An Overview of the Stark Law in Relation to Medical Staff Services

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Road Map

Legal Overview
Stark Law
Stark Exceptions
FMV and Commercial Reasonableness
Violations
Disclosures
Conclusion

Contracting Compliance

Anti-Kickback Statute
False Claims Act / CMP
Tax Exemption Issues
Stark Law
**Federal Anti-Kickback Statute**

Criminal Statute that requires **intent**

May not *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 (e.g., hospital payments to referring physicians).

Safe Harbors:
- Transactions fitting w/in Safe Harbors are immune, regardless of intent.
- Failure to fall within a safe harbor does not necessarily mean that the conduct is prohibited by the anti-kickback statute.

**Civil Monetary Penalties Law**

Imposes civil liability related to:

- Improperly filed claims (false statements, information, records, omissions);
- Inducement to beneficiaries;
- Payments by a hospital to physicians to reduce or limit services;
- Arrangements with excluded providers; and
- Failure to grant HHS/OIG with access to records.

$10,000-$15,000 fine per incident; treble damages, exclusion. Higher fines if kickback issues are involved.

**False Claims Act**

Imposes civil liability upon any person who:

- knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
- knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. (applies retroactively to remove intent requirement); or
- knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government.

$5,500-$11,000 fine per false claims, treble damages, possible exclusion.
Whistleblowers

Qui Tam actions.

Original source of incident.

Anti-retaliation protection – broadly applies even if no qui tam is filed under FCA.

Government may intervene.

Relators receive 15-30% of judgment.

State Self-Referral Acts

Most states have their own version of the Stark Law (‘mini-Stark’)

Some state laws mimic Stark Law, but many states have more nuanced laws, which may include:

- A broader definition of “designated health services”
- Different exceptions or safe harbors

The Medical Board in the particular state may be a helpful resource.

Federal Physician Self-Referral Statute (Stark Law) 42 U.S.C. § 1395nn

Prohibits physician from making referrals for certain “designated health services” (DHS) payable by Medicare to an entity (e.g., Hospital) with which the physician (or immediate family member) has a “financial relationship,” unless an exception applies.

In absence of applicable exception, provider may not bill for improperly referred DHS.

Strict liability

- (i.e., intent does not matter).
Stark law vs. Anti-Kickback Statute

<table>
<thead>
<tr>
<th>The Federal Stark Law</th>
<th>The Federal Anti-Kickback Statute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Civil</td>
<td>Criminal</td>
</tr>
<tr>
<td>No proof of intent – conflict of interest presumed</td>
<td>Requires proof of unlawful intent – &quot;knowing and willful&quot; and intent to induce</td>
</tr>
<tr>
<td>Applies only to arrangements with physicians</td>
<td>Applies to any referral source (broadly defined)</td>
</tr>
<tr>
<td>Referral prohibited unless arrangement meets an exception</td>
<td>Safe harbor immunizes, but failure to bill within a safe harbor or exception does not make the arrangement illegal (facts and circumstances analysis)</td>
</tr>
<tr>
<td>Prohibits only Medicare referrals (see below)</td>
<td>Applies to referrals of federally funded state healthcare programs, in addition to Medicare and Medicaid</td>
</tr>
<tr>
<td>Refund of improper billings, civil penalties</td>
<td>Incarceration, fines</td>
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</table>

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Stark Law - 42 U.S.C. § 1395nn

If a physician, or his/her immediate family member, has a financial relationship with an entity that provides designated health services ("DHS"), then:

- The physician may not refer DHS to the entity for which payment may be made by Medicare; and
- The entity may not bill Medicare for any DHS referred by the physician
- Unless the financial relationship falls within an exception.
The Stark Law

Compliance with an exception is mandatory
- 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

Stark Penalties

Denial of payment for any services rendered by an entity in violation of Stark
Civil monetary penalties ($15,000 per claim, $100,000 for circumvention schemes).
Exclusion from Medicare/Medicaid.
Penalties from other laws – FCA

Consequences of Not Reporting a Stark Law Violation

Affordable Care Act
- Intentional failure to report = False Claim
- Actual knowledge; deliberate ignorance; reckless disregard

False claims
- $5,500 - $11,000 per claim
- 3x damages
- Felony charges; imprisonment; fines

Whistleblowers; qui tam relators
- Seeking share of repayment
- Attorney’s fees
Stark Analysis

Is a physician involved?

Does the physician refer Medicare or Medicaid beneficiaries for DHS?

Is there a “financial relationship” with an entity that furnishes DHS?

Does the arrangement meet an exception?

What is a Referral?

A request by a physician for a DHS item or service payable under Medicare including:

- The request by a physician for, or ordering of, any DHS.
- The request by a physician for consultation with another physician.
- Any test or procedure ordered, performed or under the supervision of the consulting physician.
- A request by a physician for the establishment of a plan of care that includes the provision of DHS.
- Certifying or re-certifying the need for DHS.

What does not constitute a Referral?

Services personally performed by the referring physician.

If (i) the request is the result of a consultation initiated by another physician and (ii) the tests or services are furnished by or under the supervision of the pathologist, radiologist or radiation oncologist (or a member of his/her group practice), the following are not considered referrals:

- A request by a pathologist for clinical diagnostic laboratory tests or pathological examination services;
- A request by a radiologist for diagnostic radiology services; or
- A radiation oncologist for radiation therapy services.
**Designated Health Services**

The term “DHS” includes:

– Clinical laboratory services
– Physical therapy services
– Occupational therapy services
– Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound 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
– Outpatient speech-language pathology services

**What is a Financial Relationship?**

For purposes of Stark, the following have been identified as constituting financial relationships:

– Ownership or Investment Interest
– Compensation Arrangement

Relationships may be direct or indirect

**“Stand In The Shoes” Rule**

A physician is considered to “stand in the shoes” of his/her “physician organization”

Rule significantly narrows the types of compensation that will be subject to the indirect compensation analysis

Essentially, if the only intervening person or entity between the referring physician and DHS entity is the physician organization, then the physician’s indirect relationship under Phase II with the DHS entity is a direct relationship under Phase III
“Stand in the Shoes” Example

Clinical Services Agreement between Hospital and Group Practice under prior law would have been considered under the rules for indirect compensation arrangements.

“Stand in the Shoes” rule deems that physicians stand in the shoes of the Group Practice and are deemed to have a direct financial relationship with the Hospital that requires use of a Stark exception other than the indirect compensation exception.

What is a Financial Relationship?

Professional Services Agreements
- Medical Director
- President of Medical Staff
- Department Chair

Non-monetary Compensation

Incidental Medical Staff Benefits

Employment Agreements

Office Space or Equipment Leases

Recruiting Agreements/Income Guarantees

Loans

Call Coverage Agreements

Professional Courtesy

Compliance Training

What is a Financial Relationship?

Computers/iPADs/PDA’s

Printers/Office Equipment

Billing and Collection Services

Office Clerical Staff

Nurse Practitioners/Physician’s Assistants

Answering Service

Gift certificates

Free goods, medical waste disposal, office cleaning

Trips

Dinners

Tickets to sporting events, concerts, entertainment

Parties

Cigars
Road Map

Legal Overview
Stark Law

Stark Exceptions

Stark Exceptions

Legal Overview
Stark Law

Stark Exceptions

Stark Exceptions

Compensation Exceptions

There are 23 compensation exceptions

Key concepts/requirements

– Compensation is fair market value.
– Compensation is set in advance. Percentage-based compensation arrangements are currently permissible in some cases as long as formula is set forth in advance.
– Compensation not based on volume or value of referrals.
– Compensation is commercially reasonable.
– There is a written arrangement.
– Signed by both parties on or prior to effective date.

Compensation Exceptions

Compensation Exceptions

Compensation Exceptions

Frequently Used Compensation Exceptions

Personal Services Arrangements
Fair Market Value (used as a “catch-all”)
Non-Monetary Compensation
Medical Staff Incidental Benefits
Lease Arrangements (either space or equipment)
Employment
Recruitment
Compliance Training
Personal Services Arrangements

Set out in writing and signed by all parties when or before it takes effect.

Covers all of the services to be furnished.

The aggregate services are reasonable and necessary for the legitimate business purposes of the arrangement.

Term of at least 1 year.

The compensation is set in advance, does not exceed FMV.

PSA Key Terms and Conditions

Services.
- Define all of the services to be provided.

Billing/Compensation.
- What is the compensation method?

PSA Key Terms and Conditions

Independent Contractor.

Coverage.
- Type and amount of coverage (on-site, 24/7, etc.) required

Medical Staff Membership.
- “Clean Sweep” provisions (hospital-based clinical services)

Term and Termination.
- “without cause” and “for cause”

Restrictive Covenants.
- Confidentiality
- Non-solicitation of employees and/or patients
- Non-competition
PSA Contract Issues

Compliance Guidance:
- Document need for services. No overlap.
- Do the duties require a physician?
- Specify exact scope of services.
- Number of hours reasonably necessary.
- Qualifications.
- Per unit FMV compensation.
- Require Monthly Timesheets for some agreements.
  - Hourly (Medical Director, Consulting Physicians, MS President, Department Chair)
  - Itemize services performed.
  - Condition of payment.
  - No travel.
- Review timesheets prior to payment.

Fair Market Value Exception

Basic Elements
- In writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the arrangement.
- Term can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.
- FMV compensation, set in advance, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.
- Commercially reasonable
- Does not violate the AKS

Non-Monetary Compensation Exception

Compensation from an entity in the form of items or services (no cash or cash equivalents) not to exceed an aggregate of $392 per year (2016).

Not determined in any manner accounting for the volume or value of referrals or other business generated between by the referring physician.

Compensation may not be solicited by the referring physician.

Arrangement does not violate the Anti-Kickback Statute.
Non-Monetary Issues

Documented tracking – gift log.
Coordination among entire system.
Centralized reporting.
Education and training.

Non-Monetary Compensation Exception

The $392 limit applies to calendar year
The $392 limit is updated annually
See: www.cms.hhs.gov/PhysicianSelfReferral/
See: http://www.kriegdevault.com/info/stark-act

Non-Monetary Compensation Exception

If a hospital inadvertently exceeds the annual limit, the hospital will still be deemed to be in compliance if i) the value of the excess is no more than 50% of the limit, and ii) the physician returns the excess by the end of the calendar year or within 180 consecutive calendar days, whichever is earlier. NOTE: Can only be used once every 3 years.

Hospitals can hold 1 formal medical staff event per year without including the cost in this exception.
Non-Monetary Compensation Exception

Allocation example:
- $1,000 painting to 5 physician group
- $1,000 must be allocated to each physician
- Cannot allocate 1/5 to each physician

Non-Monetary Compensation Exception

“[F]ree CME could constitute remuneration to the physician depending on the content of the program and the physician’s obligation to acquire CME credits.”
Phase II, page 16114
CMS has clarified in letters to ACCME “…we do not consider on-site CME to be remuneration if it is primarily for the benefit of the hospital’s patients, for example, training on the prevention of nosocomial infection. However, CME that is not primarily for the benefit of the hospital’s patients is considered remuneration.”

Non-Monetary Compensation Exception

Preamble, on Page 16112 of Phase II, stated that “[the Medical Staff Incidental Benefits Exception] was not intended to cover the provision of tangential, off-site benefits, such as restaurant dinners or theater tickets, which must comply with the exception for non-monetary compensation up to $355.”
**Medical Staff Incidental Benefits Exception**

Items or services used on the hospital's campus may be given to members of its medical staff if:

- Item or service is provided to all members in the same specialty without regard to volume or value of referrals.
- Item or service is provided only during periods when the medical staff members are making rounds or involved in other services that benefit the hospital and its patients.

**Medical Staff Incidental Benefits Exception**

The item or service is reasonably related to the delivery of medical services at the hospital.

Each item or service is less than $33 (2016) per benefit.

**Medical Staff Incidental Benefits Exception**

The exception specifically recognizes that “internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web-site or in hospital advertising, meets the “on campus” requirement…” (emphasis added)

But not access to a third party internet site - e.g. for CME.
Tracking Non-Monetary Compensation

The OIG assumes that DHS providers track the non-monetary compensation given to each referring physician.

Space and Equipment Rental Exceptions

Written arrangement with term of at least 1 year.
Specifies the premises or equipment to be covered.
Exclusive use by lessee.
Rental charges set in advance, consistent with FMV and do not take into account the volume or value of referrals or other business generated.

Employment Exception

Requirements of exception:
- The employment is for identifiable services.
- Fair market value compensation.
- Compensation not based on volume or value of referrals.
- No writing requirement
- Compensation is commercially reasonable even if no referrals made to employer.
Productivity bonuses are allowed
- May include DHS that he/she personally performs.
Physician Recruitment

The Basics of the Recruitment Exception:
Physician relocates to hospital service area.
Joins the hospital medical staff.
Physician not required to refer patients.
Not based on volume/value of referrals.
Physician may establish privileges at other hospitals.
Signed, written arrangement.
Does not apply to non-physician practitioners.

Compliance Training

Compliance training:
- Provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area
- Training is held in the local community or service area regarding the basic elements of a compliance program
  - Example: establishing policies and procedures, training of staff, internal monitoring, or reporting; specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided.
  - Includes programs that offer CME credit, provided that compliance training is the primary purpose of the program.

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How Does Stark Define Fair Market Value?

“The value in arm’s length transactions, consistent with the general market value.”

For assets, it means “the market price at which bona fide sales have been consummated for like type assets in a particular market.”

What is General Market Value?

General Market Value is the price that an asset would bring as a result of bona-fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or compensation that would be included in a service agreement, as the result of bona-fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, at the time of the agreement.

Fair Market Value for Professional and Administrative Services

CMS stated in the preamble to the regulation that “nothing precludes parties from calculating FMV using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits the definition.”

Ultimately, determining FMV requires a case-by-case analysis of the nature of the transaction, its location, services, productivity and other relevant factors.
Key FMV Points under Stark

Referrals between the parties cannot be considered.

FMV is determined upon the sale or at the time the service agreement is executed.

Local market conditions are factors (i.e., specialty in the market, depressed real estate market, difficulty obtaining physician participation).

What is Commercially Reasonable?

Many services exceptions under Stark require that payment be “commercially reasonable even if no referrals were made” between the parties.

Commercial reasonableness looks to the reasonableness of the business arrangement in general.

An arrangement is commercially reasonable if the agreement is “a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of referrals.”

What is Commercially Reasonable?

These examples may not be commercially reasonable:

- Paying for services when no services are rendered.
- Having two medical directors when only one is necessary.
- Paying a physician for questionable consulting services.
- Renting equipment full-time when it is used only once a month.
- Purchasing a building with no intention of using the building.
**Documentation**

When FMV and/or commercial reasonableness are implicated, documentation is key.

- Consistent use of objective, statistically viable and relevant data.
- Rationale / methodology used to determine FMV should be clear and well documented – show your work.
- Prospective, independent, expert valuation is typically the best approach. Nationally-recognized survey data are also used.
- Valuation reports should clearly and accurately describe the arrangement and all relevant facts.
- Account for changes in FMV over time.

**Road Map**

- Legal Overview
- Stark Law
- Stark Exceptions
- FMV and Commercial Reasonableness
  - Violations
  - Disclosures
- Conclusion

**What is a Stark Violation?**

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

Technical violations described as unintentional errors
- 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 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 FMV and not determined based on volume or value of referrals or any other business generated between the parties

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 July 3, 2011 (even if one of the signature dates matches the effective date)

Payment Error
- Payments actually made differ from amount agreed to in written arrangement
  - Arrangement satisfies all elements of personal services
  - Amount actually paid, though different than the writing, is within fair market value range

Expired Agreement
- Expired agreement for President of Medical Staff
  - Arrangement satisfied all elements of an exception during first year of arrangement
  - Parties continue to act under the same terms of the compliant arrangement beyond the written term
  - No evergreen provision
  - Holdover rules may help cure
“Technical” Violation Options

Once noncompliance with a technical element of an exception is known, is there anything that can be done?

First know the facts – sometimes even facts that are difficult to determine

Various Holdover Provisions
Temporary Non-Compliance Provisions
Missing Signature Allowance

Exceptions that do not require a writing. Most common options:

- Indirect compensation analysis
- Bona Fide Employee

State Law Arguments (?)

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Disclosure

Disclose?

- Yes, otherwise obligation and false claim liability

To Whom?

- Fiscal Intermediary (FI) / Medicare Administrative Contractor (MAC)
  - Statutory explanation – letter simply stating Stark violation and repayment
- CMS
- Self-Referral Disclosure Protocol (SRDP)
- OIG (if colorable AKS violations)
  - Provider Self-Disclosure Protocol (SDP)
- Others – Are they still viable options?
  - DOJ?
  - US Attorney’s Office?
Repayment

How much?
- Small amount – Fiscal Intermediary
- Large amount indicates CMS Self-Referral Disclosure Protocol
  - Filing tolls 60 days
  - Amount determined later

CMS’ Voluntary Self-Referral Disclosure Protocol (SRDP)

Issued in Sept 2010
Purpose: to resolve actual or potential violations of the Stark Law
Goal of reduced liability
Why the need for Stark SRDP?
- CMS’ historic position on Stark Law (no compromise)
- OIG’s position on AKS violations (lower level issues resolved as a multiple of physician compensation but will not accept “Stark only” disclosures)

SRDP

SRDP is for “Stark-only” violations
- If the matter raises AK issues, use OIG’s SDP
SRDP tolls the 60-day reporting requirement under ACA §6402
SRDP requires detailed analysis of Stark exception elements
SRDP requires calculation of referral value (‘amount due and owing’) by arrangement and year
SRDP asks about “existence and adequacy of a pre-existing compliance program”
CMS has not publicized its settlement formula
- No minimum settlement number (like OIG’s $50,000)
- No multiplier formula (like OIG’s minimum 1.5x damages)

SPDP has very definite “look-back” period
- Based on 4-year reopening period in 42 CFR § 405.980(b)
  (until the proposed rule at 77 FR 9179 is finalized)

SRDP may take more time
- Resolution under SDP averages less than 12 months
- SRDP queue seems much slower

### CMS SRDP V. OIG SDP

<table>
<thead>
<tr>
<th>KEY CONSIDERATIONS</th>
<th>CMS SRDP</th>
<th>OIG SDP</th>
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</thead>
<tbody>
<tr>
<td>Applies to Stark Law Violations</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Applies to Non-Stark Law Violations (e.g., Violations of the Anti-Kickback Statute)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Applies to “Mixed Facts” Situations Implicating Both the Stark Law and Anti-Kickback Law</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Submission Toll 60-Day Requirement to Identify and Repay Overpayments</td>
<td>Yes</td>
<td>TBD</td>
</tr>
<tr>
<td>Disclosing Party Must Provide a Complete Legal Analysis, Including Which Elements of Applicable Exception Are Not Met</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Government Given Access to Attorney-Client Privilege Material</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Disclosing Party Must Provide Detailed Financial Analysis of the Scope of Potential Non-Compliance with Initial Disclosure</td>
<td>Yes</td>
<td>Optional</td>
</tr>
<tr>
<td>Settlement Amount Based on Multiple of Compensation Paid to Physician(s)</td>
<td>TBD</td>
<td>Yes</td>
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### SRDP: Factors Considered, Reducing Amount Due and Owing

- Nature and extent of improper or illegal practice
- Timeliness of self-disclosure
- Cooperation in providing additional information
- Litigation risk
- Financial position of disclosing party
Recent CMS notice of expedited process

CMS invited comments on expedited process
- Notice at 79 Fed Reg at 25133 (May 2, 2014)
- Not rulemaking
- Could be applied to pending submissions

Possible criteria for expediting?
- Document-only deficiencies
- Absence of FMV issues
- Potential community impact

Issuance date?

SRDP settlement experience to-date

Settlements posted on CMS website

131 settlements to-date:
- High = $815,405
  - Multiple violations
- Low = $60
  - Single IOAS violation by physician practice in OH (Sept. 2011)
- Statistics unreliable because CMS seldom reveals number of violations or aggravating factors

Types of Violations Disclosed

<table>
<thead>
<tr>
<th>EMR consulting</th>
<th>Non-monetary comp limits</th>
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<tr>
<td>Call coverage</td>
<td>Employed physician comp</td>
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<tr>
<td>Medical staff leadership</td>
<td>Residency program services</td>
</tr>
<tr>
<td>Office rent</td>
<td>Hospitalist coverage</td>
</tr>
<tr>
<td>Medical directorships</td>
<td>Recruitment arrangements</td>
</tr>
<tr>
<td>Professional services</td>
<td>Clinic coverage</td>
</tr>
<tr>
<td>Locum tenens</td>
<td>And more!</td>
</tr>
<tr>
<td>DME orders</td>
<td></td>
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<tr>
<td>Test supervisions services</td>
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Settlement observations

CMS has staunchly refused to disclose any settlement formula—however:
- So-called “technical” violations appear to be settling for nominal sums (e.g., < $15,000 per violation)
  - Missing signatures
  - Expired (but otherwise compliant) contracts
  - Lack of written arrangement (but otherwise compliant arrangement)
- Little/no relation to value of tainted referrals
- Outcomes seem consonant with pre-SRDP lobbying by AHA and current proposals to amend Stark Law

Settlement observations

CMS’ proposed resolution amount is communicated as non-negotiable
No appeal rights for any claims resolved through the SRDP

Settlement release

CMS’ form release is very limited—no release from potential liability under:
- FCA
- CMP statute
- CMP provisions of the Stark statute
- Program Fraud Civil Remedies Act
- Mandatory/permissive exclusion authorities
- Common law claims (e.g., mistake, restitution, unjust enrichment or fraud)
- Reopening of paid claims, cost reports
Duty to Update

Duty to supplement initial SRDP disclosure?
- “CMS expects to receive ... information from the disclosing party that relate to the disclosed matter without the need to resort to compulsory methods.”
- “cooperation in providing additional information related to the disclosure" is an express settlement criterion under the SRDP
- “A disclosing party that ... fails to fully cooperate during the self-disclosure process will be removed from the SRDP”

Consequence of removal:
- Removal from SRDP reinstates 60-day period back to the date of submission
  - Failed self-disclosure suddenly becomes prima facie FCA violation

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Conclusion- Summary of Key Points
Generally, no payment to physicians without a contract.
Document FMV and commercial reasonableness.
Payments based on services personally performed.
Term of at least one year but use overall limits.
Compensation based on services personally performed or influenced – not referrals or limitations of service.
Centralize contracting process.
Implement the arrangement as written.
Track Non-Monetary Compensation
Ask questions!!
Conclusion- Preventing Future Issues

Compliance/Monitoring programs and corrective action plans

Contract management software

Ongoing periodic reviews

- Develop a schedule to review periodically, on an ongoing basis, each compensation relationship.
- Ensure that the parties are complying with the terms of the arrangement.
- Ensure that proper documentation supports the compensation and services under contracted.
- Ensure that proper documentation and justification supports any changes to the relationship or compensation.