Practitioner’s Toolkit for Addressing “Technical” Violations of the Stark Law

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Presentation Outline

• Overview of the Stark Law  
• “Technical” Violation  
• Examples  
• How to Address These Violations  
• Tips if Self-disclosure is Best Option  
• Questions
The Stark Law

• The Physician Self-referral Law
  • Section 1877 of the Social Security Act
  • 42 CFR 350 et seq
• Prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies
• Also prohibits an entity from presenting a claim for payment as a result of a prohibited referral

The Stark Law

• Designated Health Services
  • 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
The Stark Law

- Financial Relationship
  - May be ownership/investment interest or compensation arrangement
  - May be direct or indirect
  - Involves “remuneration” which is defined as any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind (with few statutory exceptions—see 1877(h)(1)(C) and 411.351)

- **Question:** Do the provision of services create a financial relationship?

The Stark Law

- Compliance with an exception is mandatory if the physician makes referrals for DHS to the entity with whom he (or his immediate family member) has a financial relationship
  - There are a number of specific exceptions both statutory and regulatory
  - Secretary has the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse
  - Prohibition is limited to referrals for DHS
  - Intent of the parties is irrelevant (“strict liability”)
  - Civil penalties

- **Question:** If an arrangement is not in compliance, are the tainted referrals limited to referrals that flow from the services being provided?
What is a “Technical” Violation?

- These “technically” don’t exist
- Stark is a strict liability law
  - All elements of an exception must be satisfied
  - If any one element is not satisfied, the arrangement results in a violation
- Difficult to reach consensus on one definition of technical violations
- Described as an unintentional error
  - Not linked to the volume or value of referrals
  - Physician was either compensated within Fair Market Value or compensation fell outside FMV inadvertently

What is a “Technical” Violation?

- Most often fall into category of
  - No writing or insufficient documentation
  - A missing signature
  - Timing issues
  - Payment errors
- These types of violations only arise in the context of compensation arrangements – not ownership/investment
“Technical” Violation (cont’d)

• Documentation deficiency
  • Implicates the Stark law
  • Does not involve a violation of the anti-kickback statute (AKS)
  • Does not comply with a Stark law exception due to the parties’ failure to follow a documentation requirement of the exception, including timing of the execution of required documents

• Payment deficiency
  • Implicates the Stark law
  • Does not involve a violation of the anti-kickback statute
  • Involves underlying facts (other than the erroneous or mistaken payment) that would have met an exception

“Technical” Violation Proposal

• Has been suggested that CMS create an exception to address technical violations
  • Technical Deficiency Exception
    • No violation of AKS
    • Written agreement or amendment
    • Compensation adjustment (for payment deficiencies only)
    • Transparency requirements
    • Inadvertent noncompliance
“Technical” Violation Examples

*Missing Signature*

- Missing signature on a personal services contract that otherwise satisfies all elements of an exception
  - Set out in writing
  - Specifies services covered
  - Term of at least 1 year
  - Compensation set in advance
  - Consistent with fair market value and not determined based on volume or value of referrals or any other business generated between the parties

“Technical” Violation Examples

*Payment Error*

- Payments actually made differ from amount agreed to in written agreement
  - Agreement as drafted satisfies all elements of rental of office space exception
  - Amount actually paid, though different than the writing, is within fair market value range
“Technical” Violation Examples

Expired Agreement

- Expired agreement for medical director services
  - Agreement satisfied all elements of exception during first year of arrangement
  - Parties continue to act under the same terms of the compliant agreement beyond the written term
  - No evergreen provision

Date Gap

- Gap between effective date and signing date
  - Effective date at the top of the agreement states January 1, 2011
  - Date next to the last signature line says February 3, 2011 (even if one of the signature dates matches the effective date)

- Question: Does it matter whether the late signer is the hospital or the physician?
“Technical” Violation Toolkit

• First know the facts – sometimes even facts that are difficult to determine
• Various Holdover Provisions
• Temporary Non-Compliance Provision
• Missing Signature Allowance
• Exceptions that do not require a writing. Most common options:
  • Indirect compensation analysis
  • Bona Fide Employee
  • State Law Arguments (?)

“Technical” Violation Tools

• Once noncompliance with a technical element of an exception is known, is there anything that can be done?
• Some possible approaches but these depend on multiple factors
  • Specific facts
  • What level of risk the client is comfortable with
  • Government’s known policy position on certain topics
“Technical” Violation Tools

• Holdover provisions
  • Rental of office space
  • Rental of equipment
  • Personal services (but note, no holdover allowance in the FMV Exception)
  • Six-month grace period following the expiration of an otherwise compliant agreement
• Temporary noncompliance with signature requirements
  • Can be used for exceptions requiring signatures
  • Must obtain signatures within 90 days for inadvertent errors
  • Within 30 days for not inadvertent errors
  • Limitation on the frequency of use

Question: What evidence is sufficient to show that all you are missing is a signature?

“Technical” Violation Tools

• Temporary noncompliance
  • Complied with an exception for at least 180 consecutive days immediately preceding noncompliance
  • Noncompliance occurred for reasons beyond the entity’s control
  • Does not violate AKS
  • Must rectify noncompliance within 90 days
  • Can be used only once every 3 years for same referring physician

• Question: What does it mean for the noncompliance to occur “for reasons beyond the entity’s control?”
“Technical” Violation Tools

• Exceptions that do not require a writing (helpful if missing an agreement entirely, or missing a signature, or the documentation lacking in some other way)
  • Indirect compensation (but watch out for Stand in the Shoes)
  • Services unrelated to DHS
  • Employment
  • Payments by a physician
  • Group Practice
• Do other writings viewed together satisfy the exception
  • All information does not have to be on one page
  • Less formal documents may be sufficient
    • Emails?
    • 855’s?
    • Endorsed checks?
• State contract law arguments

“Technical” Violation Tools

• Drafting considerations for future arrangements
  • Evergreen provisions
  • Date on signature page or not?
  • Requiring flat number of hours, versus a range
  • Cross referencing (and maintaining) a master contract list
“Technical” Violation Tools

• Note: failure to comply with superfluous contract requirements does not create a Stark law violation, unless the requirement impacts compensation, in which case it could stop the agreement from being “set in advance”
• Examples
  • Failure to submit timesheets
  • Failure to submit notices
  • Failure to maintain required insurance
  • Failure to utilize identified subcontractors

“Technical” Violation Hypo Discussion

*Missing Signature*

• Hospital and Physician entered into a personal services agreement that satisfied all elements of the exception
• However, the physician did not sign the final version of the agreement
• Both parties operated under the terms of the agreement
• Options?
  • Within the temporary noncompliance for missing signatures? Inadvertent? Not inadvertent?
  • Other documentation reflecting agreement to final contract terms? Draft agreement?
  • State contract law?
  • Indirect compensation analysis?
• What if both parties signed the contract, but that version cannot be located?
  • Affidavits?
“Technical” Violation Hypo Discussion

Lack of Formal Writing

- Physician provides medical director services for cardiology department of hospital.
- The arrangement is not reduced to a formal writing.
- Physician, like all other medical directors in the hospital, receives quarterly stipend of $250 for these services.
- Medical staff bylaws discuss medical director positions. Physician is a member of the medical staff.
- Options?
  - Course of conduct
  - Adequacy of other documents to reflect agreement (invoices, cancelled checks)
- Any difference if the physician is serving in an elected leadership position of the medical staff?

“Technical” Violation Hypo Discussion

Timesheet Deficiency

- Physician has agreement to provide medical director services. Agreement states that she will provide “no less than 15 hours a month” providing these services for a monthly payment of $1500.
- Agreement requires monthly timesheets to document services provided.
- Physician’s timesheets document less than 15 hours for several months but payment was made in full.
- Other timesheets do not contain adequate documentation of services provided.
- Options?
  - Average of hours?
  - Other ways to document she provided required number of hours?(calendars, appointments, set hours for certain tasks each week)
- What if the agreement is silent regarding the provision of less than 15 hours, but the hospital pays on a pro rata basis?
“Technical” Violation Hypo Discussion

Payment Error

• Physician has medical director agreement with hospital. Agreed to payment of $1500 per month.
• When the agreement is drafted, an older version is used and includes a payment of $1000 per month.
• Physician is paid the agreed upon amount of $1500.
• Options?
  • Is there any role for state contract law concepts in interpreting the Stark Law?
  • Meeting of the Minds?
  • Scrivener’s Error?
  • Mutual Mistake of Fact?

“Technical” Violation Hypo Discussion

Payment Error

• Physician group leases medical office space at an agreed to fair market value rate per square foot for the region.
• Group wants to increase office space the next year. When current space is measured it is discovered that the current office space is 200 square feet larger than previously recorded.
• Options?
  • What if rent paid is still within fair market value for the larger space?
Probably Not “Technical” Violations

- Facts are critical to consider
- Not everything can be categorized as a technical violation
  - No written contract when required
  - Compensation above Fair Market Value
  - No payment of rent for medical office space

- *Would a settlement agreement between the parties change the analysis?*

What Next?

- Once analysis is complete, where do you stand?
  - How comfortable are you with determination that violation did not occur?
    - What risk does this approach carry?
    - Is it a viable option to do nothing?
  - Return the overpayment to the contractor
    - Minimal repayment amount
    - Expense of other options greater than overpayment
  - Report violation to the Government (OIG, DOJ)
  - Voluntary self-disclosure
Self-referral Disclosure Protocol

• Section 6409(a) of the Patient Protection and Affordable Care Act (ACA)
• Process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute
• Gives the Secretary of HHS the authority to reduce the amount due and owing for violations of Section 1877

Self-disclosure Considerations

• What if analysis leads to self-disclosure as an option?
  • Weigh risks of disclosing vs. not disclosing
    • Qui tam relator
    • Government investigation
    • Agency position on policy
    • Uncertainty related to final outcome of a self disclosure
    • Comfortable with analysis that not a violation if questioned
    • Litigation risk
Self-disclosure Considerations

• What do we know about CMS self-disclosures at this point?
  • CMS posted 13 settlements in 2012
    • Includes settlement amount but not initial overpayment
    • General statement of conduct, no details
    • Seven disclosures involved personal services arrangements
    • Three exceeded non-monetary compensation
  • Other exceptions disclosed and settled included:
    • fair market value (both medical director services and leadership stipends),
    • physician recruitment,
    • *bona fide* employment and
    • equipment lease exceptions

Self-disclosure Considerations

• What type of violation have you discovered?
  • Disclosure via the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) is for Stark violations only
  • OIG protocol is not appropriate for Stark only violations
  • *If both* Stark and Anti-kickback, disclosure should not be made to CMS
Self-disclosure Considerations

- 60-Day Overpayment Rule
  - Section 6402(a) of the Affordable Care Act
  - Providers and suppliers must return overpayments within 60 days of identifying its existence
  - Failure to report and return overpayment can result in False Claims Act liability
  - Submission under the SRDP suspends this obligation

Self-disclosure Considerations

- Self-disclosure or Advisory Opinion
  - Separate processes
  - SRDP cannot be used to obtain a CMS determination as to whether an actual or potential violation of the Stark law occurred
  - Can disclose actual or potential violations of the Stark law via the SRDP
  - How is a potential violation different from advisory opinion request?
    - Potential violation- conduct has occurred, aware of exception arrangement should have satisfied, unsure if each element was fully satisfied; must be prepared to resolve noncompliance
    - Advisory opinion- conduct is proposed or currently in existence, asking a true question of appropriateness of exception for the arrangement
Self-disclosure Process

• Voluntary process
• Be sure that noncompliance has ended
• Alert CMS to any matter that may be time sensitive
  • Follow up with analyst assigned
• Inability to pay will be considered
  • Disclosing party must raise this

Self-disclosure Process - Tips

• Structure of disclosure is important
  • Most efficient to follow the format of the SRDP document itself
  • Include relevant documents
  • Don’t include unnecessary information
  • Include element by element analysis
  • Estimates are allowable for overpayment calculations
• Avoid arguing no violation occurred
  • Offer alternative analysis
  • Present mitigating factors
• Cooperation with CMS is considered
Questions?

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