Stark Reality

by

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Health Care Law

- Medical malpractice; negligence; informed consent
- Contracts; employment; leases; restrictive covenants
- Products liability
- False claims; disallowed referrals; other fraud
“Everyone agrees that the system by which Medicare pays doctors is deeply flawed. It rewards doctors based on volume of services they deliver, with no measure of their quality of care... This creates all kinds of distortions in the market for medical care.”

A review of Stark Law is thus, timely, and that’s what I will do with this talk
Physician Self Referral Law

• Enacted in 1989, Section 1877 of the Social Security Act only applied to physician referrals of Medicare patients for clinical laboratory services

• In 1993 and 1994, Congress expanded the prohibitions for other Designated Health Services (DHS)

• Original intent was to prevent unethical referrals which were increasing the costs of health care; not unexpected in a “fee for service” model
Stark I

• Originally meant to prevent physician self-referrals on Medicare claims only

• Case law now appears which shows the self-referrals are not allowed for both Medicare and Medicaid
Stark II actually applied to States

- No Medicaid payments will be made to the states which have paid for DHS which would be in violation of the Stark I
- Remember, most Medicaid payments are made by the States which will be reimbursed by the Federal government
- The ruling seems to be that Stark Law applies to physicians referring their Medicaid patients
**US ex rel Baklid-Kunz v. Halifax Medical Center**

- Hospital tried to argue that Stark was not violated because providers were reimbursed by the State and not the Federal government.
- Court ruled against the hospital because the Federal government reimbursed the State for Medicaid payments.
- Hospital also lost under the False Claims Act (FCA); this can be financially devastating.
Stark reality

- Limits business relationships into which a physician may enter
- It’s a complicated set of laws; the application is dependent on the facts of the situation
Stark reality

• Initial prohibitions applied only to clinical lab services where “financial relationships” existed for the referring practitioner (Stark I)
• Stark II extended the prohibitions to a broader range of health services
Stark Law

• Prohibits physician referrals to an entity for designated health services (DHS) for Medicare and Medicaid patients if the physician (or an immediate family member) has a financial relationship with that entity
Stark and the VA

• By law, the VA cannot bill Medicare for care it provides to veterans
• Since Medicare cannot be billed, the VA is not subject to the Stark Laws
Financial relationships

• Direct ownership or investment interest
• Indirect ownership or investment interest
• Direct compensation arrangement
• Indirect compensation arrangement
Direct compensation

- Physician renting office space from a hospital
- Hospital employing a physician
- Hospital renting equipment from a physician
- Nursing home paying physician as an independent contractor to serve as the home’s medical director
Osheroff v. Tenet Healthcare Corp

- Realtor alleges that Tenet charged rent to physicians below fair market value to induce (and reward) physician referrals
- Court denied Tenet’s motion to dismiss even though there were no allegations of self-referral
- Tenet’s certification of compliance thru its Medicare compliance agreement is enough to be liable for a False Claims Act
Osheroff v. Tenet

• Parties reached a settlement that is pending approval by the Department of Justice

• Government’s stance was that Tenet caused the State of Florida to submit false claims to the federal government for services furnished on the basis of improper referrals
Indirect compensation

• Unbroken chain between the physician and the entity to which he is referring; for example, the physician owns stock in a for profit hospital, the hospital contracts with the clinical laboratory to provide services to the hospital’s patients; an unbroken chain exists between the physician and the laboratory
Compensation

- Does the compensation vary with the number or value of referrals; if so, this is not allowed
- A compensation arrangement may be excepted if it is a personal services arrangement or is for “fair market value”
Personal services

• A hospital pays a surgeon to take call to meet the requirements of EMTALA; this would be allowed under the exception for personal services or for fair market value

• Only one of the exceptions is needed to permit what would otherwise be a prohibited referral
Immediate family

• Stark law defines “immediate family” to include husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother or stepsister, father-in-law, mother-in-law, brother-in-law, sister-in-law, grandparent or grandchild; and spouse of a grandparent or grandchild
Circumvention

• Any scheme or arrangement that has a principal purpose of assuring referrals by the practitioner to a particular entity meant to violate Stark is not allowed

• Physician A and B agree to refer their patients to the others diagnostic or treatment facility; this would be a prohibited circumvention
Referrals

• Stark only applies to referrals
• It is **not** a referral if the DHS is personally performed by the referring physician
• Example; my patient needs a bronchoscopy. It is ok for me to perform the bronchoscopy
Penalties

- **Denial of payment** for the DHS provided
- **Refund of monies** received by the entity for amounts collected
- **Payment of civil penalties** ($15,000 for each service that a person “knows or should know” was provided in violation of the Stark Law)
- **Three times the amount** of the improper payment received from Medicare
More Penalties

- **Exclusion from Medicare programs** and/or state healthcare programs such as Medicaid and other Federal health care programs.

- Payment of Civil penalties up to $100,000 for each attempt to **circumvent** the law; this focused on cross referrals whose principle purpose was to assure referrals to a particular entity—direct referrals not allowed, these circumventions were really “indirect” referrals and the law wanted to prevent these also.
Federal Health Care Programs

• Medicare and Medicaid
• Veterans Administration ???
• Public Health Service ???
• Military ???
Jail Time

• There is no jail time for violating Stark, however, there are several State laws which forbid self-referrals and there is jail time associated with those violations.

• The prosecutor may decide to level charges involving both Stark and State law; all the Stark penalties can apply and now, jail time is in play as violations of State law.
Internal Revenue Service

• Electronic medical record can be linked to income tax forms
• Provider ordering tests can be linked to income from DHS that he has ordered
• Audits can be used to identify Stark violations
• Pretty clever!
Stark exceptions

• The law makes it seem that any referral to a colleague in your group is fraught with danger since it would be hard to prove that you don’t have a “financial interest” in the group

• Recognizing this problem, Congress has made numerous exceptions where the law will not apply

• These exceptions are what make the law so complicated; this also allows some lawyers to make a living
Stark Law

• Stark Law only applies for Medicare and Medicaid beneficiaries

• Only applies for referrals for Designated Health Services; lithotripsy is not a DHS so that referral would be allowed
DHS?

- Clinical laboratory services
- Physical therapy, occupational therapy, and outpatient speech-language pathology services
- Radiology and certain other imaging services unless they are integral to performing a medical procedures not identified with CPT codes as a radiology or imaging procedure
Imaging that is integral to the procedure is allowed

- Immediately prior to a medical procedure or immediately following a medical procedure when necessary to confirm placement of an item placed during the procedure; central line placement, chest tube, feeding tube are examples
DHS as part of a bundle

- DHS does not include services reimbursed as part of a composite rate; LIMA to LAD in the OR, PCI for other vessels, all done in the Hybrid OR. This would be billed as a bundle so it would be allowed under Stark.

- Have to be careful to not unbundle as that would be considered billing fraud under other laws.
Stark exceptions

• Requests by a pathologist for clinical diagnostic tests and path examination services are not “referrals”

• Requests by a radiologist for diagnostic radiology services are not “referrals”

• Requests by a radiation oncologist for ancillary services needed for provision of radiation therapy are not “referrals”
Exceptions

• If the provider writes an order for DHS, *but does not direct where the Medicare beneficiary should receive the DHS*, this will not be a “referral” even if there is a compensation relationship with the referring provider.
Academic Medical Center

• Faculty physician compensation must be set in advance and not related by the volume or value of the physician’s referrals or other business generated within the academic medical center
Physician recruitment exception

- Protects remuneration that is provided by the hospital in order to recruit a physician to relocate into the area served by the hospital
- Allows group practices to impose practice restrictions if they do not “unreasonably restrict” the recruited physician’s ability to practice in the geographic area served by the hospital
How about productivity bonuses?

• OK if it’s based directly on DHS personally performed by the referring physician
• Example: Physician orders ultrasounds and then personally interprets the ultrasound
• His bonus can be tied to the number of ultrasounds he read over the course of the year
Productivity bonuses

• OK if it’s based directly on DHS that are “incident to” services that the physician personally performed
• Example: Physician performs a physical exam and then orders physical therapy based on the findings of the physical exam
• Bonus may be paid based on the provision of the physical therapy services
Productivity bonuses

• Be careful; CMS takes the position that radiographs, lab tests and other diagnostic tests cannot ever be billed as “incident to”

• Bonuses cannot be paid based on these types of tests unless the physician performed them himself
Productivity bonuses

- Ok for DHS not personally performed or “incident to” so long as the productivity bonus is not directly related to the volume or value of the physician’s DHS referrals
- For this to occur, the bonus must be based on the physician’s total patient encounters; not DHS payable by any Federal program or private payer; less than 5% of the practice’s total revenue
Affiliation agreement between private practice entity and a medical school calls for the entity to “provide payment of “overage” to the college of medicine for neurosurgeons on the geographic full-time faculty of the Department of Neurosurgery. This payment will be based on a formula, to be negotiated from time to time related to the aggregate compensation of the full-time faculty”
Test question

• Hard to figure from the wording, but it looks like the entity will pay the Medical School some percentage of the payments received by the entity from work sent to it by the Medical School; this looks like a kick-back and this is not allowed
Summary of Stark Reality

• This is a very complex law which the courts are still trying to sort out;

• Be sure to have your Health Care Attorney go over any contract that your practice is involved in or is contemplating

• *Ignorance of the law is not a defense*
Federal laws

• The overwhelming theme is to cut costs by decreasing physician reimbursement (although hospitals and other health care providers are included)

• Understanding the basics of the laws will help keep us out of trouble; the penalties can be severe
Senate Finance and House Ways and Means

• Working on a permanent “doc fix”—legislation which will allow the federal government to determine “applicable appropriate use criteria,” for a full range of outpatient medical services delivered to seniors

• This will be extended to all care under the Affordable Care Act (ACA)
Affordable Care Act

- Independent Payment Advisory Board (IPAB) is tasked to find savings in Medicare without affecting coverage or quality
- IPAB has been granted authority to make changes; previously, Congress had to pass a law for changes to take effect
- Congress can overrule but only with a supermajority
IPAB

• Must reduce payments to doctors, hospitals, and other providers
• The Board is minimally accountable to the President; he can only remove a member for negligence or malfeasance
• Other executive employees work at the “pleasure of the President;” this is a huge change
IPAB; Constitutional?

• By giving the Board the authority to make rules “relating to” Medicare, the Congress is giving up the power it previously exercised.

• Remember, the Congress makes the law, the Executive enforces the law...
Supreme Court?

• Cannot get involved unless someone with “standing” can bring a suit (case or controversy); this may not happen for years

• For the time being, the IPAB will not be subject of any oversight—judicial, Congress, or the President

• I think this violates the “separation of powers” built into the Constitution, but I’ve been wrong before
Learn the law

• “Those who cannot remember the past, are condemned to repeat it.” George Santayana

• Often quoted as “Those who fail to learn the lessons of history are doomed to repeat them.”

• I hope my little lessons in history on Stark and other laws will help you as we all navigate through some turbulent times in Health Care
Animal House—the movie

• “Knowledge is good”
Questions