Stark Law Basics for Health Care Providers

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Stark Law
Basics for Health Care Providers
Today’s Presenters

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Introduction

• Medicare and Medicaid Fraud and Abuse Prevention Laws
  – Ethics in Patient Referrals Act (the “Stark Law”)
  – Anti-Kickback Statute
  – The False Claims Act (FCA)
  – Exclusion Authority
  – Civil Monetary Penalties Law

• Application to providers and physicians
Fraud, Waste and Abuse

- **Fraud** – obtaining something of value through intentional misrepresentation or concealment of material facts

- **Waste** – incurring unnecessary costs as a result of deficient management, practices, systems, or controls

- **Abuse** – any practice that is not consistent with the goals of providing patients with services that are medically necessary, meet professionally recognized standards, and are fairly priced
A. Statutory Prohibition

• The federal self-referral statute, commonly referred to as the Stark Law, prohibits a physician from referring any "designated health services" payable by Medicare to an "entity" with which the physician, or an "immediate family member," has a "financial relationship," unless all the requirements of an applicable exception are met.

• The Stark Law also prohibits entities from billing for the referred services and imposes reporting and refund obligations.

• It is a strict liability statute which means the lack of intent to make a prohibited referral is not a defense.

• The scope of Stark extends to Medicaid, although the context has yet to be well defined. Some enforcement actions are now asserting liability based on prohibited referrals of “Medicaid” patients.
B. Designated Health Services (DHS)

1. Clinical laboratory services;
2. Physical therapy, occupational therapy, and speech-language pathology services;
3. Radiology and certain other imaging services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
4. Radiation therapy services and supplies;
5. Durable medical equipment and supplies;
6. Parenteral and enteral nutrients, equipment, and supplies;
7. Prosthetics, orthotics, and prosthetic devices and supplies;
8. Home health services;
9. Outpatient prescription drugs; and
10. Inpatient and outpatient hospital services.
C. Financial Relationships

- The Stark Law and accompanying regulations define a "financial relationship" to include both compensation arrangements and investment and ownership interests. Direct and indirect relationships are covered.
- Basically, giving anything of value, cash or in kind, constitutes “remuneration” giving rise to a compensation arrangement.
- “Physician” is broadly defined in the regulations to also include, in addition to medical doctors and osteopathic physicians, dentists, chiropractors, optometrists, and podiatrists.
- “Immediate family member” is also broadly defined.
- Physician “owners” now stand in the shoes of their physician organizations and are treated as having direct relationships.
D. Exceptions in General

- To avoid liability, the compensation arrangement or the investment or ownership interest must meet all requirements of an enumerated exception.

- Exceptions vary depending on whether relationship is an ownership or investment interest, or a compensation arrangement.

- CMS stated that all exception requirements must be met at time of referral for designated health services.

- Turning back the clock to correct a noncompliant arrangement was not contemplated under the statute according to CMS.
E. Commonly Used Exceptions for Compensation Arrangements

• Leases of Space or Equipment
• Bona Fide Employment
• Recruitment
• Fair Market Value
• Isolated Transactions
Leases of Space or Equipment

- **Space or equipment leases** (requirements such as written agreement signed by parties, description of premises or equipment, 1 year term, exclusive use, reasonable and necessary for legitimate business purposes, not excessive, fair market value, not based on the volume or value of referrals or other business generated between the parties, commercially reasonable even if no referrals).

  (Also note: compensation cannot be calculated based on a percentage of revenue generated by using the space or equipment or “per click” method. CMS cautions that on-demand and time-based rental agreements are or can be problematic, and although CMS did not extend prohibition on percentage based compensation to service arrangements, it may do so in the future)
Leases of Space or Equipment

Recent Enforcement Activity

• March 5, 2013. Georgia hospital self-disclosed to OIG and agreed to pay $50,000 CMP related to free use of hospital space by physician.

• September 11, 2012. Massachusetts hospital self-disclosed to OIG and agreed to pay $1,149,396 CMP related to free or less than FMV space lease and staffing and services performed without a written agreement.

• October 3, 2011. Wisconsin hospital self-disclosed and agreed to pay $204,150 related to providing space, services and supplies to certain physician groups without a written agreement and without collecting payment.
Bona Fide Employment

COMPENSATION & BENEFITS

HOSPITAL

EMPLOYMENT

PHYSICIAN
• **Bona fide employment** (requirements such as identifiable services, fair market value and not based on the volume or value of referrals, commercially reasonable, productivity bonus allowed if based on physician’s personally performed services)
Bona Fide Employment

Recent Enforcement Activity

• May 1, 2013. Montana hospital self-disclosed and agreed to pay $3,950,000 related to physician incentive compensation based on the volume or value of referrals (i.e., using referrals of certain DHS to calculate bonuses).

• April 3, 2013. Utah hospital self-disclosed and agreed to pay $25,500,000 related to bonus compensation based on the volume or value of referrals (and improper leasing arrangements).

• June 22, 2012. New York hospital self-disclosed and agreed to pay $604,780 related to above fair market value salary and benefits to a single physician for leadership, teaching and administrative services.
Recruitment (requirements such as payment induces physician to relocate practice, written agreement signed by parties (including, existing practice, if one), payment not based on the volume or value of any referrals or other business generated between the parties, relocation requirements, income guarantee criteria, limits on practice restrictions if physician joins a group)
Fair Market Value

COMPENSATION

HOSPITAL

ITEMS OR SERVICES

PHYSICIAN

COMPENSATION

PHYSICIAN

ITEMS OR SERVICES

HOSPITAL
• **Fair Market Value** (requirements such as written agreement signed by the parties, identifiable services, specifies timeframe, compensation for same items and services cannot change for at least 1 year, fair market value, not based on the volume or value of referrals or other business generated between the parties, commercially reasonable, does not violate Anti-Kickback Statute or federal or state law or regulations governing billing or claims submission)
Fair Market Value

Recent Enforcement Activity

• May 8, 2013. Jury found $39 million Stark violation by Tuomey Healthcare System, a South Carolina hospital that paid part-time employed physicians 131% of net revenues, despite hospital’s reliance on third-party fair market valuation. Under the False Claims Act, DOJ requested treble damages, plus $5,500 per claim, for a total penalty of $237 million.

• May 3, 2013. Adventist Health and White Memorial Medical Center, California affiliated hospitals, agreed to pay $14.1 million to resolve claims they illegally transferred medical and non-medical supplies and inventory to referring physicians at less than FMV, and compensated physicians above FMV to provide teaching services.

• October 25, 2012. North Carolina hospital self-disclosed and agreed to pay $584,700 in part because of possible failure to satisfy FMV exception for medical director and hospice services.
Isolated Transactions (requirements such as fair market value, not based on the volume or value of referrals or other business generated between the parties, commercially reasonable, no additional isolated transactions for 6 months and additional rules for installment sales)
F. Other Stark Concepts

• **Period of Disallowance.** Medicare claims for DHS arising from a prohibited referral (i.e., arising from a financial arrangement that does not satisfy an applicable Stark exception) are generally disallowed, and the period during which referrals are prohibited is the “period of disallowance.” With limited exception, payments from Medicare as a result of prohibited referral for DHS must be refunded in a timely fashion.

• **Burden of Proof.** Although a payment denied due to prohibited referral may be appealed, the burden of proof is on entity submitting claim to establish that service was not furnished pursuant to a prohibited referral.
The Stark Law

Exceptions (very limited)

• Entity receives Medicare payment, but lacks knowledge of the identity of the referral physician, and the claim otherwise complies with applicable law.

• For certain exceptions and only once every 3 years, arrangements compliant for 180 days prior to non-compliance may be brought back into compliance within 90 days, provided (i) the non-compliance was outside of entity’s control, (ii) corrective steps were taken, (iii) the arrangement does not violate the Anti-Kickback Statute, and (iv) the claim/bill complies with federal/state laws.

• If compensation arrangement fails to comply with signature requirement, the parties have 90 days to obtain required signatures if inadvertent; 30 days if non-compliance was not inadvertent. Can use only once every 3 years.
The Stark Law

G. The Stark Self-Referral Disclosure Protocol

• CMS has implemented a self-referral disclosure protocol for Stark violations (the “SRDP”). The SRDP is unique in that all information must be included in an initial detailed and far reaching submission, rather than allowing for supplementation upon completion of an investigation, including, a complete legal analysis of the application of any Stark law exceptions to the facts and circumstances. A provider must agree that no appeal rights attach to claims settled by way of the SRDP. Moreover, CMS may use the submissions for referral to law enforcement for consideration under civil and criminal authorities and to make recommendations as to resolution of FCA, civil money penalty and other liability.

• During the CMS verification process, “CMS must have access to all financial statements, notes, disclosures and other supporting documents without the assertion of privileges or limitations . . . .” CMS says it will not request attorney-client privileged documents in the normal course, but if materials are needed in CMS’s belief to resolve disclosure, it is willing to discuss ways to avoid a waiver. Additionally, if new matters are uncovered during the verification process, they may be treated as outside the SRDP.
The Stark Law

• Overpayments must be refunded within sixty (60) days of identification or by the due date for any corresponding and applicable cost report, whichever is later, the submission (when confirmed as received by CMS) of an SRDP suspends such timeframes until such time as the SRDP is withdrawn, removed or settled. During the pendency of the SRDP, CMS will not accept overpayment refunds related to the claims reviewed under the SRDP until the completion of the inquiry, but CMS encourages the disclosing party to place the funds for the presumed overpayment in an interest-bearing escrow account.

• The SRDP authorizes CMS to reduce the amount due and owing for violations disclosed under the SRDP based on several mitigating factors: (1) the nature and extent of improper or illegal practice; (2) the timeliness of self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risks associated with the matter disclosed; and (5) the financial position of the disclosing party.

• There is, however, no requirement that CMS show leniency under the SRDP, and they may seek to obtain the entire amount of an overpayment demand resulting from a self-disclosure, as well as penalties. Therefore, it is of upmost importance that a provider confirm a violation prior to making a self-disclosure. The SRDP cannot be used to obtain a CMS determination as to whether a violation has occurred, and a provider who withdraws or is removed from the protocol after it has been initiated may face higher fines and penalties or even exclusion from federal health care programs. Moreover, parties should not concurrently disclose the same conduct under both the Office of Inspector General (OIG) Self-Disclosure Protocol and the SRDP.
H. Penalties

- Medicare refusal of payment
- Overpayment refund obligation
- Civil Monetary Penalties for knowing violations of up to $15,000 per violation or $100,000 per arrangement for circumvention schemes
- Program Exclusion
- FCA liability
A. Statutory Prohibition

- Under the Anti-Kickback Statute, it is a felony if any person knowingly and willfully solicits or receives any remuneration in return for referring an individual to a person for the furnishing or arranging for the furnishing, or in return for purchasing, leasing, ordering, arranging for or recommending purchasing, leasing or ordering, or offers or pays any remuneration to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing, or to purchase, lease, order, arrange for or recommend purchasing, leasing or ordering, of any good, facility, service or item for which payment may be made in whole or in part under a federal health care program, including Medicare or Medicaid (i.e., the law applies to both payer and recipients of kickbacks).

- Neither actual knowledge of the anti-kickback statute nor specific intent to violate the statute is required. A claim resulting from an anti-kickback violation can constitute a false claim.
B. Key Terms or Concepts

- **Remuneration.** Broadly defined to include anything of value made directly or indirectly, overtly or covertly, in cash or in kind, and includes kickbacks, bribes and rebates (e.g., payment of rent in excess of fair market value, providing services for free in exchange for agreement to refer, etc.)

- **One Purpose Test.** If one purpose is to induce referrals, the statute can be violated, even if other legitimate business purposes exist. The OIG has also said an improper purpose can taint even a fair market value transaction.

- **Statutory Exceptions** (e.g., properly disclosed discount arrangements or other reductions in price, payments to employees, certain risk sharing and other arrangements with managed care organizations)

- **Regulatory Safe Harbors.** Congress authorized the OIG to promulgate regulations that specify permissible practices or safe harbors. There are currently over 25 safe harbors (e.g., office leases, employment arrangements, recruitment and sale arrangements, and personal services arrangements. Although both the Stark Law and the Anti-Kickback Statute must be complied with, failure to meet an Anti-Kickback Statute safe harbor does not mean the arrangement is illegal, but all elements of the safe harbor must be met for protection.
C. Enforcement

- Prison
- Up to 3 times the amount of the remuneration
- Up to $50,000 per kickback
- Program exclusion
- FCA liability
A. Fraud Enforcement and Recovery Act of 2009 (FERA)

- FERA clarified that it is a violation of FCA to knowingly and improperly avoid or decrease an obligation to pay or transmit money to the “Government”

- “Obligation” includes the retention of an overpayment and constitutes a false claim if a known overpayment
B. Overpayment Refund.

PPACA expanded the FCA by imposing more stringent requirements for refunding known overpayments. The overpayment must be refunded by the later of sixty (60) days after the overpayment is identified or by the due date of any corresponding cost report, if applicable, and accompanied by an explanation and report. Failure to refund the overpayment by the applicable due date constitutes an obligation under the FCA, giving rise to potential false claims liability. Expanded exclusion authority and civil money penalties for people who do not report known overpayments were also included in PPACA. Enforcement authority is finding violations of Stark could result in false claims, so Stark refund obligation gives rise to potential False Claims liability.

C. FCA Enforcement

- Up to 3 times the actual program loss (e.g., the amount of an overpayment)
- $11,000 per claim
General Disclaimer

This webinar is not intended to provide legal advice, but rather a general overview of some of the common laws and/or regulations that may apply to certain types of financial arrangements and is for information purposes only. A thorough review of the applicable up-to-date laws, regulations and relevant commentary, as applied to the unique facts and circumstances of any given transaction, is always advisable.
QUESTIONS?
Thank You

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