Hospital-Physician Contracting: Compliance Issues and Strategies

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Focus of Presentation

- Overview of Fraud and Abuse Laws applicable to hospital-physician contractual relationships
- Identification of hospital-physician contracts for compliance tracking and review purposes
- Lessons learned from practical experiences, recent settlements and cases
- Potential changes to the Stark Law and challenges for contractual arrangements

Hospital-Physician Contracting: Fraud and Abuse Laws

- Federal Anti-Kickback Statute
- Physician Self-Referral Law (Stark Law)
- False Claims Act
- Civil Monetary Penalties Law
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
- Remuneration includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly

Anti-Kickback Statute - Penalties

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

Anti-Kickback Statute: Safe Harbors

- Select safe harbors for physician contracts:
  - Employment Safe Harbor, 42 U.S.C. §1320a-7(b)(3)(B); 42 C.F.R. §1001.952(i)
  - Personal Services Safe Harbor, 42 C.F.R. §1001.952(d)
The Stark Law

The Physician Self-Referral Statute, 42 U.S.C. §1395nn, prohibits:

- 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.
- 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

Stark Law: Exceptions

Common Stark Law exceptions for hospital-physician contractual relationships:

- Bona fide employment, 42 C.F.R. § 411.357(c)
- Personal services exception, 42 C.F.R. § 411.357(d)

The Stark Law

- Strict liability statute, proof of specific intent to violate the law is not required
- Sanctions include:
  - Overpayment/ Refund liability of amounts collected as a result of improper billing
  - False Claims Act Liability
  - Civil monetary penalties and program exclusion for knowing violations
  - Potential $15,000 CMP for each service
False Claims Act

- Prohibits the *knowing* submission of false claims or the use of a false record or statement for payment with government funds
- Covers claims presented to any health care program funded in whole or in part by federal funds
- “Knowing” includes actual knowledge, deliberate ignorance and reckless disregard for the truth or falsity of the information

False Claims Act - Penalties

- Monetary penalties of between $5,500 and $11,000 per claim, plus 3 times the damages sustained by the government
- Possible exclusion from participation in Federal health care programs and from employment by entities receiving federal health care funds
- Criminal penalties for submitting false claims include imprisonment and criminal fines

Hospital-Physician Contracting: Compliance Risks
Identifying Hospital-Physician Contractual Relationships

- Stark Law
  - Financial Relationships (compensation, ownership)
- Anti-Kickback Statute
  - Remuneration (anything of value, direct or indirect)

Identifying Hospital-Physician Contractual Relationships

- Consider using the definition of “Focus Arrangements” in OIG Corporate Integrity Agreements
- “Focus Arrangements” are defined in part as every agreement and transaction:
  - That involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value, and with any actual or potential source of health care business or referrals; or
  - Is between [i.e., Hospital/Health System] and a physician (or a physician’s immediate family member) who makes a referral to [i.e., Hospital] for DHS (in the Stark Law).

Examples of Hospital-Physician Contractual Relationships

- Joint ventures
- Employment Agreements
- Professional Service Agreements
- Medical Director Agreements
- Space and Equipment Leases
- Co-Management Agreements
- Management Agreements
- Staffing Agreements
Examples of Compliance Risk Areas in Contractual Relationships

- Fair market value / commercial reasonableness
- Written agreement(s)
- Following the terms
- Providing services within the scope of the agreement
- Effective date/termination

Compliance Strategies: Governance

- Approval process
- Involvement and oversight by board or board committee
- Periodic reporting on contractual arrangements
Compliance Strategies: Internal Review and Tracking

- OIG “Focus Arrangements Procedures” in corporate integrity agreements
- Maintain a centralized tracking system
- Monitoring the use of leased space, medical supplies, medical devices, equipment, etc…
- Written review and approval process
- Require compliance officer to review the arrangements
- Implement effective responses with suspected violations

Recent Stark Law/Anti-Kickback Cases

  - $118 million settlement resolved allegations that Adventist violated the False Claims Act by maintaining improper compensation arrangements with referring physicians
  - Allegations that Adventist willing to absorb persistent losses because they were offset by referral revenue to the hospital

Recent Stark Law and Anti-Kickback Cases

  - $69.5 million settlement to resolve FCA allegations related to physician compensation arrangements that were above FMV and not commercially reasonable due to internal tracking of contribution margins from referrals
Potential Changes to the Stark Law: Address MACRA, APMs and Other Payment Models

- Senate Finance Committee convened a roundtable of participants to discuss changes to the Stark Law necessary to implement MACRA, and options in both the fee-for-service payment model and alternative payment models
- Overview of Senate Finance Committee Report
  - Expanded Waivers
  - Reduced penalties for technical violations
  - Simplified definitions and exceptions

Senate Finance Committee Report: Common Stark Law Barriers - Volume and Value of Referrals Standard

- Many Stark Law exceptions provide that compensation paid to a referring physician must not take into account the volume or value of referrals
- Counter to basing physician compensation on the number of patients whose treatment a physician oversees and to the type of treatment
- Example: prevents paying physicians incentives for care redesign to improve outcomes

Senate Finance Committee Report: Suggestions for Stark Law Reform

- Repeal the Stark Law in its Entirety
  - AKS can address the same conduct
- Repeal Compensation Arrangement Prohibitions
  - Limit the Stark Law to ownership/investment interests
- New Risk Revenue Waiver/Exception
  - Problematic arrangements could be addressed under the AKS and gainsharing CMP
Senate Finance Committee Report:
Suggestions for Stark Law Reform

- Create new or expand existing waivers
  - Expand waivers available to All Payers
  - Create new waiver based on current Stark exceptions for prepaid plan enrollees for MIPS, APMs and ACOs
- Create New Exceptions
  - A new “APM Exception” for all MACRA alternative payment model financial arrangements and expressly allow for compensation arrangements that take into account the volume or value of referrals, and not impose a fair market value requirement

Senate Report on Potential Stark Law Changes: Technical Violations

- Determine Penalties for Technical Violations by using mitigating factors and considering whether:
  - Violation is technical or substantive;
  - Failure to meet an exception was innocent or unintentional;
  - Has corrective action taken place;
  - Were the services reasonable and necessary;
  - Were access to a physician’s services required in an emergency situation; and
  - Any harm suffered by the Medicare program.

Questions?