care program funds
  - Federal healthcare programs
    - The Anti-kickback Statute
    - Stark Law
    - False Claims Act
  - State laws have followed suit
    - Self-Referral prohibitions
    - State anti-kickback statutes
    - Fee-splitting prohibitions

Federal Anti-Kickback Statute
42 U.S.C. §1320a-7b

Overview

- Enacted in 1972
- *No person may offer, pay, solicit, or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in exchange for either: (i) the referral of patients covered by* ***government-funded health care programs****; or (ii) the leasing, purchasing, ordering, or arranging for or recommending the lease, purchase, or order of any item, good, facility, or service covered by the programs.*

General Terms:

- As a health care provider, you generally cannot:
  - pay any person or entity for referrals; or
  - accept payment from any person or entity in exchange for referrals.
- Intent-based statute
  - Very broad application
- This applies to government-funded programs:
  - Medicare, Medicaid, Tricare, Medicare Advantage, Medicaid managed care

Anti-Kickback Penalties

- Penalties
    - Recently increased under The Bipartisan Budget Act of 2018 signed by President Trump in February 2018
- Civil monetary penalties
    - $25,000 - $50,000 per violation
- Treble damages (3x)
- Criminal fines
    - Up to $25,000
- Imprisonment
    - Maximum 5-10 years
- Exclusion from federal healthcare programs

Stark Law
42 U.S.C. §1395nn

- Prohibits a physician from referring Medicare or Medicaid patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship.
  - A "financial relationship" exists when the physician (or an immediate family member) has a:
    - direct or indirect ownership or investment interest in an entity
    - direct or indirect compensation arrangement with an entity
- Physician includes MD, DO, DDS, DMD, DP, OD, DC
  - Includes immediate family member (spouse or child)
- Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral

Designated Health Services

- DHS include the following:
    - Clinical laboratory services;
    - Physical therapy, occupational therapy, and outpatient speech-language pathology services;
    - Radiology and certain other imaging services;
    - Radiation therapy services and supplies;
    - Durable medical equipment and supplies;
    - Parenteral and enteral nutrients, equipment, and supplies;
    - Prosthetics, orthotics, and prosthetic devices and supplies;
    - Home health services;
    - Outpatient prescription drugs; and
    - Inpatient and outpatient hospital services

Stark Law in Layman's Terms

- Like the AKS, the Stark law has exceptions to allow certain financial arrangements
- Physicians should not invest in or enter into a contractual arrangement with any entity to which it refers DHS *unless an exception is met*
  - This includes arrangements with the group practice

Stark Law Penalties

- Strict Liability – do not need intent
  - Expired agreement
- Refund of overpayments
  - Every claim that resulted from physician referral
- Civil monetary penalties
  - $15,000 per violation
  - Higher if intent is present
- Treble damages (3x)
- Exclusion from federal healthcare programs

The False Claims Act

- Federal law that makes it a crime for any person or organization to knowingly make a false record or file a false claim regarding any federal healthcare program
  - Deals with fraud and abuse in billing and claims submission
- All claims submitted must be: true, complete & accurate
  - False means wholly or partially untrue
- The terms “knowing” and “knowingly” mean a person has
  - actual knowledge of the information
  - acts in deliberate ignorance
  - reckless disregard of the truth or falsity of the information related to the claim.

The False Claims Act Penalties

- Civil monetary penalties and criminal monetary penalties
- $5,500 - $11,000 per each false claim filed
- Plus treble damages (3X the amount of the claim)
- Criminal fines
- Imprisonment
- Implementation of a Corporate Integrity Agreement (CIA) – 5 year term
- Exclusion from Medicare, Medicaid & any governmental program (anywhere from 6 months to permanently)
- Statue of Limitation: In some instances, application of the law up to 10 years

Duty to Refund Overpayments

- ACA includes a provision that providers must disclose and return any overpayments that result from mistaken or erroneous claims.
    - Final Rule issued February 12, 2016
    - 6 years after statute passed
    - 4 years after Proposed Rule published
- Key Takeaways:
    - Applies to Medicare Parts A and B (Medicare Parts C and D are covered under a separate rule)
    - 6-year lookback period
    - 60 days begins once the overpayment is "identified"
    - 6-month investigation or due diligence period

Common Billing Mistakes

- Inaccurate or incorrect coding
- Upcoding
- Unbundling of services
- Billing for medically unnecessary services, or other services not covered by the relevant health care program
- Billing for services not provided
- Duplicate billing
- Insufficient documentation
- False or fraudulent cost reports

Most Common Types of Healthcare Fraud

- Billing for services not rendered.
- Billing for non-covered services as a covered service.
- Mispresenting dates of service.
- Misrepresenting locations of service.
- Misrepresenting provider of service.
- Waiving of deductibles and/or co-payments.
- Incorrect reporting of diagnoses or procedures and unbundling of services.
- Overutilization of services.
- Corruption (kickbacks and bribes).
- False or unnecessary issuance of prescription drugs.

See CMS Fact Sheet *available at* https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/fwa-factsheet.pdf.

Case Studies in Compliance

Broward Health – Ft. Lauderdale, Florida

Illegal Physician Compensation (Anti-Kickback and Stark Violations)

- Broward Health allegedly compensated at least nine employed physicians at rates above the fair market value and based compensation on patient referrals.
- The rate was determined based on the physician's ability to increase patient referrals to the hospital system, in violation of Stark and Anti-Kickback Statutes.
- Whistleblower alleged that Broward Health tracked the value of physician referrals and pressured physicians to increase referral volume when the referrals fell short of targeted goals.
- Broward Health settled the case for approximately $70 million for violations of Stark and Anti-Kickback Statutes.
- The lawsuit fell under the False Claims Act because federal law prohibits reimbursement from Medicare for services provided to patients that were illegally referred.

Adventist Health System – Altamonte Springs, Florida

Illegal Physician Compensation (Anti-Kickback and Stark Violations)

- Adventist Health System allegedly paid bonuses to physicians based on the number of patients referred to Adventist Health System owned facilities.
- The Health System encouraged doctors to purchase practices in certain areas in order to control referrals in specifically defined geographic areas.
- A former physician was the whistleblower.
- The Health System agreed to settle for $118.7 million
- The lawsuit fell under the False Claims Act statute because federal law prohibits reimbursement from Medicare for services provided to patients that were illegally referred

Improper Delegation / Supervision

- Adventist allegedly billed for and received reimbursement for radiation oncology services provided to Medicare patients without the required supervision of a qualified medical professional, as required by Medicare.
- A former radiation oncologist for Adventist filed the qui tam action.
- Because the procedures were not properly billed because of the lack of required supervision, Adventist violated the False Claims Act.
- Adventist agreed to settle for $5.4 million, and the whistleblower will receive approximately $1 million.

21st Century Oncology

- Provider knowingly submitted false attestations to CMS concerning employed physicians' use of EHR software
- Employees falsified data, fabricated software utilization reports, superimposed EHR vendor logos onto reports to make them look legitimate
- Qui tam brought by former Interim Vice President of Financial Planning (he received $2,000,000)
- Total settlement was $26,000,000
- CIA
    - Internal compliance reform
    - IRO conduct annual claims and arrangements reviews

Patient Privacy and Access to Information

HIPAA

Protects privacy and security of a patient's protected health information.
- Must comply with the Privacy Rule and the Security Rule.

May only disclose patient information if:
- To the patient or to a third party when instructed by the patient in writing
- For treatment, payment or health care operations
- Pursuant to patient authorization

HITECH – Expanded scope of HIPAA (business associates, breach notification); Provided EMR incentives and penalties

FACTA – Identity theft protection requirements for "creditors" (Medical Identity Theft)
- Not applicable to private practices
- Most likely applicable to hospitals

HIPAA Penalties

- Civil penalties (significantly increased by HITECH):
  - Did not know of violation, and would not have known by exercising reasonable diligence: $100 - $50,000 per violation, max of $1.5 million per calendar year
  - Violation due to reasonable cause: $1,000 - $50,000 per violation, max of $1.5 million per calendar year
  - Violation due to willful neglect, corrected within 30 days: $10,000 - $50,000 per violation, max of $1.5 million per calendar year
  - Violation due to willful neglect, not corrected within 30 days: $50,000 per violation, max of $1.5 million per calendar year

- Criminal penalties:
  - Fines of up to $50,000 and/or imprisonment of not more than one (1) year for intentional disclosures of protected health information.
  - Criminal penalties of $100,000 and/or imprisonment of not more than five (5) years for obtaining or disclosing protected health information under false pretenses.
  - Criminal penalties of $250,000 and/or imprisonment of not more than ten (10) years for obtaining protected health information with the intent to sell, transfer or use it for commercial advantage, personal gain or malicious harm.

HIPAA Compliance Plan

- Policies and procedures to protect against HIPAA violations
- Annual training – Must actually understand and follow the plan

Common HIPAA Mistakes

- Social networking, pictures, “friending” patients
- EHR look-up of celebrities, family, friends
- Patients of other providers
- Disclosures to family/friends involved in the patient’s care

21st Century Cures Act

- Improve interoperability of EHRs for providers

- Allow for ease of access to data for patients and authorized entities - i.e. prevent "information blocking"
  - Defines information blocking
  - Establishes penalties

Information Blocking Defined

"Information blocking" is defined as any practice that is likely to **interfere** with, **prevent**, or **materially discourage access**, **exchange**, or **use** of electronic health information, and if conducted by a health care provider, such provider *knows* that the practice is unreasonable and is likely to be considered information blocking.

Other Legal Issues

- Medicare/Medicaid exclusion lists
- State specific prescribing rules (i.e., OAARS; pain rules)
- State specific billing rules (i.e., fee splitting; self-referrals; kickbacks)
- National Practitioner Data Bank
- Medical staff issues (privilege denials; peer review; due process rights)
- Sexual harassment and disruptive behavior

Thank You & Questions

- **Jeana M. Singleton**
  - Member, Executive Committee, General Counsel, Brennan Manna & Diamond, LLC
  - jmsingleton@bmdllc.com
  - 330-612-8425 (cell)
  - https://www.linkedin.com/in/jeana-singleton-48693119/