

Avoiding an October Surprise: Strategies for Complying with the New Stark Law Rules

TELNET 2504 June 18, 2009 1-2 pm EDT

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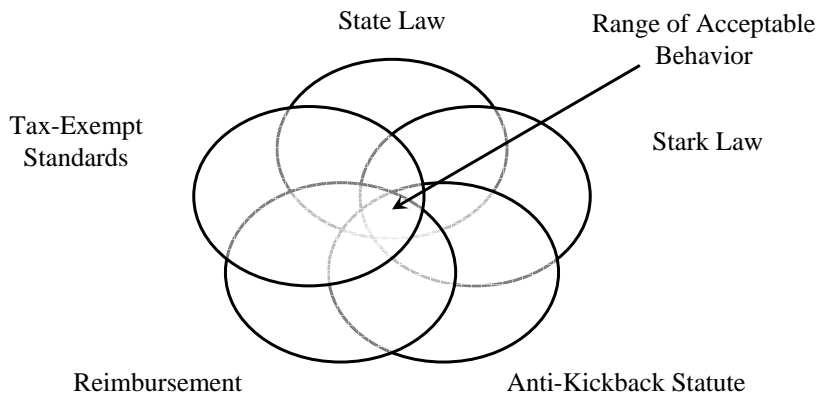
The Expanding Scope of the Stark Law

The Environment Has Changed!

DANGER

Government Regulators
and/or Court Ahead

The Regulation of Healthcare



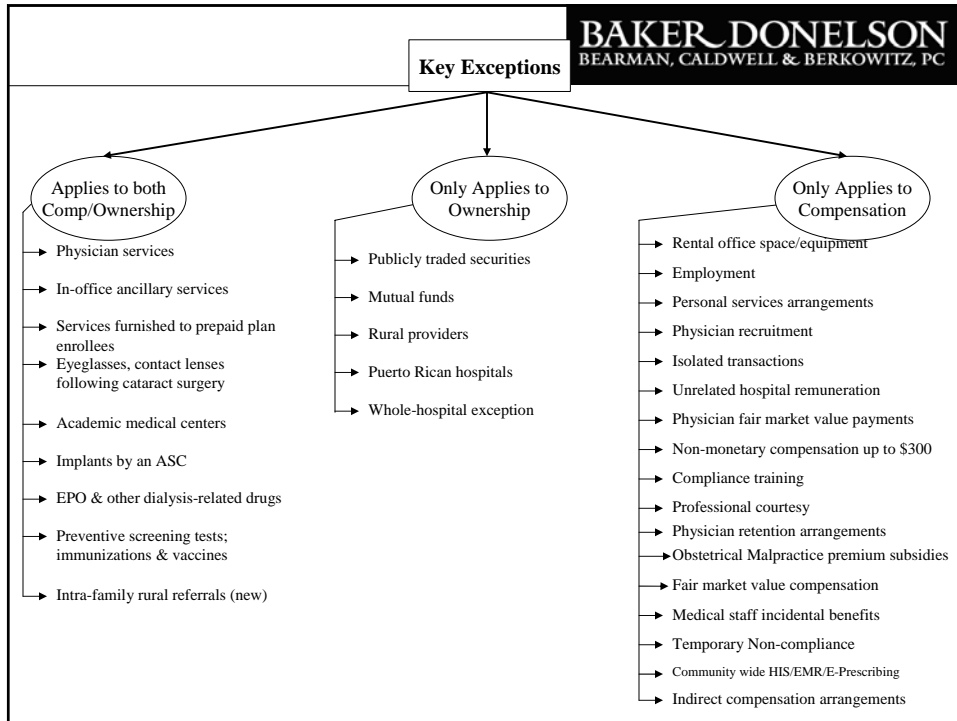
The Basic Stark Law Prohibitions

- Stark II prohibits a physician from making referrals to an entity with which he/she has a financial relationship for the provision of designated health services which may be paid for by Medicare and/or Medicaid
- Also, prohibits the entity from billing any payor for prohibited referrals
- Intent is not a factor—strict liability



Sanctions & Other Enforcement Risks

- **Payment Denial**
- **Refund**
- **Civil Monetary Penalties (“CMPs”)**
 - \$15,000 for knowingly presenting or causing another to present improper claim
 - \$100,000 for “circumvention scheme”
- **Exclusion**
- **Civil False Claims Act Exposure**

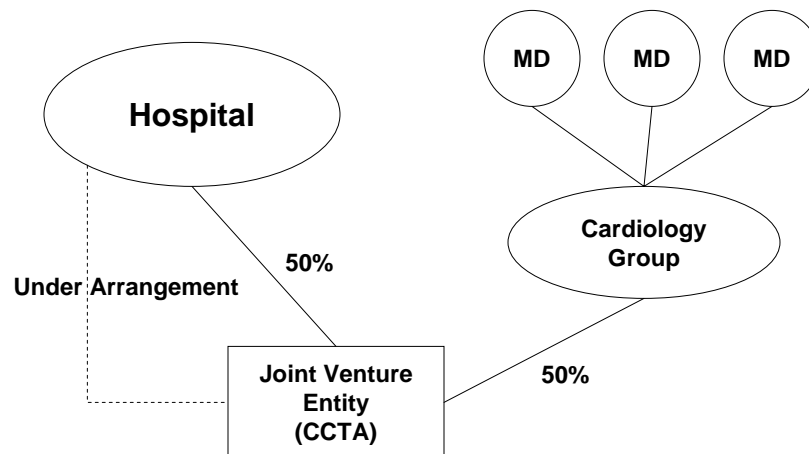


- BAKER DONELSON**
BEARMAN, CALDWELL & BERKOWITZ, PC
- ## The Times They Are A Changing
- **January 1, 1992: Stark I in effect**
 - **October 20, 1993: Stark I proposed rule published**
 - **January 1, 1995: Stark II in effect**
 - **August 14, 1995: Final Stark I rule published**
 - **January 9, 1998: Proposed Stark II rule (63 FR 1659)**
 - **January 4, 2001: Phase I final rule, effective January 4, 2002 (66 FR 856)**
 - **March 26, 2004: Phase II final rule, effective July 26, 2004 (69 FR 16054)**
 - **July 12, 2007: Proposed MPFS update rule (72 FR 38122)**
 - **Sept. 5, 2007: Phase III final rule, effective December 4, 2007 (72 FR 51012)**
 - **November 15, 2007 – Final rule MPFS update rule (72 FR 64161)**
 - **January 3, 2008: Delaying effective date of some MPFS update rule**
 - **April 30, 2008 – Proposed rule (73 FR 23683)**
 - **August 19, 2008 – Final rule (73 FR 48434)**

10-01-09 Change to the Stark Law

- **Expanding definition of “entity” furnishing DHS**
 - Current:
 - Entity is the person or entity that submits the bill to Medicare for payment for the DHS (or has a right to do so)
 - Effective 10-1-09:
 - Entity will also include the person or entity that performs the DHS
 - Intent: Include under arrangement service providers
 - Not intended to include management, staffing or leasing arrangements (assuming you can distinguish!!!)
 - For purposes of analysis, a single referral may have to comply with two exceptions because you have two entities furnishing DHS
 - *Colorado Heart Institute v. Leavitt*, Civil Action No. 1:08-cv-01626 (D.D.C. Sept. 23, 2008)

CCTA Joint Venture Under Arrangement



Importance of Change

- **Quasi-provider joint ventures (management agreements, under arrangements, etc.) depend on the physician ownership not being an ownership interest in an entity furnishing DHS**
 - Importance: No need to comply with a Stark Law exception for ownership
 - Allowed physicians who could not own an interest in a service joint venture to do so without regard to the Stark Law
 - Consider impact to cardiac cath lab arrangements
- **Effective 10-01-09, such physician ownership arrangements will have to be structured to fit within an exception to the Stark law (or restructured)**

Impact on Physician-Owned Under Arrangement Service Providers

- **Effective 10-1-2009: Will need to comply with ownership exception**
 - Even if wholly-owned by physicians, in-office ancillary services exception not available
- **Most will need to be unwound or restructured**
- **Can still continue under arrangement if:**
 - Physician does not make referrals (radiologists, pathologists, and radiation oncologists)
 - Arrangements that comply with rural provider exception

Impact on Management Arrangements

- **“We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS.” 73 Fed. Reg. 48,726 (Aug. 19, 1008)**
- Could capture some turn key arrangements or staffing plus arrangements

Impact on Lithotripsy Arrangements

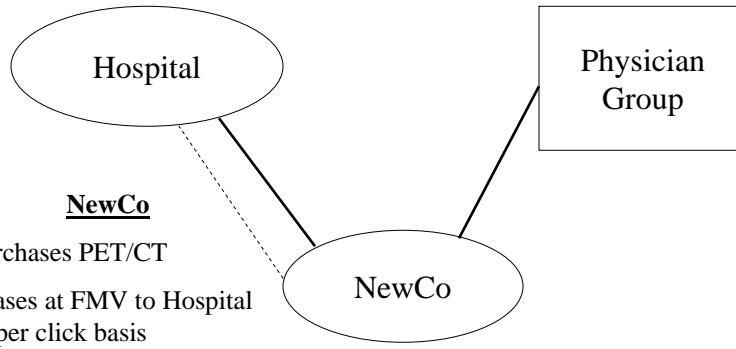
- **CMS’ Position: Lithotripsy is not a DHS but if make furnished in hospital then a DHS**
 - *American Lithotripsy Soc. v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002)
- **That is, if billed as a hospital outpatient or inpatient service, a non-DHS service would be a DHS**
- **Accordingly, lithotripsy services furnished under arrangement by a urologist could result in a referral relationship without a corresponding Stark exception if the urologist makes referral for services other than lithotripsy to the hospital**
- **May be able to restructure as service arrangement and still pay on a per click basis**

Dealing with Uncertainty

- **Proposed Changes to Stark Law would treat under arrangement entity as an “entity” for Stark purposes**
- **CMS has indicated that they are still considering and future action will be through a separate rulemaking**
- **Must disclose risk**
- **Have easy unwind provisions**
- **Weigh benefit against costs if prohibited in 12 -24 months**

Per-Click and Percentage Compensation Arrangements

CCTA Joint Equipment Venture



- Purchases PET/CT
- Leases at FMV to Hospital on a per click basis

Percentage-Based And Per-Click Arrangements

- **Beginning October 1, 2009, percentage-based and per-click payment arrangements are no longer permitted for:**
 - Office space leases
 - Equipment leases
 - Fair market value compensation arrangements
 - Indirect compensation arrangements
- **New regulations do not affect gainsharing**
- **New regulations do not affect pro rata distribution of costs/expenses**
- **New regulations do not affect physician services, including medical director or other administrative services**

Office Space and Equipment Lease Exceptions

- In writing
- Space/equipment may not exceed what is reasonable and necessary and must be exclusively used by lessee
- Term must be at least one year
- Rental charges must be *set in advance* and consistent with fair market value
- Rental charges may not take into account referrals or other business generated between the parties
- Must be otherwise *commercially reasonable*, even if no referrals were made between the lessee and lessor

Exceptions (continued)

- **May terminate with or without cause at any time, but may not enter into another lease for the same space or equipment during the first year of the original lease term**
- **Month-to-month holdovers allowed for up to 6 months**
- **Operating and capital leases are eligible**
- **“Exclusive use” includes subleases if lessee does not share rented office space/equipment with lessor when rented**

Percentage-Based History

- In Phase I Stark regulations, CMS took position that percentage-based compensation arrangements did not meet Stark's definition of "set in advance"
- In Phase II regulations, CMS discussed percentage-based compensation in context of personal services (e.g., physician services and productivity bonuses)
- In Medicare's 2008 proposed Physician Fee Schedule, CMS noted physicians/entries using percentage compensation for renting office space and equipment

A Percentage of What?

- **Compensation under these certain leases cannot be based on percentage of revenue:**
 - Raised
 - Earned
 - Billed
 - Collected
 - Attributable to services performed or business generated in the space or by use of the equipment

Why CMS Is Targeting

- Heightened risk of program and patient abuse (e.g., incentive to refer unnecessarily for DHS)
- Percentage-based arrangements may not result in fair market value payments
- Hospitals may be entering into these arrangements despite fact the hospital has sufficient volume to purchase its own equipment for fear of losing referral stream from those physician owners

Per-Click Leases

- No longer allowed to the extent charges reflect services to patients referred by lessor to lessee

Why CMS Is Targeting

- **Heightened risk of program and patient abuse (e.g., incentive to refer unnecessarily for DHS)**
- **Fair market value may not be met if a lessee is paying substantially more for equipment owned by referring physicians than by a non-physician owned company**
- **Commercially reasonable standard may not be met if:**
 - lessee has sufficient volume to justify purchasing the equipment
 - physician lessors “hold-up” hospital or threaten to move their referrals to another hospital if the equipment is not leased from them
 - outdated or lesser technology used to control costs and increase profits to lessors

Lithotripsy Stark Law FAQ

- **1-22-2009 FAQ**
- **Question: Can a physician-owned lithotripsy company contract with a hospital to furnish lithotripsy under arrangement and charge a per use or percentage-based fee?**
- **Yes**
 - So long a urologists are not making any other referrals for DHS to the Hospital
 - A service agreement coupled with furnishing the “tools of the trade” can comply only with the personal services exception
 - Hence, the per click and percentage-based restrictions will not apply
- **Note if providing under arrangement still have to comply with an ownership exception to the Stark law if urologists are going to make referrals for services other than lithotripsy to the hospital**

Action Steps

- **Identify affected lease arrangements**
 - 1 – **Contracts database?**
 - 2 – **Master lists of equipment/office space rented?**
 - 3 – **Institutional knowledge?**
 - 4 – **Accounting (e.g., payment to and from third parties)**
 - 5 – **Legal opinions?**
- **Confirm change is necessary**
- **Initiate contact with other parties to the agreements**
- **Amend compensation structure accordingly**

Alternatives

- **Physician owners might divest their ownership interests**
- **Physician owners may stop referring DHS to the Hospital**
 - **Remember DHS includes inpatient and outpatient hospital services**
- **Modify compensation structure**

Increased Stark Oversight & Enforcement

Stark Enforcement Has Arrived

- **Kings Daughters' Hospital & Health Services (Dec. 3, 2008) settled for \$391,500 a self-disclosed violation that employed physician compensation included a component for services not personally performed by the employed physician.**
- **Memorial University Medical Center (Savannah, Georgia) (Apr. 2008) settles Stark violation whistleblower suit brought by physician for \$5,080,000 (whistleblower takes \$863,000).**
- ***U.S. ex rel. Villafane v. Solinger*, No. 3-03-cv-519 (W.D. Ky Apr. 8, 2008) interpreting the academic medical center exception.**
- ***U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, (January 29, 2009) reversing grant of summary judgment to hospital finding that the grant of exclusive privileges to an anesthesiology group could create in-kind remuneration sufficient to constitute a financial relationship under the Stark law.**
- **CMS Unveils New Claim Denial Code for Stark Violations (CARC 213)**

OIG New Position on Stark Self-Reporting

- **March 24, 2009 Open Letter to Health Care Providers**
 - OIG will no longer accept disclosure of a matter that only relates to Stark Law violation
 - Must include a “colorable anti-kickback statute violation
 - Now requires a minimum \$50,000 settlement amount to resolve
- **CMS has indicated in the past that it has no authority to settle Stark violations**
- **Where does that leave providers?**
 - Department of Justice ???
 - Carrier ???

Disclosure of Financial Relationships Report (“DFRR”)

- **May 2007: CMS provided notice of its intent to send DFRR to 500 hospitals to request information regarding hospital’s ownership, investment and compensation arrangements**
- **April 2008: CMS pulled the DFRR before OMB approval obtained**
- **May 2008: CMS again expressed its intent to move forward with DFRR (including a copy of the 16 page form)**
- **December 2008: Indicated that it will send the DFRR to 400 hospitals**
 - 60 days to respond
 - Officer must certify the response
 - Arrangements in effect during cost reporting period ending in 2006
 - Penalty of \$10,000/day

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