Searching for Clarity Amid a Sea of Confusion

Stark and Anti-Kickback Compliance in Today’s Market

Robert G. Homchick
roberthomchick@dwt.com
Stark and Anti-kickback

- **Stark Law**
  - Applies to Physicians and entities who furnish Designated Health Services (DHS) to Medicare patients
  - Unexcepted financial relationship between a physician and an entity furnishing DHS triggers referral and billing prohibitions

- **Anti-kickback Statute**
  - Applies to everyone
  - Prohibits offering, soliciting, paying or accepting remuneration to influence the ordering or referral of items or services paid for by a federal health care program
  - Intent based statute—failure to fit within an exception or safe harbor not dispositive
Stark Compliance Challenges

- Stark statute is poorly drafted
- Stark regulations are both massive and complex
- CMS perpetually tinkering, revising, expanding, changing the parameters of the law through regulations
Stark Confusion: Entity

- In the 2009 IPPS Final Rule CMS amends the definition of “Entity” to include:
  - The person who performs a service billed as a DHS
  - The person who bills Medicare for a DHS
- This means that the physician’s financial relationship with the entity performing the under arrangements services must fit within a Stark exception
Stark Confusion: Entity

- Entity includes whoever is **Performing** the services billed as DHS to Medicare
- CMS did not define “Perform”
- If a medical group does everything except bill for a service it has likely performed the service
- CMS states, however, that providing space, equipment, personnel, management or other discrete services does not constitute “performing the service”
- Many aggressive interpretations in the market
  - Using multiple companies
  - Slicing and dicing the services
  - Beware of the Easy Fix
Stark Confusion: Agreement

- Many Stark exceptions require a written agreement signed by the parties reflecting key terms
- What constitutes a signed writing
  - Multiple documents?
  - Electronic signature?
  - Level of detail?
  - Timing?
  - Can agreements be signed and made effective as of a past date?
- What is the effect of state law?
  - If a contract enforceable under state law will it be deemed a “written contract” for purposes of Stark?
Stark Confusion: Amendments

- Many Stark exceptions require both that the compensation be "set in advance" and that the agreement be for a term of at least one year.
- Unclear to what extent one can amend an agreement during the first year of a term.
  - Most likely can amend aspects of agreement that do not affect compensation.
  - CMS has indicated in commentary that you can amend compensation if the amendment remains in effect for a year.
    - Really?– the exception will swallow the rule.
Stark Confusion: Evergreen Clause

- Stark Law does not prohibit evergreen renewal clauses
  - Recent case law suggests automatic renewal may create risk
    - Christiana Care settled FCA claims for $3.3M
    - Contract with Neuro group for EEG reads
    - Fees alleged to be above FMV
    - Evergreen clause in contract – Fees not adjusted for several years
Stark Confusion: Incentive Payments

- Incentive payments for personally performed services generally ok
- Incentive payments based on quality metrics ok
  - But one must be careful in selecting quality criteria
    - Infection rates
    - Readmission rates
- Incentive payments for efficiency difficult to fit within Stark exception
- Tension with Medicare’s P4P initiatives
- Stark “Shared Risk” Exception
  - broader than most assume it to be
Stark Confusion: Electronic Health Record Technology Donations

- Hospitals and other DHS entities can donate to physicians up to 85% of the cost of qualifying EHR Technology
- The exception references only physician donees
  - What about donations to Groups?
  - What about licenses used by NPs employed by Groups?
- Measuring Costs of EHR technology?
- Qualifying EHR Technology that includes other functions?
Stark Confusion: Settlement of Disputes

- Hospitals should be able to settle disputed claims involving physicians.
- Threshold question is whether the dispute is *bona fide* and the proposed settlement commercially reasonable.
- A number of questions can arise:
  - What if lease dispute settled by termination of the lease but past due rent not repaid?
  - Can hospital loan a physician the funds to repay the hospital for excess compensation the physician received?
  - When the parties negotiate a settlement will CMS accept the settlement payments as the return of “all” excess compensation for purposes of calculating the period of disallowance?
Stark Confusion: Violations

- If there is a Stark violation what should you do?
  - Historically, no established mechanism for reporting and resolving Stark violations
  - CMS took the position it did not have the authority to compromise Stark violations
  - OIG doesn’t accept technical Stark violations in Voluntary Disclosure Protocol
  - DOJ: no helpful process
  - US Attorney’s Offices all over the map
Health care reform Legislation includes provision requiring CMS to establish a disclosure protocol within 6 months. Also gives CMS the authority to reduce the amount owing as a result of a Stark violation, taking into consideration:

1. The nature and extent of the improper or illegal practice
2. The timeliness of such self-disclosure
3. The cooperation in providing additional information related to the disclosure
4. Other appropriate factors
Anti-kickback Confusion: Employment Relationships

- A statutory exception and regulatory safe harbor protect remuneration paid pursuant to a bona fide employment arrangement.
- There is no fair market value or commercial reasonableness requirement under the kick-back safe harbor.
  - Government has tried to impose such a requirement by arguing that payments in excess of FMV are not for bona fide employee services and therefore outside of the exception.
  - Many disagree with Government on this point.
  - Note: Stark employment exception may require FMV but if physicians employed by captive PC or non profit affiliate of hospital – indirect analysis should apply.
Anti-kickback Confusion: Employment

- Employment of Physicians (by hospital where permitted or by foundation or captive PC) traditionally thought to be a low risk model
- Recent enforcement activity focusing that hospital/foundation employment of physicians and the attendant salary subsidies
- Covenant Medical Center -- FCA settlement arising out of hospital employment arrangements with specialists
  - No cap on compensation
  - Physicians earning far above the 90th percentile
  - Case of rewarding hard work or paying to induce referrals?
  - Would a cap have saved this arrangement?
    - What about the physician who hits the annual cap in September?
Paying physicians based upon their number of work RVUs has been generally accepted.

Setting the formula, however, is not as easy as one would think.
- Confusion generated by the compensation surveys
  - Beware of foibles, bias and problem of small numbers
- What 75th Percentile?
  - In general, a physician who works at a volume consistent with the 75th percentile will be above the 90th percentile in compensation if his/her wRVU rate is set at the 75th percentile.
  - Surveys show an inverse correlation between number of wRVUs and amount paid per wRVU.
Anti-kickback Confusion: Valuation Opinions

- Recent enforcement activities suggest that obtaining a valuation opinion will not necessarily deter the government from challenging FVM of compensation
  - Covenant Medical Center
- Are opinions worth the cost?
- What factors should be considered in determining whether to get a FMV opinion and, if so, who to use?
Anti-kickback Confusion: Salary Subsidies

- Many if not most hospital physician integration models involve some level of subsidy from the hospital or system to the entity that employs or contracts with the physicians
- Average annual subsidy paid by hospital per physician in an employed or captive model is $85,000
- Is the ongoing subsidy of physician practices appropriate?
- What factors should be considered?
  - Market rate compensation for both employed and physicians in private practice
  - Strategic goals of Hospital or Health System
  - The Hospital’s Mission
- Note Stark SITS support for mission payments
Anti-kickback Confusion: Contractual Joint Ventures

- Venture’s involving either expansion of services by one party or co-management of an existing service line raise the specter of being characterized as a contractual joint venture
- Why? That’s the key question
- It is possible to create either a service line joint venture or co-management agreement in a manner that raises limited kickback risks
  - FMV
  - Commercially reasonable transaction
  - Both parties making substantial and necessary contributions
Neither Stark nor the Anti-kickback statute prohibits a hospital from assigning block time in OR or elsewhere.

Basis on which OR time allocated and value of the block time has not been questioned until recently.

The Christ Hospital (TCH) accused of assigning “Heart Station” time to cardiologists based on value of referrals—

Disgruntled Cardiologists allege Heart Station Time = opportunity to earn income and filed qui tam.

TCH negotiating settlement rumored to be $100 million.
Anti-kickback Confusion: Physician-Vendor Relationships

- Pharma companies and device manufacturers are in the middle of a wave of enforcement activity relating to:
  - Best price/AWP
  - Off label use
  - Inducements to physicians and other customers
- Vendors are reassessing how to manage relationships with physicians/hospitals
  - Pharma Code
  - AvaMed Code
Anti-kickback Confusion: Physician-Vendor Relationships

- Many hospitals are struggling with how to monitor or regulate physician/vendor relationships
  - No clear answer
  - Be careful what you ask for . . .
  - Clinical Research considerations
- Sunshine Act?
- Physician owned distributorships
  - Manufacturers objections
  - OIG letter
  - But no enforcement