

Corporate Compliance Education

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Agenda

- Discuss the “what” and “why” of Corporate Compliance
- Review 7 elements of a robust compliance program
- Discuss some of the laws with which we must comply
 - Anti-kickback Statute
 - Stark (Physician Self-Referral law)
 - False Claims Act
- Discuss what you can do to assist with the compliance program

What is Corporate Compliance?

- Corporate Compliance refers to an institutional program designed to ensure an organization's compliance with federal, state and local laws and regulations as well as organizational policies and ethical standards.

Why Have a Compliance Program?

- Demonstrates to the community of the organization's commitment to corporate citizenship
- Reinforces the organization's culture of ethics, integrity, accuracy to all employees and provides guidelines for leadership compliance responsibilities
- Provides an expectation of employee, provider and contractor behavior
- Provides procedures to correct misconduct
- Effective communications for Board of Directors through an organized framework for regulatory compliance tracking and reporting

Why Have a Compliance Program?

- Legal duty to government and private payers
- Protects the financial viability of the organization (cost effective – savings)
- Voluntary implementing vs. CIA (Corporate Integrity Agreements)
- An effective program may mitigate sanctions imposed by the government

U.S. Sentencing Guidelines – Compliance Program Effectiveness

- Guidelines determine sentences based on:
 - Conduct associated with the offense
 - Criminal history
- 1991 – Guidelines introduced concept of compliance program and effective elements
 - Amended in 2004 and 2010
 - More descriptive
 - Description of what makes a program “effective”
 - Potential to reduce culpability score
 - 2010 – Compliance Officer with “direct reporting obligation” to Board

To Whom do We Have to Comply?

- Numerous Regulations for Compliance (just a few examples...)
 - Joint Commission
 - Centers for Disease Control (CDC)
 - Food and Drug Administration (FDA)
 - Office of Civil Rights (OCR)
 - Department of Health and Human Services' Office of Inspector General (OIG)
 - National Fire Protection Agency – Life Safety Codes
 - Department of Transportation
 - Occupational Safety and Health Administration
 - Internal Revenue Service
 - U.S. Department of Justice (Sentencing Guidelines)
 - State Medicaid Fraud Units
 - Attorney General
 - State Regulatory Agencies
 - Michigan Department of Community Health (MDCH)
 - MIOSHA
 - Civil Rights
 - Michigan Department of Transportation (MDOT)
 - Department of Treasury
 - Relationship to Regulatory Standards and Quality – False Claims

Compliance Program (7 Elements)

- In 1998, the Federal Government recommended that each organization adopt a voluntary compliance program. It was suggested that the following seven elements be **part of each compliance program.**

Compliance Program (7 Elements)

- **1. Written Standard of Conduct and Policies and Procedures that Promote Compliance**
- **2. Designation of a Compliance Officer and Compliance Committee**
 - Privacy Officer
 - Security Officer

Compliance Program (7 Elements)

- **3. Education & Training**

- Orientation
- Annually thereafter
- Specialized training for high risk areas (i.e. marketing, billing)
- Annual Board Education
- Compliance Newsletters and Alerts

Compliance Program (7 Elements)

- **4. Effective Lines of Communication**
 - In compliance training, employees are informed to first speak with their immediate supervisor, manager or director with compliance concerns
 - If employees feel uncomfortable sharing the information with their leader, they may contact their compliance officer or use the compliance hotline

Compliance Program (7 Elements)

- **5. Enforcing Standards Through Well Publicized Disciplinary Guidelines**
 - Violation Penalties (up to and including termination and criminal penalties)
 - Non-compliance with policies and procedures

Compliance Program (7 Elements)

- **6. Auditing & Monitoring**

- Audits: Any review, monitor, or evaluation, conducted for the purpose of determining compliance with federal or state law, regulation, 3rd party payer requirement, licensing or accreditation standard or financial reporting
- Audit types
 - Internal or external reviews as ID with compliance work plan
 - Compliance officer/department reviews
 - External reviews – auditors, 3rd party payers

Compliance Program (7 Elements)

- **6. Auditing & Monitoring (con't)**
 - Policies
 - Needed for auditing and monitoring
 - Must include response, follow-up and resolution
 - Processes
 - Information to key individuals
 - Timely Correction
 - Plan going forward

Compliance Program (7 Elements)

- **6. Auditing & Monitoring (con't)**
 - Annual planning
 - OIG Guidance and annual OIG plans
 - Risk Assessment (U.S. Sentencing Guidelines)
 - Consideration of government reports (CERT, RAC, etc.)

Compliance Program (7 Elements)

- **7. Responding to Detected Offenses and Remediation and Employment Practices and Sanction Screening**
 - Must have procedures for responding to known issues and a corrective action plan
 - Background checks and verification of qualifications for employees, physicians and vendors
 - Criminal background checks
 - Licensure checks
 - Medicare/Medicaid exclusion checks
 - Terrorist data base checks
 - Impact of excluded individual
 - CANNOT BILL FOR ANY SERVICES PROVIDED!
 - Possible criminal sanctions

Key Compliance Laws

- Medicare/Medicaid C.O.P.s
- Anti-Kickback Statute
- Stark – I, II, II phase III
- False Claims Act
- EMTALA
- HIPAA/HITECH Privacy and Security
- Mental Health Code

Anti-Kickback Statute

Anti-Kickback Statute

- Knowing and willful conduct involving solicitation, receipt, offer, or payment of any kind of remuneration (including a kickback, bribe or rebate) in exchange for
 - Medicare or Medicaid patient referral, or
 - Purchase, lease, or ordering of any good or service under which payment from federal health program is made

Remuneration

Any type of cash or in-kind benefit that can be given a monetary value and can include:

- Cash or other compensation
- Meals, travel expenses, and entertainment
- Gifts and other free items or services
- Free or reduced-cost office or consulting services

Safe Harbors

- Specific exceptions protecting certain arrangements from prosecution under the anti-kickback statute
- Organizations must align themselves as close as possible to the Safe Harbor for potential protection
- The safe harbors are listed on the OIG

<http://oig.hhs.gov/fraud/safeharborregulations.html>

Common Safe Harbors

- Space rental
- Equipment rental
- Personal services and management contracts
- Referral services
- Employee compensation
- Cooperative hospital service organizations
- Electronic prescribing and health record arrangements

Anti-Kickback – Federal Penalties

- Criminal Penalties
 - Criminal Statute – felony charges (5yrs and/or \$25k fine)
 - Potential financial liability under False Claim Act
- Civil Money Penalties
 - Loss of Medicare & Medicaid provider status
 - Civil Monetary penalties of \$50k per act, plus damages equal to 3x the remuneration involved

Michigan Anti-kickback Statutes

- Public Health Code
 - Physician or other health providers
- Health Care False Claim Act
- Medicaid False Claim Act
- Penal Code
 - Physician or surgeon

Key Differences from Physician Self-Referral (Stark) Law

- Under the anti-kickback statute, there must be the requisite intent or there is no violation; under Stark, intent is not required—if there is an ownership or financial interest, referrals are prohibited regardless of intent
 - AKS is based on “intent”, whereas Stark is a “Strict Liability”
- Anti-kickback applies to all providers; Stark applies only to physicians
- Anti-kickback is a criminal statute with potential for civil penalties; Stark is a civil statute

Stark Law

(Physician Self-Referral Law)

Overview of the Stark Law

- The Stark Law: A Closer Look

1. Strict Liability Statute
2. Prohibits physicians from making referrals for “designated health services” (“DHS”) payable by Medicare to entity with which the physician (or an immediate family member) has a “financial relationship,” unless an exception applies.
3. Prohibits the entity from filing claims with Medicare for those referred DHS.

*Stark violation can be used to generate False Claim liability

Definitions - Immediate Family Member

This includes the physician's:

- Husband or wife
- Birth or adoptive parent
- Child
- Sibling
- Stepparent
- Stepchild
- Spouse of a grandparent or grandchild
- Father-in-law or mother-in-law
- Stepbrother or stepsister
- Son-in-law or daughter-in-law
- Brother-in-law or sister-in-law
- Grandparent
- Grandchild

Definitions - DHS

- “Designated Health Services” (11) means any of the following items or services
 - Clinical laboratory services.
 - Physical therapy services.
 - Occupational therapy services.
 - » Radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services.
 - Radiation therapy services and supplies.
 - Durable medical equipment and supplies.
 - Parenteral and enteral nutrients, equipment, and supplies

Definitions - DHS

- “Designated Health Services” means any of the following items or services (cont.)
 - Home Health services.
 - Prosthetics, orthotics, and prosthetic devices and supplies.
 - Outpatient prescription drugs.
 - Inpatient and outpatient hospital services
- The Center for Medicare and Medicaid Services publishes an annual list of HCPCS codes covered as DHS

Financial Relationships

- Ownership/investment: Direct or indirect
 - Stock, partnership, limited liability company membership and loans
- Compensation Arrangement
 - Any arrangement involving remuneration (direct or indirect)

Michigan

- Implications of Stark Law on Michigan Law (MCLA 333.16221 (e) (iv)) – Public Health Code
 - Violation of the Stark Law constitutes “unprofessional conduct.”
 - Violation of Stark Law can result in disciplinary action under Michigan laws governing physician licensure.

Exceptions: General (Regardless of Physician's Financial Interest)

1. In-office ancillary services
2. Physician services
3. Academic medical centers (AMC)
4. Prepaid plans – services by an organization to enrollees
5. Implants furnished by an ambulatory surgery center (ASC)
6. Dialysis-related outpatient prescription drugs
7. Preventive screening tests, immunizations, and vaccines
8. Eyeglasses and contact lenses after cataract surgery
9. Intra-family rural referrals

Exceptions: Ownership or Investment Interests

- Ownership in publicly traded securities
- Mutual funds
- Rural provider exception

Exceptions: Compensation Arrangements

1. Rental of office space
2. Equipment rental
3. Bona fide employment relationships
4. Personal service arrangements
5. Remuneration unrelated to the provision of DHS

Exceptions: Compensation Arrangements

6. Physician recruitment
7. Incidental Benefits; Isolated transactions
8. Certain group practice arrangements with a hospital
9. Payments by a physician for items and services
10. Charitable donations

Exceptions: Compensation Arrangements

11. Non-monetary compensation up to \$355
12. Fair market value compensation
13. Medical staff incidental benefits
14. Risk-sharing arrangements
15. Compliance training

Exceptions: Compensation Arrangements

- 16. Indirect compensation arrangements
- 17. Referral services
- 18. Obstetrical malpractice insurance
- 19. Professional courtesy
- 20. Retention payments in underserved areas
- 21. Community-wide health information systems
- 22. Electronic Health Records Technology Arrangements

Stark Penalties

- Civil Money Penalties
 - Loss of Medicare & Medicaid provider status
 - Civil Monetary penalties of \$15k per service, plus damages equal to 3x the remuneration involved & \$100k circumvention scheme
- Denial of Payments
- Payment Refunds
- Exclusion from CMS programs

Michigan Stark

- Implications of Stark Law on Michigan Law (MCLA 333.16221 (e) (iv)) – Public Health Code
 - Violation of the Stark Law constitutes “unprofessional conduct.”
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False Claims Act

False Claims Act Basics

- Knowingly and willfully submit, cause to be submitted or fail to report/correct to Govt.
 - Claim for services not rendered
 - Claim for services not ordered by a physician
 - Claim for medically unnecessary services
 - Poor quality
 - Improper documentation practices
 - Submit false information
 - Upcoding and DRG creep
 - 72 hour DRG payment window violations
 - Duplicate Billing
 - Bills for services resulting from physician relationship that violates Anti-kickback and physician referral laws
- Federal and State False Claims Laws

The False Claims Act and the Definition of “Knowingly”

- The False Claims Act defines “knowingly” broadly to include the submission of claims in a “reckless disregard” of the truth or falsity of the claim
- This language is intended to prevent submission of a claim in “deliberate ignorance” of whether or not the claim is true
- No proof of specific intent to defraud is required
 - Struthious Conduct: Conduct of an ostrich (head in the sand)

Who is Liable Under the False Claims Act?

- Any person or entity connected with the submission of a false claim can be liable, including:
 - Providers
 - Beneficiaries
 - Health plans that do business with the federal government
 - Billing companies
 - Contractors

The False Claims Act and the Government

- Government enforcement entities are taking aim at False Claims Act violations by healthcare providers. These entities include the following:
 - The Office of Inspector General (OIG) of the Department of Health and Human Services
 - Department of Justice (DOJ)
 - Federal Bureau of Investigation (FBI)
- Deficit Reduction Act ('05) emphasized enforcement
- Whistleblower (qui tam) provisions

Penalties

- \$5,500-\$11,000 for each claim
- Up to 3 times the amount of damages the government sustains
- MI – False Claims laws
 - \$5,000-\$10,000 per claim
- Potential Criminal Penalties for intentional violations

Michigan and FCA

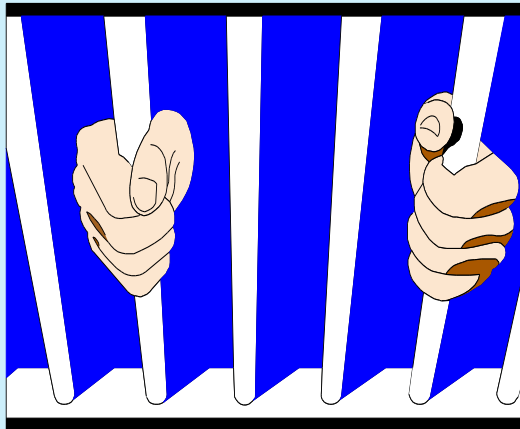
- Medicaid False Claim Act
 - Qui Tam Provision
- Health Care False Claim Act
- Insurance Code
- Public Health Code
 - Physicians and other health professionals ramifications
- Social Welfare Act

What Can You Do To Be Compliant?



- **Begin by:**
 - Documenting the care that was provided to the patient – accurately & completely!
 - Only billing payers for the services that were ordered & provided
 - Clarifying any issues as necessary
 - **KNOW THE POLICY!** (or ask about it)

What Happens If We Fail To Comply??



- Organizations and individuals can suffer heavy penalties ranging from:
 - Fines
 - Criminal Penalties
 - Medicare/Medicaid Exclusion

The Compliance Hotline (coming soon...)

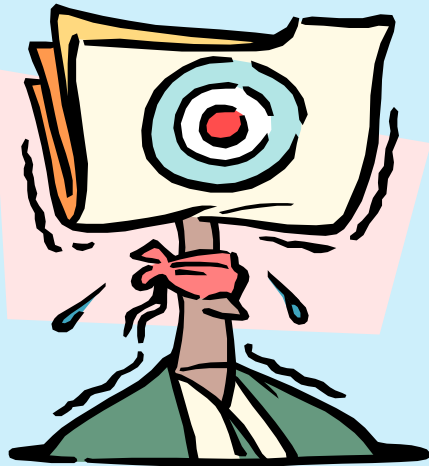


- **Anonymous**
- **24/7 Voice Mail**
- **Report information you may have regarding a possible violation of laws or ethical standards**

What Kinds Of Things Should I Report?

- Violations of law
- Inappropriate gifts, entertainment or gratuities
- Improper use of Agency property
- Violations of patient confidentiality
- Discrimination or harassment
- Stealing/Misuse of assets

Non-Retaliation Policy



- You should feel comfortable providing information about possible legal or ethical violations to the hotline without fear of retaliation. No adverse action will be taken against you by the Agency based on a good-faith complaint.

Whistleblower Protection Act

- State statute that protects employees who bring possible violations of law or ethics to the attention of their employer
- Allows individual to bring suit on behalf of government
 - May receive up to 30% of penalties
- Must have documented evidence
 - Government can decline to bring suit if evidence is insufficient
- Requires non-retaliation protections

Conclusion

- **Compliance and participation and cooperation in your organization's compliance program is important, not only because of the fines, criminal penalties and loss of funding that can result if you don't participate, but because it is the right thing to do.**