Physician Relationship Audit Workshop: A Practical Guide to Auditing Physician Relationships and Addressing Identified Issues

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Overview

• Basics of Stark Law and AKS
• Reasons for Review of Physician Relationships
• Audit Process for Review of Physician Relationships
• Responses to Audit Results
• Tips to Avoid Liability for Noncompliant Relationships

Basics of the Stark Law

The Physician Self-Referral Statute ("Stark Law"), 42 U.S.C. 1395nn, prohibits:

1. Physicians from referring Medicare/Medicaid patients for certain designated health services (DHS) to an entity with which the physician or a member of the physician’s immediate family has a financial relationship—
2. It also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for a DHS furnished as a result of a prohibited referral.

Unless an exception applies.
Strict Liability Law

- Intent is Not Relevant
  - Does not matter if the prohibited financial relationship results from innocent error or inadvertence
- Technical Violations = Violations

Examples of Financial Relationships

- Direct or Indirect Ownership:
  - Equity/stock
  - LLC membership interests
  - Partnership interests
  - Secured debt, loans
- Direct or Indirect Compensation:
  - Leases between health care facilities and physicians or physician groups
  - Medical director agreements and other service agreements
  - Independent contractor relationships with physicians
  - Employment arrangements
  - Incidental medical staff benefits
- Look for any remuneration!
- Bottom Line: Does the arrangement create any sort of benefit for a physician or his or her immediate family member?

Stark Exceptions

Common Elements to Many Compensation Exceptions

- Written agreement signed by both parties
- One year minimum term
- Compensation set in advance
- Fair market value
- Commercially reasonable (includes the concept of “needed and necessary”)
- Compensation cannot take into account volume or value of referrals or other business
- NO percentage or “per-click” compensation for space or equipment leases
### Basics of the Anti-Kickback Statute

- Criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce referrals of items or services reimbursable by a federal health care program
  - No actual knowledge or specific intent required
- “Remuneration” includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly

### Anti-Kickback Statute Liability

- Criminal and civil penalties
- $25,000 per offense
- Imprisonment up to 5 years
- Civil monetary penalties (exclusion and $50,000)
- False Claims Act liability (3 times damages)

### Anti-Kickback Statute: Safe Harbors

- Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Sale of practice
- Warranties
- Discounts
- Employees
- Group Purchasing Organizations
- Waiver of Beneficiary Coinsurance and Deductibles
- Beneficiary incentives offered by Health Plans
- Price Reductions Offered to Health Plans
- Practitioner Recruitment
- OB Malpractice Insurance Subsidies
- Investments in Group Practices
- Cooperative Hospital Service Organizations
- Ambulatory Surgical Centers
- Referral Arrangements for Specialty Services
- Price Reductions Offered to MCOs
- Price Reductions Offered by Contractors to MCOs
- Ambulance Replenishing
- Electronic Prescribing
- Electronic Health Records
- Health Centers
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Reasons for Review of Physician Relationships

• Changes in Anti-Kickback Statute and False Claims Act
• Enhanced penalties and liability for retention of overpayments for longer than 60 days
• Increased regulatory scrutiny and enforcement actions
• Demonstration of effective compliance program

False Claims Act

• The Federal False Claims Act (31 U.S.C. § 3729) makes it unlawful to, among other things,
  ► Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval;
  ► Knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim;
  ► Knowingly make, use, cause 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 conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the Government.
False Claims Act after FERA

- Reverse false claims after Fraud Enforcement and Recovery Act of 2009
  - “Any person who . . . 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))

False Claims Act and PPACA

- Under PPACA, overpayments must be reported and returned by the later of:
  - 60 days after the date on which the overpayment was identified; or
  - The date any corresponding cost report is due, if applicable.
- Failure to return an overpayment constitutes:
  - An “obligation” for the purposes of the FCA; and
  - Grounds for the imposition of civil monetary penalties.

False Claims Act Penalties

- Violations of the Federal False Claims Act are punishable by:
  - civil penalties of $5,500 - $11,000 per claim plus 3 times the amount of damages which the Government sustains as a result of the false claim; and
  - discretionary exclusion from participation in the Medicare and Medicaid programs.
False Claims Act - Qui Tam Provisions

- The "Qui Tam" provisions of the Federal False Claims Act allow private citizens (called "relators") with knowledge of past or present fraud to file suits on behalf of the federal government.
- If the "whistleblower suit" is successful, the relator may receive 15-30% of the government's recovery.
  - The whistleblowers (and their attorneys) involved in the 2009 Pfizer False Claims Act settlement received more than $102 million.

Focused Arrangements as Part of CIA Review

CIA's define "focused arrangements" as:
- Between entity and actual source of health care business or referrals to medical center and involves, directly or indirectly, the offer, payment, or provision of anything of value;
- Between entity and any physician who makes a referral to medical center for designated health services; or
- Is between entity and any physician (or a physician’s immediate family member) or medical practice that involves, directly or indirectly, the offer, payment or provision of anything of value in anticipation of that physician becoming an actual source of health care business or referrals (e.g., for purposes of recruitment)

Physician Arrangements in the Headlines

"Healthcare System – Judge Orders Health System to pay $237 Million"
- The issue: The hospital offered 10-year employment contracts to 19 specialists in exchange for performing all outpatient procedures at the Hospital or its other facilities, as they were concerned that referring physicians would shift outpatient procedures from their hospital to their own practices or an ambulatory surgery center.
  - Compensation was based off of net cash collections for outpatient procedures and productivity bonus that was found to be above Fair Market Value
- On May 8, 2013 a Federal jury found that the hospital’s compensation agreements with 19 employed physicians ran afoul of the Stark law, which turned the hospital’s claims for Medicare services by the 19 physicians into false claims.
- On September 30, 2013 a federal judge ordered the Healthcare System was ordered to pay more than $237 million for violating False Claims Act and Stark law.

http://www.justice.gov/usao/nce/press/2013/2013-may-10_03.html;
Source: Report on Medicare Compliance: Volume 22, Number 35 10/7/13
Physician Arrangements in the Headlines (cont.)

"Florida Hospital System Agrees to Pay the Government $85 Million to Settle Allegations of Improper Relationships with Referring Physicians"

- The issue: The hospital entered into contracts with six medical oncologists that provided an incentive bonus that improperly included the value of prescription drugs and tests that the oncologists ordered and the hospital billed to Medicare. The hospital also allegedly paid three neurosurgeons more than the fair market value of their work.
- In a Nov. 13, 2013, ruling, the U.S. District Court for the Middle District of Florida ruled that the hospital’s contracts with its medical oncologists violated the Stark Law. The case was set for trial on March 3, 2014, on the government’s remaining claims.
- On March 11, 2014, the parties reached a settlement whereby the hospital paid $85 million to settle the claims and agreed to enter into a Corporate Integrity Agreement.


Physician Arrangements in the Headlines (cont.)

Physician and Cardiology group settle Stark-based case

- A physician and a cardiology group have agreed pay $1 million in connection with their allegedly improper compensation relationships with a regional hospital and medical center.
- Usually it is the hospitals that face Stark-based FCA allegations, however this case demonstrates that there is exposure for physicians under Stark as well.


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Audit Process for Review of Physician Relationships

• Objective
  ► Determine whether all transactions that potentially meet the definition of a physician contract are included in the database.

• Goal
  ► Every payment to a physician should be matched to a contract and its required documentation.
  ► Payments without a corresponding contract or documentation are flagged for additional investigation.

Audit Process for Review of Physician Relationships

• Step One -- Establish the audit parameters.
  ► Who performs audit?
    ◾ Can it be done effectively by a member of your team?
  ► Will the audit be performed under privilege?
  ► What is the purpose and scope of the audit?

Audit Process for Review of Physician Relationships

• Step Two – Gather documents for review.
  ► Determine how entity tracks contracts and payments
    ◾ Centralized database? If not, where is all information?
  ► Fair market value information for agreements
  ► Inventory of equipment and space being used by physicians
  ► Time records and logs
  ► General ledger accounts, accounts payable distribution & vendor master file
  ► Accounts payable and payroll information for payments to physicians
  ► Accounts receivable for payments from physicians
Audit Process for Review of Physician Relationships

- Step Three – Review and analyze documents.
  - Is there a written agreement for all payments to or from physicians?
  - Is expected time commitment included?
  - Is the agreement expired?
  - Is the agreement at FMV and commercially reasonable?
    - Has it been reviewed in the past 2-3 years?
  - Are the parties complying with the terms of the agreement?
  - Does the agreement comply with requirements of the applicable Stark exception?

- Step Four – Conduct interviews of personnel to verify information and fill in any gaps.
  - Performance of duties
  - Continued business need
  - Change in relationship or arrangement
  - Walk through of facility to determine if undocumented space or equipment rentals
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Common Issues

• Expired agreements
  ▶ 6-month holdover provision?
  ▶ Renewal provisions of agreement?
  ▶ Other writings to support extension?
• Lack of proper approvals
  ▶ Other writings to support approval?
• No written agreement or other "technical" deficiency
  ▶ Several writings that together support agreement?
  ▶ Temporary noncompliance argument?

Common Issues

• Lack of documentation to support payment or noncompliance with payment terms, rates or caps
  ▶ Schedules or other documents to support work?
• Changed duties or payment terms
  ▶ Documentation to support change?
• Lack of FMV support
  ▶ Consider obtaining retrospective valuation?
  ▶ Other contemporaneous documentation to support?
### Potential Responses to Common Issues

- Repayment of claims
- **CMS Voluntary Self-Disclosure Protocol**
- **OIG Self Disclosure Protocol**
- U.S. Attorney’s Office or State Attorney General Office

### Potential Responses to Common Issues

- Realize the threat of whistleblowers
  - Who might be a whistleblower?
  - Application of False Claims Act
  - You can not afford the risk of not taking appropriate steps to try and minimize this risk.

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Tips to Avoid Liability for Noncompliant Relationships

• Implement a contract approval process that covers the initiation, development, review, approval, and performance
  ► Legal review by experienced regulatory counsel
  ► Approval by appropriate management and governing body
  ► Keep documentation that the contracted work is necessary and at fair market value
  ► Documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed arrangements do not violate the Anti-kickback Statute and Stark law

Tips to Avoid Liability for Noncompliant Relationships

• Ensure that any arrangement meets the following:
  ► In writing, signed by both parties
  ► Meets applicable Stark exception
  ► In a database or contract management system
  ► No relationship to referrals
  ► Needs assessment to justify position or activity
  ► Documentation related to FMV determination
  ► Payment and performance reviews and approvals

Tips to Avoid Liability for Noncompliant Relationships

• Create and maintain a database of all existing and new or renewed physician arrangements and establish detailed procedures for entering into arrangements
  ► Only one database should be used
  ► Maintain centralized database that implements requirements recommended by the OIG in CIAs
  ► Reconcile database with payments made/received under physician arrangements at least quarterly (i.e., test of completeness and accuracy of the contract database)
  ► Require all related documentation to be stored in database
Tips to Avoid Liability for Noncompliant Relationships

- Update agreements if there is a change in the relationship (i.e., changes in services, space, or compensation)
- Detailed tracking of remuneration between all parties to arrangements
  - No payment without documentation
  - If the arrangement involves services, track service and activity logs
  - If the arrangement involves space or equipment, monitor the use of leased space or equipment

Tips to Avoid Liability for Noncompliant Relationships

- Ensure compliance program addresses physician arrangements
  - Increase emphasis on existence of adequate systems of internal control and risk management
  - Require all "covered persons" to agree to abide by the organization’s Code of Conduct in connection with arrangement
  - Provide training on the regulatory requirements for compliant arrangements and potential risk areas

Tips to Avoid Liability for Noncompliant Relationships

- Ensure compliance program addresses physician arrangements
  - Periodically audit existing physician arrangements to ensure continued compliance
  - Develop policies and procedures to investigate and take appropriate corrective action, including the timely report and refund of identified overpayments if there is a concern that a physician arrangement may not be in compliance