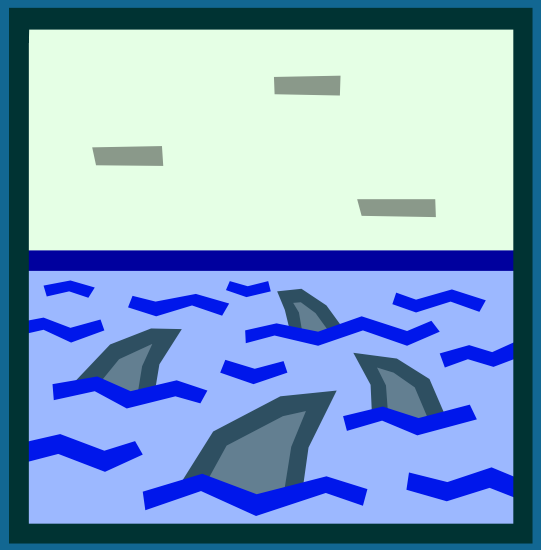


Searching for Clarity Amid a Sea of Confusion

Stark and Anti-Kickback Compliance in Today's Market

Robert G. Homchick
roberthomchick@dwt.com

Stark and Anti-kickback

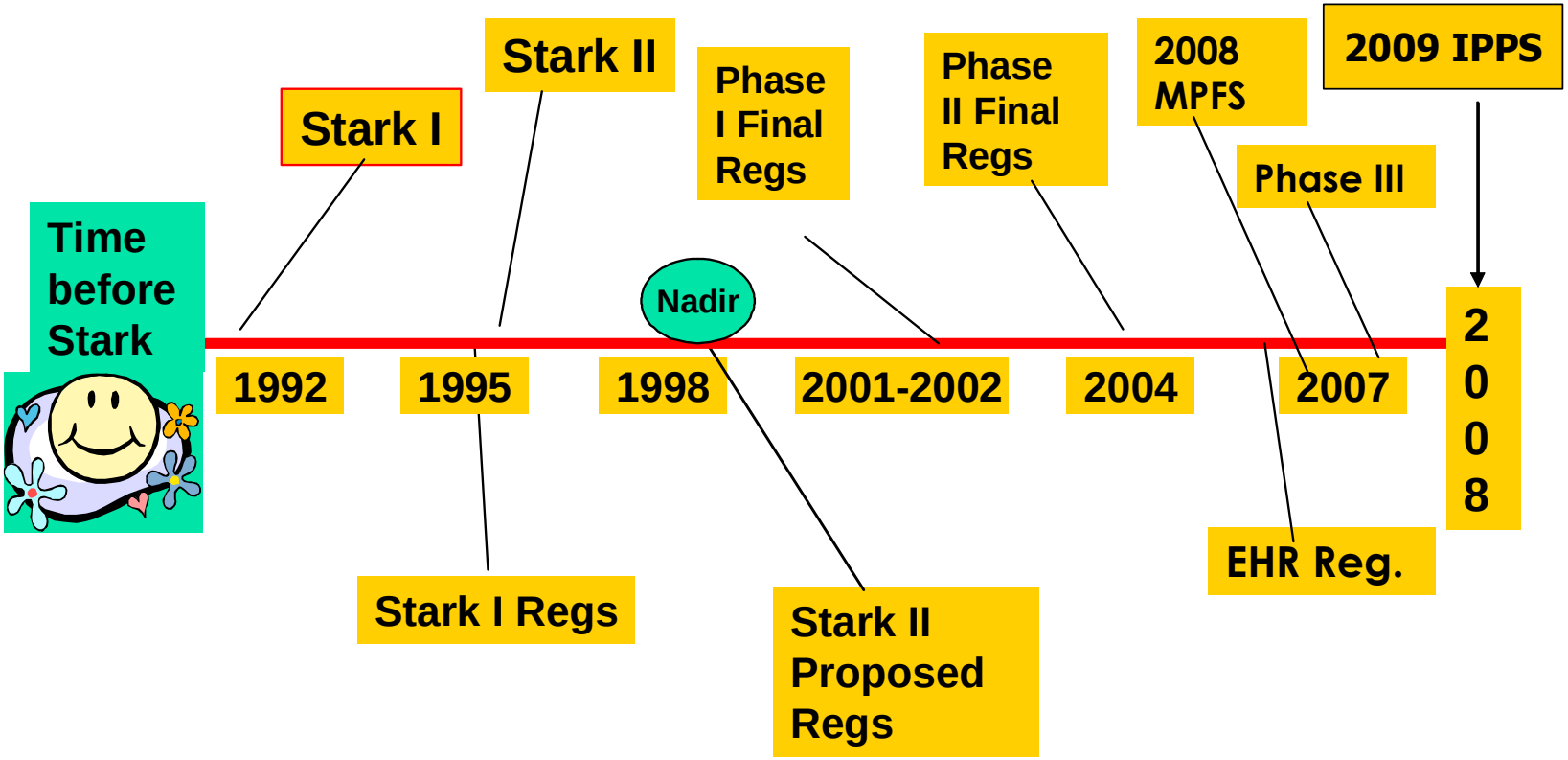
- Stark Law
  - Applies to Physicians and entities who furnish Designated Health Services (DHS) to Medicare patients
  - Unexcepted financial relationship between a physician and an entity furnishing DHS triggers referral and billing prohibitions
- Anti-kickback Statute
  - Applies to everyone
  - Prohibits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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

Stark Timeline



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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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?

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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?

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

Stark Clarity: Disclosure Protocol

- 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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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?

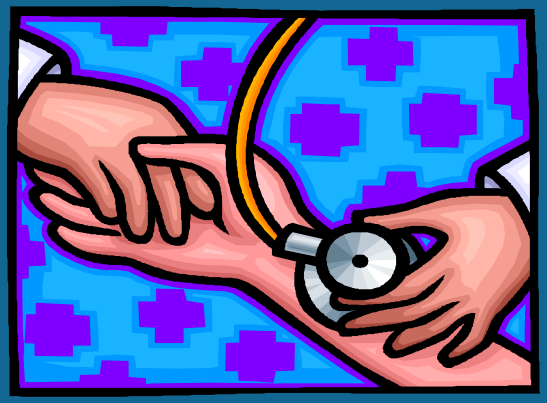
Anti-kickback Confusion: work RVUs

- 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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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?



Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

Anti-kickback Confusion: Block time

- 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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER