Physician Self-Referral (Stark) Laws, Fraud & Abuse Claims: Practical Counsel

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Presentation Outline

- Overview of Applicable Statutes and Regulations
- New Emphasis on Physicians regarding Fraud, Abuse, Waste, and Errors
- Affordable Care Act: *"The New World Order"*
- Brief Roadmap to Being Compliant
- Questions & Answers

Five Significant Federal Laws

- Anti-Kickback Statute
- Physician Self-Referral Act (Stark)
- Exclusion Statute
- Civil Monetary Penalty Law

In a nutshell --- if the federal government pays for any items or services to Medicare beneficiaries, the federal fraud and abuse laws are immediately invoked

Definition: Fraud

Medicare ***fraud*** is:

Obtaining or attempting to obtain services or payments by dishonest means with

INTENT, KNOWLEDGE and WILLINGNESS that results in the securing of a benefit

Definition: Abuse

Medicare ***abuse*** is:

When an entity does not follow good medical practices, inconsistent with accepted sound medical, business, or fiscal practices, and results in unnecessary costs, improper payments or services not medically necessary

Definition: Ignorance

NOT A DEFENSE!!!

Anti-Kickback Statute

Anti-Kickback Statute

§ 1128B of the Social Security Act

- Anti-Kickback Statute makes it a "criminal offense" to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program

- For purposes of the anti-kickback statute, *"remuneration"* includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind

Anti-Kickback Statute

- Where remuneration is paid *"purposefully"* to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated
- The statute ascribes liability to parties on *both* sides of an impermissible "kickback" transaction
  - Vicariously liability??

Common Anti-Kickback Risks

Common Risks

- Physician Recruitment
  - Hospital relationships
    - Improper financial arrangements
    - Free or low rent arrangements

- Physician Relationship with Vendors
    - Pharmaceutical and Device Manufacturers
      - Sham consulting agreements
      - Free Samples

False Claims Act

False Claims Act

Any entity who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government

(3) Conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government

(4) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government

Prohibits the submission of false or fraudulent claims to a government entity/payor …

Troubles begin ….

- Services not actually rendered
- Services not medically necessary
- Services established as low quality and virtually worthless
- Services are “upcoded”
- Services already included in a global fee
- Services performed by an improperly supervised or unqualified employee
- Services performed by an employee who has been excluded from Federal healthcare programs

Caveat: All Physicians

Federal government's payments are based on:

- Claims being submitted by physicians must be "implicitly *and* explicitly" certified by the physician that documents/claims are accurate
- Physicians must authenticate claims or documents are NOT only accurate but also complete
  - Support documentation for items or services needs to support the claim submission

Physician Self-Referral

The Stark Reality

Physician Self-Referral Act

§ 1877 of the Social Security Act

Prohibits a physician from making *referrals* for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation)

Stark Reality

- Originally known as the Ethics in Patient Referrals Act of 1989
- Became effective on January 1, 1992
- Referred to as the "Stark Law" because Congressman Pete Stark sponsored the bill
- Stark Law's initial prohibition applied only to clinical lab services
  - Stark I - 1993
- Stark Law prohibition expanded to apply to a broader range of "designated health services" (DHS)
  - Stark II – 1995
- Stark Laws relaxed and exceptions created
  - Stark III - 2007
- ***Stark Law only applies when the referral concerns a Medicare beneficiary***

The following items or services are DHS:

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- 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
- Inpatient and outpatient hospital services

What is a “referral”?
When does a “referral occur”?

What if Stark is violated?

- Denial of payment
- Refund of payments
- Imposition of civil monetary penalties by the Centers for Medicare and Medicaid Services (CMS)
- Assessment of a penalty by the Office of the Inspector General (OIG)
- Civil monetary penalty for involvement in a circumvention scheme
- Exclusion from Federal health care programs

Self-Policing of Violations

- On September 23, 2010, CMS published the Medicare self-referral disclosure protocol ("SRDP") pursuant to Section 6409(a) of the Patient Protection and Affordable Care Act (ACA)
- The SRDP sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute

Exclusion Statute

- Under the Exclusion statute, a physician who is convicted of a criminal offense can be banned from Medicare for:
  - Medicare fraud
  - Patient abuse
  - Patient neglect or
  - Illegal distribution of a controlled substance
- Physicians who are excluded may not bill directly or indirectly to a government program
- **New criminal activity - Misbranding of drugs**

New World Order:
The Affordable Care Act

ACA EXPLAINED IN SIMPLE TERMS

- Quality
- Accessibility
- Affordability
- Portability
- Solvency

Fraud and Abuse Enforcement

EQUALS

Solvency of Medicare

10 Titles of ACA

Title I. *Quality, Affordable Health Care for All Americans*

Title II. *The Role of Public Programs*

Title III. *Improving the Quality and Efficiency of Health Care*

Title IV. *Prevention of Chronic Disease and Improving Public Health*

Title V. *Health Care Workforce*

Title VI. *Transparency and Program Integrity*

Title VII. *Improving Access to Innovative Medical Therapies*

Title VIII. *Community Living Assistance Services and Supports Act*

Title IX *Revenue Provisions*

Title X. *Reauthorization of the Indian Health Care Improvement Act*

Important Provisions in Title VI

(1) Identify, investigate, and cease fraudulent and abusive practices
(2) Identify, investigate, cease waste and errors of providers
(3) Minimize inclusion of *new providers* into the Medicare program
    - Stringent enrollment process
(4) Eliminate *old providers* from the Medicare program
    - Aggressive revalidation application process
(5) Recover billions of dollars in improper payments
(6) Cut the Medicare fee-for-service error rate in half

ACA: Enhanced Enforcement

Passage of ACA allowed for enhanced enforcement of *fraud, waste, abuse and error*

- Allocated additional funds for enforcement efforts
- Allocated abilities to increase investigation staff/agents
- Increased the authority of said staff/agents

Definitions Evolve

- Fraud and abuse is still prevalent
  - Actual knowledge
  - Known willingness
  - Deliberate ignorance
  - Reckless disregard
- Medicare, Medicaid no longer tolerates "ERRORs"
  - Human error
  - Computer error
  - Sloppiness
  - Laziness
  - Lack of sophistication
- Medicare, Medicaid no longer tolerates "WASTE"
  - Incurring unnecessary costs as a result of deficient management, practices, or controls

“Original Enforcers” Evolve

Health and Human Service (HHS)

- Office of the General Counsel (OIG)
- Administration on Aging (AOA)
- Centers for Medicare & Medicaid Services (CMS)
- Department of Justice (DOJ)

Department of Justice

- United States Attorneys
- Civil Division
- Criminal Division
- Civil Rights Division

The New Enforcers

- HEAT - Health Care Fraud Prevention and Enforcement Action Team
- MRA – Medical Review Auditors
- MAC – Medicare Administrative Contractors
- CERT - Comprehensive Error Rate Testing
- STPR – State Wide Probe Reviews
- NCCI - National Correct Coding Initiative
- ZPICs - Zone Program Integrity Contractors
- RACs - Recovery Audit Contractors

What are they Auditing/Inspecting?

- Derelict in duties under regulations, guidance documents
  - Fraud
  - Abuse
  - Errors
  - Waste
- Compliance with state and federal regulations
- Examination of Medicare related billing
- Clean claims inspection
- Relationships between facilities and ancillary providers
  - Contracting
  - Rendering of quality

Who are they?

- Professional staffers deployed in
  - Washington, DC
  - Regional
  - Field
  - Semi-Field
  - Unidentified venues
  - Government and outside contractors
- Professionals conduct
  - Audits
  - Evaluations
  - Investigations
  - Guidance to the industry
  - Impose “civil” monetary penalties, assessments administrative sanctions

Who do they work with?

- Health and Human Services
- Department of Justice
- Federal Bureau of Investigation (FBI)
- US Attorney Offices
- Executive Branch (White House)
- Legislative Branch (Congress)
- All 50 states
  - Regulatory agencies
  - Legislative bodies
  - Law Enforcement

What have we learned thus far?

(1) Caveat Emptor
(2) Semper Paratus

Is your practice prepared?

Fact Pattern:

You are the owner of a physician practice. On a random Monday a man enters your place of business and introduces himself. He is an official government auditor/inspector. He hands your receptionist an “official” piece of paper and states he is at the office to conduct an audit.

What should the receptionist do?

Who is the person?

- Who is it?
  - Important to identify what organization person is representing
  - Should show identification
- Private Organizations under Contract with CMS
  - Recovery Audit Contractors
  - Zone Program Integrity Contractors
  - Medicare Carriers
- Federal Law Enforcement:
  - HHS-OIG
  - FBI
  - DOD
  - IRS
  - FDA

Who is the person?

- State Law Enforcement:
  - State Police
  - Local Police
  - Sheriff

- United States Attorneys' Office
- State Attorney General Office
- State Medicaid Fraud Control Units

What type of document?

What type of document is being served/delivered?

- HHS-OIG Subpoena
- Search Warrant
- Request for general documentation
- Request for employee files
- Request for billing or coding information
- Request for patient information
- Revalidation – On-site inspection

(1) Do your employees know how to respond to such an occurrence?
(2) Do you have a proper protocols in place?

Need policies and procedures in place

- Compliance program
- Training/educating ALL employees
- Written policy distributed to all employees

- Point of contact person
  - Employee in authority
  - Knows your business operations
- Phone tree
  - Compliance Officer
  - Office Manager
  - Owner/Chief Executive Officer
  - Chief Financial Officer
  - General Counsel

Protocols in Place

- Want to put policies in place to control the situation
- Government has a right to talk to your employees
  - NEVER tell employees to NOT talk or interact
- Government has the right to inspect/audit/enter premises
- Want to limit amount of persons interacting with enforcement agents
- Want to show "deference" to the process but privileges are in place to protect employees
- Taking the "5th or is it the 6th an option?

Empower your staff …

- Identify point person(s)
- Implement detailed and easy to follow policies and procedures/protocols
- Commit to in-house education/training
- Training through educational resources
  - Brown bags
  - Webinars
  - Seminars
- Implement a detailed "compliance program"

Implement a Detailed Compliance Program

Mandated Compliance Program

Medicare providers *MUST* have comprehensive compliance program in place by March 23, 2013

Compliance Program:
Mandatory vs Voluntary

- Office of Inspector General (OIG) has been encouraging Medicare and Medicaid providers to *"adopt voluntary"* compliance programs
- Patient Accountability and Affordable Care Act (PPACA), compliance programs are no longer voluntary for Medicare and Medicaid providers
  - Compliance Programs are "*mandatory for those providers who participate in any federal healthcare program"*

Compliance Program

- Specifically, Section 6401 of ACA requires healthcare providers to establish compliance and ethics programs that contain certain "core elements" as a condition of their participation in the federal healthcare programs
- To date, HHS has not defined the "core elements" but should not deter providers from implementing a workable, organic compliance program
  - Good faith effort
  - Seven elements of an effective compliance program to date is in the Federal Sentencing Guidelines – on recommendations/ideas

(7) Core Elements Identified

1. Designate a chief compliance officer in charge of operating the program
2. Develop and distribution of written policies, procedures and standards of conduct
3. Implement regular education and training program for employees
4. Develop an internal audit system to identify problem areas
5. Develop a system to report deficiencies and problem areas
6. Develop a process where employees can come forward without fear of retaliation
7. Develop a means to quickly remedy problems in a systematic, transparent way

Select Compliance Officer (CO)

- The designation of a chief compliance officer and other appropriate bodies should a be full-time, longer term employee(s) that understand the business OR has served in the capacity in other businesses/organizations
- Many companies use their HR or office manager as designated officer

Some responsibilities of a CO

- Constant monitoring
- Complexity of regulations
- Implementation of regulatory changes
- Conducts risk assessment
- Internal audits
- Integrity of documentation
- Compliance training for employees
- Enforcement trends
- reporting
- Retaliation
- Sanctions on employers

Develop Written Policies

- Looks like a code of ethics or standards of conduct
- Similar to a “mantra” that all good business’ should put into place
  - Best practices for one’s own company
  - Hiring good, quality employees remains important
    - Criminal background checks especially with those in middle/higher management

Education/Training

- Regularly review and update training programs for ALL employees who “touch” Medicare billing, coding, claims, etc
- Test employees’ understanding of training topics
- Maintain documentation to show which employees received training
- Make sure the Board of Directors receive training
  - Starts at the top!
- Attend conferences and webinars, subscribe to publications and OIG’s email list
- Monitor OIG’s website and other government resources

Internal Auditing

- Perform proactive reviews in coding, contracts, and quality of care
- Create an audit plan and re-evaluate it regularly
- Identify your organization's risk areas
- Use your networking and compliance resources to get ideas and see what others are doing.
- Don't only focus on the money – also evaluate what caused the problem
- Create corrective action plans to fix the problem
- Refer to sampling techniques in OIG's Self Disclosure Protocol and in Corporate Integrity Agreements (CIAs) to get ideas

Self Audit/Policing

- Review office procedures and policies
- Review 10 (??) or more randomly selected records for Medicare patients
- Review claims of select records
- Review EOBs of the select records

Lines of Communication

- Have open lines of communication between you and employees
- Maintain an anonymous " reporting method" to report issues
  - Retaliation is a serious for not-reporting
  - Enforce a non-retaliation policy for employees who report potential problems
- Use surveys or other tools to get feedback on training and on the compliance program
- Use newsletters or internal websites to maintain visibility with employees

In a Nutshell …

A compliance program must be "effective in detecting and preventing criminal, civil, and administrative violations" and "in promoting quality of care" within your business and as it pertains to Medicare, Medicaid and other government payor programs …

Summation of Presentation

- Know key laws and regulations that govern your practice
- Recognize such laws and regulations are ever-evolving
- Recognize the ACA has vast implications to physicians
- Recognize industry is being investigated for fraud, abuse, waste and errors
- Enforcement efforts are increasing annually
- Understand sanctions/penalties
- Minimize such sanctions by self-policing
- Educate germane staff on new enforcement efforts
- Implement a thorough compliance program

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