Advanced Stark

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Agenda

• Who is the “Referring Physician”?
• Fair Market Value post-Bradford and what it means to be "commercially reasonable"
• Maneuvering through the Indirect Compensation Definition and Exception
• Co-Management with Gainsharing Arrangement – A Case Study
• Innovative Compensation Arrangements
• Voluntary Disclosure
• Q and A
Who is the “Referring Physician”?

- Two challenging circumstances:
  - Stark self-disclosures
    - Which DRG payments have to be included in Medicare payment calculation?
    - Depends on who the “referring physician” is
  - Stark-related litigation
    - Gov’t has to prove that the physicians with the financial relationship made DHS referrals
    - Is a physician’s name on a UB claim form dispositive?
Who is the “Referring Physician”?  

• Simplistic answer: the physician who made the DHS referral, or to whom the referral is imputed  
• Begs question: what is a “referral”?  
  • Technical definition, but boils down to a request, order or (re)certification of the need for DHS  
  • 42 C.F.R. § 411.351 (defining “referral”)  

Who is the “Referring Physician”?  

• Based on the definition of “referral,” the physician who:  
  • Wrote the hospital admission order  
  • Ordered the lab or scan  
  • Scheduled the surgery  
  • Signed the plan of care that included DHS  
• But wait . . . not that simple
Who is the “Referring Physician”? 

• Statutory/Regulatory Two-part Analysis: 
  • Did the physician with the financial relationship refer Medicare beneficiaries 
    • “to the entity” 
    • “for the furnishing of DHS” 

CMS 

• CMS’s published position: 
  • The Stark law’s provisions on what constitutes a referral “for” DHS have to be read together with the law’s prohibition on referrals “to the entity” with which the physician has a financial relationship for which there is no exception. 
CMS Example

• A physician-owner of a PT company who establishes a PT plan of care for a hospital patient discharged to a SNF does not make a referral to his PT company unless he knows or should know that the SNF uses his PT company
  • 66 Fed. Reg. 872-73 (Jan. 4, 2001) (Stark II Phase I rule)

CMS Example

• A physician who writes an order or prescription for DHS that can be filled at any number of places, has not made a referral to an entity unless the physician suggests or informs the patient that she can fill the script at a particular location
  • 66 Fed. Reg. 873 (Jan. 4, 2001) (Stark II Phase I rule)
Referral “to the entity” is Key

- Statutory and regulatory prohibition
  - “the physician may not make a referral to the entity for the furnishing of designated health services”
- Does not say:
  - “the physician may not make a referral of DHS that is furnished by the entity”

CMS’s Public Remarks

- Position: For SRDP purposes, every physician who orders a hospital service during the patient’s admission is responsible for the admission
  - entire DRG payment should be counted as a Medicare overpayment
Raises Thorny Questions

• Does a consulted physician who orders a lab test during a patient’s hospital stay refer the patient to the hospital for the lab test?
• Even if the consulting physician is “tainted,” if the admitting/attending physician is not “tainted,” doesn’t the hospital have an independent basis for retaining the DRG payment?

Example A

• What if the patient walks into the ED, and is subsequently admitted to the hospital by a hospitalist for stabilization as required by EMTALA?
  • Did the admitting physician refer the patient to the hospital?
  • Has ANY physician referred this patient to the hospital for outpatient or inpatient hospital services?
Example B

• What if, on the referral of his regular physician, a patient schedules an appointment with a hospitalist service for evaluation for admission to the hospital?

• If the hospitalist ultimately admits the patient, did the hospitalist refer the patient to the hospital?
  • Wasn’t the patient already referred to the hospital by his regular physician?

Example C

• What if a surgeon is asked to consult on an admitted inpatient, and the decision is made to perform surgery?

• The surgeon schedules the OR, ordering hospital services, but did she refer the patient to the hospital for these OR services?
Contrary Policy Argument?

• Stark is not just concerned with referrals
  • Stark is concerned with overutilization of DHS arising from financial incentives
    • E.g., physician ownership of in-office DHS
  • In the case of hospital referrals, shouldn’t Stark be implicated if a “tainted” doc is in a position to increase utilization once the patient is admitted by another doc?

Contrary Policy Argument?

• Hospitals are predominantly paid a fixed DRG payment insensitive to utilization
  • Why would a hospital pay physicians incentives to increase its costs?
“Referring Physician” and Proof of Referral

- Hospital medical records, billing systems and claim forms use various labels:
  - Admitting Physician
  - Attending Provider (used on UB)
  - Operating Provider (used on UB)
  - Other Operating Physician (used on UB)
  - Rendering Physician (used on UB & 1500)
  - Referring Physician (used on UB & 1500)
  - Ordering Physician (used in 1500 instructions)

- Are all of these physicians “referring physicians” for Stark purposes?

Example

- What if a hospital is sued by a relator under the FCA, and the only evidence the Gov’t has of a referral is the “tainted” physician’s name and NPI on the UB as the “Operating Provider”?
  - Primary responsibility for performance of the surgery or procedure
  - Does this even establish that the surgeon ordered the surgery, let alone referred the patient to the hospital for the surgery?
Fair Market Value post-Bradford
What it means to be "commercially reasonable"

Hypothetical

- Hospital is negotiating to purchase a 10 physician cardiology practice that currently has in-office PET, echocardiography and a nuclear camera. Hospital has received a valuation of the practice that allocates $1.2 million to the FMV of the practice to account for revenues from this testing.
- Hospital intends to keep this testing in the practice post acquisition.
- Is this permissible under Stark?
U.S. ex rel Singh v. Bradford Regional Medical Center

U.S.Dist. LEXIS 119355 (W.D. PA Nov. 10,2010)

- Qui Tam suit alleging Stark and kickback violations.
- Two physician practice that formerly referred scans to a community hospital bought its own nuclear camera and began doing scans in-office.
- Faced with declining referrals, the hospital subleased the camera back from the practice, left it physically in the practice, but billed the scans as hospital services.

Bradford, cont’d

- Under the sublease, Bradford paid the prime lease rate, plus an additional $24,000 per month for all rights under the lease, including a covenant not to compete from the doctors.
- Bradford also paid $2,500 per month as a billing fee and rent to the practice.
Bradford, cont’d

• Court found a Stark violation.
  • Valuation was not FMV under Stark because “it takes into account the volume or value of referrals.”
  • Consideration of “anticipated referrals” in the valuation of non-compete runs afoul of this requirement.

Analysis of Practice Acquisition Hypothetical

• Impact of Bradford- Does it preclude valuation of in-office DHS in a practice acquisition?
  • Bad factual record.
  • Lease not part of a practice acquisition, only the ancillaries were at issue.
  • Practical effect of non-compete was to require referrals to the Hospital.
    • No reasonably proximate alternative vendor.
  • Hospital could have leased its own camera for far less from a commercial vendor.
Stark Commentary on Valuing Physician Practices

• “Comment: One commenter asked us to clarify that a valuation of a physician’s practice could include the value of self-generated DHS in the purchase price as long as the purchase agreement was not contingent on future referrals.

• Response: For the purposes of [the Stark Law], the valuation of a physician practice could include the value of DHS in the purchase price if the DHS provided by the selling physician fit into an exception, such as the in-office ancillary services exception, and the purchase agreement (and purchase price) is not contingent on future referrals. Depending on the identity of the purchaser, however, the inclusion of the value of ancillary revenues could implicate the Anti-Kickback statute.”


Analysis of Practice Acquisition Hypothetical

• Commentary clearly blesses valuing in-office ancillaries.

• What if the in-office ancillaries are to be moved to the hospital immediately post-closing?

• What does “Depending on the identity of the purchaser, however, the inclusion of the value of ancillary revenues could implicate the Anti-Kickback statute” mean?
Intersection of Fair Market Value and Commercial Reasonableness

- Most compensation exceptions contain the requirement that the arrangement be “commercially reasonable” even if no referrals were made.”
- “Commercially reasonable” is not defined.
- Note the dichotomy between this and FMV which must be determined without regard to the volume or value of referrals or other business generated between the parties.

CMS Preamble Language re “Commercial Reasonableness”

- “We are interpreting “commercially reasonable” to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.” 63 Fed. Reg. 1700 (Jan. 9, 1998)

- “An arrangement will be considered “commercially reasonable” in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.” 69 Fed. Reg. 16093 (Mar. 26, 2004)
Key Concepts in Commercial Reasonableness

• Some Key Questions.
  • Are the services/space/equipment actually needed or are they excessive?
  • Does the lease make sense to other commercially available options in the marketplace to either purchase or lease?
  • Do the services provided warrant the level of expertise of the contracted physician?
  • Is the arrangement profitable?
    • Is this required?
      • Can strategic benefits be considered?
      • Intangible community benefits?

Hypothetical

• A clinical laboratory agrees to place an in-office phlebotomist in a physician’s office solely to perform laboratory functions in accordance with OIG guidance. The physicians demands that the lab pay rent for the space the phlebotomist occupies. The space will only be used for that physician’s patients. There will be no public access. The square footage will be limited to what is necessary and the rental rate will be the same as that paid by all other tenants in the building. Can such a lease be consistent with Stark?
Analysis

• Fair market value has been met.
• Has commercial reasonableness been met?
  • Hard to justify on any basis other than the business from that physician.
    • Only “referrals” are precluded from consideration under Stark.
      • Defined as Medicare referrals.
    • Can non-Medicare business be used to meet this test?
      • Kickback concerns.
      • State law issues.

Indirect Compensation
Definition and Exception
What constitutes an indirect compensation arrangement?

“Simple Test” – 3 Elements

- **Element 1**: An “unbroken chain” of persons or entities that have financial relationships (even an excepted financial relationship is still a link in the chain)

- **Element 2**: Aggregate Compensation received by the referring physician from the entity with which he/she has a financial relationship must vary with, or otherwise reflect, the volume or value of referrals or other business generated between the physician and DHS entity

- **Element 3**: DHS entity must have “actual knowledge” or “act in reckless disregard or deliberate ignorance” that the referring physician receives compensation in a manner set forth in Element 2

What’s required under indirect comp. exception?

3 Requirements

- **Requirement 1**: The compensation received by the physician from the person or entity with which the referring physician is “fair market value” and does not take into account the volume or value of referrals for the entity furnishing designated health services (**but see Element 2 of Definition of Indirect**)

- **Requirement 2**: Compensation arrangement between the referring physician and the entity with the direct financial relationship must be set out in writing (except for employment arrangements), signed and specifies services

- **Requirement 3**: Does not violate Anti-Kickback Statute or any laws/regulations governing billing or claims submission
Special Rules on Compensation

• “Set in Advance” – Allows per-use/per-service and specific formulas
• “Volume or Value of Referrals” – Per-unit or per-click if the amount is FMV at inception of arrangement and does not vary during the course of the arrangement
• “Other Business Generated Between the Parties” – Per-unit and Per-Click permitted, as long as FMV and does not vary during course of the arrangement

BUT

• FY 2009 IPPS Final Rule does not allow percentages or per-click/per-use in various exceptions including indirect compensation exception

Hypothetical

• For Profit Hospital enters into an arrangement with a physician staffing company (“Staffing Company”) committing the Staffing Company’s separately organized Medical Group (“Staffing Medical Group”) to provide professional services in the Emergency, Radiology and Anesthesiology Departments
• Staffing Medical Group is owed 100% by Staffing Company, employs all of its physicians and pays them pursuant to the individual physicians’ personal productivity (i.e., not based upon ancillary services or DHS)
• Does Stark Prohibit For-Profit Hospital from paying Staffing Company 20% of all billings from the Emergency, Radiology and Anesthesiology Departments?
Hypothetical Analysis

- MOST people will ask – Does this satisfy the exception for indirect compensation?
- BUT … Is there even an “indirect compensation” arrangement between the physicians and the For Profit Hospital that implicates Stark?
  - Employed physicians are paid based upon personal productivity
  - Employed physicians are NOT paid based upon (i.e., not based upon ancillary services or DHS)
  - As such, aggregate compensation received by the referring physician from the entity with which he/she has a financial relationship DOES NOT vary with, or otherwise reflect, the volume or value of referrals or other business generated between the physician and DHS entity
Hypothetical

- DME Company enters into financial relationship with ABC Medical Group owned by Drs. Arf, Barf and Carf in which the DME Company pays the Medical Group $100,000 to provide Medical Director and Administrative Services in developing best practices for inhalation therapy.
- ABC Medical Group subcontracts with XYZ Medical Group to develop the inhalation therapy protocol for $40,000.
- XYZ Medical Group, at the direction of ABC Medical Group, wants to encourage Dr. Innocent to refer asthma patients to DME Company in order to test out the protocol and, therefore, pays Dr. Innocent $100 every time Dr. Innocent sends a patient to DME Company.
Hypothetical Analysis

• Is there an “indirect compensation” arrangement between the DME Co. and Dr. Innocent?
  • There is an unbroken chain of financial relationships between DME Co and Dr. Innocent
  • Even though most of the financial relationships do not vary based upon volume or value of referrals … Dr. Innocent’s compensation is based upon volume or value of referrals
  • But third element - Did DME Co. have “actual knowledge” or “act in reckless disregard or deliberate ignorance” that the referring physician receives compensation in a manner employed physicians are NOT paid based upon (i.e., not based upon ancillary services or DHS)
  • As such, aggregate compensation received by the referring physician from the entity with which he/she has a financial relationship DOES NOT vary with, or otherwise reflect, the volume or value of referrals or other business generated between the

Hypothetical Analysis

• Is there an "indirect compensation" arrangement between the DME Co. and Dr. Innocent?
  • There is an unbroken chain of financial relationships between DME Co and Dr. Innocent
  • Even though most of the financial relationships do not vary based upon volume or value of referrals … Dr. Innocent’s compensation is based upon volume or value of referrals
  • But third element - Did DME Co. have “actual knowledge” or “act in reckless disregard or deliberate ignorance” of how Dr. Innocent was being paid?
  • Requires “Facts and Circumstances” Analysis … Isn’t that what Kickback is to look at?
Co-Management w/ Gainsharing:
A Case Study

• Facts taken from OIG Op.12-22; supplemented with facts from OIG Op. 8-21
• Pleasant Valley Hospital (the “Hospital”) is a large, rural acute care hospital
• The Hospital operates four cardiac catheterization laboratories (the “Cath Labs”), all of which are provider-based
• The Cath Labs are the only cardiac catheterization labs within a 50-mile radius of the Hospital
• The Hospital enters into a 3-year co-management arrangement (the “Management Agreement”) with a cardiology group (the “Group”)
Co-Management w/ Gainsharing

- All of the Group’s cardiologists are shareholders
- The Group refers patients to the Cath Lab for cardiac catheterization procedures
- The Hospital bills for the facility component of procedures performed in the Cath Labs by the Group
- The Group bills separately for the professional component

Co-Management w/ Gainsharing

- Under the Management Agreement, the Group provides management and medical direction services for the Hospital’s Cath Labs in exchange for a co-management fee
- The co-management fee has two components:
  - a guaranteed, fixed fee of $500,000 per year ("Fixed Fee"); and
  - a contingent performance-based payment up to a maximum of $500,000 per year ("Max. Performance Fee")
Max. Performance Fee

• 30% of the Max. Performance Fee ($150,000) is allocated to quality of care ("Quality Fee")

• To earn the Quality Fee, the Group must increase the percentage of heart attack and heart failure patients prescribed specified drugs ("Cardiac Drugs") at discharge

Max. Performance Fee

• 60% of the Max. Performance Fee ($300,000) is allocated to cost savings (the "Cost Savings Fee")

• If the Group reduces the Cath Lab’s cardiac catheterization costs per case from its historical $X per case to a range of $Y to $Z per case (the “Target Reduction”), the Group receives the full Cost Savings Fee

• The Group can still qualify for part of the Cost Savings Fee by achieving 50% of the Target Reduction or 75% of the Target Reduction
Cost Savings Fee

- To lower the Cath Lab’s cardiac catheterization costs per case to a range of $Y to $Z per case, the Group *will have to*:
  - Substitute lower cost contrast agents and anti-thrombotic medications
  - Standardize the other types of cardiac catheterization devices and supplies they use (e.g., stents, balloons, guidewires, catheters), *thereby enabling the Hospital to obtain a deeper volume discount from a single vendor*
  - Change use of certain vascular closure devices and cutting balloons to an “as needed” basis

FMV & Commercial Reasonableness

- An independent third-party valuator has opined that the co-management fee is consistent with FMV and the Management Agreement would be commercially reasonable even there were no referrals between the parties (the “FMV Opinion”)


Stark Analysis

• Issue: Will the co-management fee qualify for a Stark exception?

• Compensation arrangement? Direct or indirect?
  • All the cardiologists are shareholders; they stand in the shoes of the Group for Stark purposes
  • The co-management fee creates a direct compensation arrangement between the cardiologists and the Hospital

• Potential exceptions?
  • The personal services (“PS”) exception or the FMV exception

Stark Analysis

• Both the PS and FMV exceptions require that the co-management fee be:
  • set in advance;
  • FMV;
  • paid pursuant to an arrangement that is commercially reasonable; and
  • determined in a manner that does not take into account the volume/value of DHS referrals or other business generated by the cardiologists for the Hospital
Stark Analysis

- Both the Fixed Fee and the Max. Performance Fee are set in advance
  - Even though Max. Performance Fee is a contingent fee
  - Based on the FMV Opinion, assume the FMV and commercially reasonable elements are met

Volume/Value Analysis

- Fixed Fee
  - Will not vary over the term of the Management Agreement
  - Assumed to be FMV
  - Reasonable conclusion: not determined in a manner that takes hospital referrals into account
Volume/Value Analysis

• Quality Fee
  • The Group cannot achieve certain quality metrics without prescribing certain drugs for more of their heart attack and failure patients

Volume/Value Analysis

• Cost Savings Fee
  • The Group cannot reduce costs per case (and qualify for the Cost Savings Fee) without at least performing the volume of cardiac catheterization cases necessary for a deeper volume discount on the Cath Lab’s cardiac catheterization devices and supplies
Volume/Value Analysis

• Cost Savings Fee (cont’d) –
  • The Group cannot earn the Cost Savings Fee without limiting use (volume) of vascular closure devices and cutting balloons to an “as needed” basis
  • Referrals for lower-cost contrast agents and anti-thrombotic medications (i.e., hospital services) are, arguably, more valuable referrals, because they mean more margin per case for the Hospital

Volume/Value Analysis

• Arguably, the amount of the Max. Performance Fee (if any), will take into account the volume of the Group’s referrals for:
  • cardiac catheterization procedures (generally)
  • vascular closure devices & cutting balloons (per case); and
  • Cardiac Drugs (relative to volume of discharged heart attack/failure patients)
Volume/Value Analysis

- Arguably, the amount of the Max. Performance Fee (if any) will take into account the value of the Group’s referrals of lower cost contrast agents and anti-thrombotic medications.
- “Unit compensation” exception to the volume/value standard does not apply; payment is not based on units of time or services.

Conclusion

- Arguably, the Max. Performance Fee will not satisfy the volume/value standard of the PS or FMV exceptions.
Alternative Analysis?

• Presumably, obtaining a deeper discount on cardiac cath supplies by purchasing them from a single vendor does not depend on the Group making more referrals for cardiac catheterizations than in the past
  • But the Stark exception doesn’t say: “takes into account more referrals,” it says: “volume” of referrals

Alternative Analysis?

• Using vascular closure devices and cutting balloons on an “as needed” basis is not necessarily the same as using fewer of these items
  • But if changing utilization of these supplies to an “as needed” basis is necessary to lower the cost per case, then, logically, it means using fewer of them on a per case basis
Alternative Analysis?

• By “inpatient and outpatient hospital services,” did Congress really mean vascular closure devices and cutting balloons?
• Isn’t Stark about overutilization? Don’t we have the CMP gainsharing rule to address incentives to reduce volume?

Alternative Analysis?

• When Congress and CMS conceive of compensation that takes the value of referrals into account, are they really thinking about referrals that lower a hospital’s costs?
• But if referrals for lower-cost contrast agents and anti-thrombotic medications are not more valuable to the Hospital, then why is the Hospital willing to pay the Group to substitute lower-cost supplies?
Alternative Analysis?

• Quality Fee is based on increasing the **percentage** of heart attack or failure patients receiving the Cardiac Drugs upon discharge, not the absolute volume
• The Group could refer a lower volume of these drugs than in the past and still earn the fee
  • But isn’t an increase in the percentage of patients prescribed these drugs still sensitive to the volume of the Group’s prescriptions?
  • Doesn’t the Group have to refer a higher volume of the drugs to whatever volume of cardiac patients they discharge?

Alternative Analysis?

• OIG has CMP authority for Stark violations
• Would the OIG give AKS immunity to an arrangement for which there is no Stark exception?
Innovative Compensation Arrangements

Conditioning Referrals

- Regulations provide that compensation paid to a physician from (1) bona fide employer or (2) per managed care or other contract, may be conditioned on the physician referring patients to a particular provider
- Certain requirements
  - In writing
  - Compensation set in advance and FMV
  - Arrangement complies with an exception
  - Referral requirement does not apply if patient expresses a different choice, patient’s insurance decides on provider or referral is not in the best medical interest of the patient
  - Required referrals relate solely to the physician’s services covered by the scope of employment or contract and requirement is reasonably necessary to effectuate business purposes
  - Note: This does not necessarily allow the physician to be paid based upon his/her referrals
Application

• Can Hospital System require employed physicians to refer to other providers within the Hospital System?
• Can employed physicians be eligible for bonus on compliance with requirement to refer within the Hospital System?
• Can employed physician be fired if fails to refer within the Hospital System?
• How must it be documented that patient prefers to go elsewhere OR that physician believes it is not in best interest of patient?
• What is the intersection with ACO and “population health” initiatives?

Incentive Compensation

• With respect to a large multi-discipline Hospital System with multiple hospitals, a SNF, Home Care Company, etc., can physicians be eligible for bonuses based upon:
  • Improved personal productivity on an individual basis
  • Improved productivity of all physicians within division/specialty
  • Improved productivity all physicians in the system
  • Improved profitability of physician’s division/specialty based solely on professional services
  • Improved profitability of physician’s division/specialty taking into consideration ancillary services
  • Improved profitability of individual hospital physician admits patients
  • Improved profitability of system overall
Voluntary Disclosure

Pertinent Statutory Provisions

• § 6409 of the ACA.
  • Mandates protocol to disclose actual or potential Stark violations.
  • Authorize Secretary to reduce overpayment liability for Stark violations

• § 6402 of the ACA.
  • Mandates the report and return of overpayments within 60 days of identification or date on which any corresponding cost report is due, whichever is later.

• Fraud Enforcement and Recovery Act of 2009.
  • Violation of FCA to “knowingly conceal…or knowingly and improperly avoid…or decrease…an obligation to pay.”
CMS Proposed Rule Regarding the 60 Day Repayment Rule

- CMS published proposed rule on 2/16/12.
  - 77 Fed Reg. 9179
- Key issues affecting SRDP.
  - Stark violations = overpayment.
  - 10 year “look-back” period.
    - Conforming change to reopening rules.
  - “Identified”= knows or acts in “reckless disregard."
  - Inquiries with “all deliberate speed.”
  - If in SRDP, must also file OP report.
    - Not if in OIG protocol.

Self-Referral Disclosure Protocol

- CMS only accepts violations or potential violations of self-referral law.
- If additional violations or potential violations of other criminal, civil, and administrative laws send to OIG.
- Cannot submit disclosure concurrently under SRDP and OIG’s Self-Disclosure Protocol.
- CMS coordinates with Law Enforcement.
- Relationship with Corporate Integrity Agreements.
Self-Referral Disclosure Protocol

• Financial Elements of Submission.
  • Total amount actually or potentially due and owing.
  • Description of the methodology used including estimates.
  • Summary of auditing activity and documents used.
  • Requires payback to beneficiaries

Self-Referral Disclosure Protocol

• Factors considered in compromising overpayments.
  • Nature and extent of the improper or illegal practice.
  • Timeliness of the self-disclosure.
  • Cooperation in providing additional information.
  • Litigation risk to CMS.
  • Ability to pay.
**Stark Self-Referral Disclosure Protocol Settlements**

- 18 settlements posted to date.
- Settlement range is $60 to $584,000.
  - Cluster of low settlements ($1,600-$6,800) involve excess non-monetary compensation.
  - High-end settlements (5 in 6 figures) involve space leases and personal service agreements.
  - Impossible to determine from the CMS website the amount of the total exposure being settled.

**Stark Self-Referral Disclosure Protocol Settlements**

**Legal Analysis**

- SRDP requires that parties identify the requirements of an exception with which their arrangement complies AND requirements with which it does not comply.
- Must provide CMS with your legal analysis.
  - No guarantee that CMS will agree with your assessment.
- Consider all available exceptions and applicable rules before determining that you have a noncompliant arrangement.
Stark Self-Referral Disclosure
Protocol Settlements

**Core Stark Compliance Analysis**

- Is there remuneration?
- Is there a compensation arrangement?
  - Direct?
  - Indirect?
- Is there a referral for DHS?
- Is the organization furnishing the DHS an “entity” (as defined in the regulations)?
- Is Medicare the payor?

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Stark Self-Referral Disclosure
Protocol Settlements

**Core Stark Compliance Analysis**

- Apply rules that were in effect during the various periods of the arrangement.
  - The Stark rules, e.g. “stand in the shoes”, have changed a number of times and the analysis may be different during certain points in the arrangement.
- Give proper, but not excessive, weight to preamble language.
  - Statutory and regulation text govern.
Stark Self-Referral Disclosure Protocol

• Exceptions to Consider:
  • Temporary Noncompliance 42 C.F.R. 411.353(f)
  • Compensation Unrelated to DHS 42 C.F.R. 411.357(g)
  • Payments by a Physician 42 C.F.R. 411.357(h)
  • “Grace Periods” 42 C.F.R. 411.353(g)
  • Isolated Transactions 42 C.F.R. 411.357(f)

Stark Self-Referral Disclosure Protocol

• Overpayment Calculation
  • With respect to physician-hospital arrangements:
    • Is the referring physician the admitting physician?
    • Did furnishing the improperly referred DHS affect the DRG payment?
      • Does this impact the amount of the overpayment?
  • Consider the SRDP “look back” period
    • Tied to reopening rules at 42 C.F.R §405.980(b)
    • FAQ 6091
  • Which programs do you consider?
    • Medicare FFS?
    • Medicare Advantage?
    • Medicaid FFS?
    • Medicaid Managed Care?
Hypothetical

- Hospital requires services of a physician on its medical staff for weekends.
- Discussion and agreement of terms between physician and Hospital on Friday.
- Services are provided on Saturday-Sunday.
- Agreement is prepared on Monday and signed by both parties on Tuesday.
- Payment is made two weeks later.
- Stark issue?

Hypothetical

- Business Team and in-house counsel draft incentive plan documents for newly employed physician with clinical productivity measures based on collections for “personally performed services.”
- Two years later, a new financial analyst is computing incentive payment for physician. The new financial analyst uncovers that, in the prior year, the wrong report was used to calculate the prior year’s incentive. In year one, the former financial analyst used all revenue generated by the physician, include DME revenue and extender services.
Hypothetical

- No one realized the mistake occurred in the calculation.
- The physician is willing and does pay back the incentive salary overpayment to employer and employer issues a revised W-2.
- Stark violation?
- Disclosure?

Hypothetical

- Hospital leases office space to several physician groups in a time share.
- Hospital property manager checks in on the unit.
- Property manager determines that one practice has been using a vacant time slot in addition to the time slot in lease agreement.
- Stark issue?
- Disclosure?
Hypothetical

• Hospital revises agreement and requires physician to lease a different office full-time for two years.
  • Stark compliant agreement.
  • At time of renewal, space is re-measured and there are 200 feet more than in initial lease.
  • Stark issue?
  • Disclosure?

Hypothetical

• Hospital wants to market its state of the art bariatric program.
  • Hospital advertises on billboards and in local newspapers, using photographs and names of the private practice physicians in the advertisements.
  • Physicians do not contribute to the advertising expense.
  • Stark issue?
  • Disclosure?
Q and A