The Stark Law and Certain Trending Arrangements: What to Know When Analyzing Lithotripsy, Neuromonitoring, and Pathology Arrangements

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AGENDA

✓ The Stark Law (brief overview)

✓ Lithotripsy Arrangements (primarily with hospitals)

✓ Neuromonitoring Arrangements (primarily with hospitals)

✓ Pathology Arrangements (primarily with ASCs)

*We will commonly use “litho,” “neuro,” and “path(-o)” during this presentation.*
The Stark Law
The Stark Law - Overview

- What is Stark?
  - Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare [or Medicaid] to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
  - Prohibits the entity from presenting or causing to be presented claims to Medicare [or Medicaid] (or billing another individual, entity, or third party payer) for those referred services.
- “Referral” does not include a referral for a service the referring physician personally performs
- Statute: 42 U.S.C. 1395nn
- Regulations: 42 C.F.R. 411.350 et seq.
The Stark Law – What Qualifies as DHS?

- Clinical laboratory services (defined by code)
- Physical therapy services (defined by code)
- Occupational therapy services (defined by code)
- Outpatient speech-language pathology services (defined by code)
- Radiology and certain other imaging services (defined by code)
- Radiation therapy services and supplies (defined by code)
- Durable medical equipment and supplies (defined at 42 CFR 411.351)
- Parenteral and enteral nutrients, equipment, and supplies (defined at 42 CFR 411.351)
- Prosthetics, orthotics, and prosthetic devices and supplies (defined at 42 CFR 411.351)
- Home health services (defined at 42 CFR 411.351)
- Outpatient prescription drugs (defined at 42 CFR 411.351)
- Inpatient and outpatient hospital services (defined at 42 CFR 411.351)
The Stark Law – Exceptions & Penalties

- Mandatory exceptions
  - Similar to AKS (e.g., personal services, employee, lease, etc.)
  - Note - limited exceptions for ownership (i.e., no “small investor safe harbor” but do have in-office ancillary services exception and some services are not DHS)

- Penalties
  - Strict liability statute, no intent required
  - Overpayment/refund obligation
  - FCA liability
  - Civil monetary penalty liability of up to $15,000 per service plus treble damages and/or $100,000 per circumvention scheme
  - Potential exclusion from federal healthcare programs
The Stark Law – Overview (cont’d)

- **What do litho, neuro, and patho have in common regarding Stark?**
  - Often considered *not* to be DHS or to involve a referral, and, thus, exempt from Stark
  - Historically, aspects of services were performed by non-physician owned entities, but trend is toward physicians as owners of companies providing these services

- **CAUTIONS** for these types of arrangements (and others):
  - Typical non-referral sources (e.g., pathologists, radiologists) should not mean disregarding Stark altogether -- certain specialties have components that cross over into the “referral” category (e.g., interventional radiologists)
  - Do not rely on excluding gov’t payors (state law, commercial bribery statutes and US Travel Act)
  - Even if not DHS, may still need to consider AKS
Lithotripsy
Lithotripsy – What is it?

- Non-invasive procedure used to treat kidney and gallbladder stones
- High energy sound waves (aka “shock waves”) are used to break up the stones into smaller pieces for easier passing
- Waves are delivered by a lithotripter machine from outside the body
- Takes about 45 minutes, with patient under some form of anesthesia
- Components of the procedure:
  - Lithotripter machine (often portable and can move between facilities)
  - Technician to operate the lithotripter
  - Urologist
  - Anesthesiologist
**Lithotripsy – Common Arrangement**

- Urologist (or group) owns the lithotripter and employs the technician.
- Urologist has a patient with kidney/gallstones so orders lithotripsy.
- Urologist sends patient to a particular hospital for the procedure:
  - Limited coverage and reimbursement for litho by non-hospital facilities, but hospitals usually receive high reimbursement for litho.
- Urologist has contract with hospital:
  - Urologist brings lithotripter and technician.
  - Hospital bills and collects for the service then pays agreed upon amount to the urologist:
    - Often set up as a per-click (aka per-patient) or percent of reimbursement.
    - Sometimes includes a transportation or set-up fee.
    - Often see rates that vary by payor type.
Lithotripsy & Stark – Rollercoaster Ride of a History

- DHS or Not DHS …Per-Click or Not Per-Click
- Litigious relationship between urologists and Secretary of HHS
- Timeline of Major Events:
  - 1998 – CMS Final Rule permits per-click arrangements
  - 2008 – CMS Proposed Rule (never finalized) – prohibits per-click arrangements (based on susceptibility to abuse)
  - 2008 -- *Council for Urological Interests v. Burwell* (D. C. Cir. 2015) – challenges definition of “entity furnishing DHS” and per-click prohibition
  - 2009 -- IPPS Final Rule (73 F.R. 48434 Aug. 19, 2008) -- Per-click prohibited if physician referred patient to the hospital for the service
  - 2009 – CMS FAQ 9556 (now 9780) – re-confirmed litho is not DHS and may be per-click for “under arrangements”
  - 2010 – OIG Settlement with United Shockwave Services for $7.3M
Lithotripsy & Stark – Court Was Not Enjoying the Ride

Quotes from *Council for Urological Interests* case (emphasis added)

- Resolving the questions before us requires that we undertake a sometimes *arduous journey through the tangled regime*. We begin our *slog* with a look at the Medicare program.

- The Secretary now believes the Conference Report is ambiguous but her explanation in the 2008 rulemaking borders on the *incomprehensible*.

- This jargon is plainly not a reasonable attempt to grapple with the Conference Report; it belongs instead to the *cross-your-fingers-and-hope-it-goes-away school of statutory interpretation*.

- If a “reasonable” explanation is “the stuff of which a ‘permissible’ construction is made,” … the Secretary’s *tortured reading* of the Conference Report is the *stuff of caprice*….What is left is the Secretary’s *bewildering statutory exegesis*—one we cannot affirm even under *Chevron*’s deferential standard of review.
Lithotripsy – The Ride May Have Stopped, but…

- Following 2009 Rule and FAQ by CMS:
  - General understanding was that CMS prohibited per-click arrangements, but prohibition not apply to litho because litho is not DHS
  - Urologist lobby claims victory and advocates per-click for litho
  - CMS cautions that if urologist is referring other patients to the hospital for DHS, then litho arrangement must comply with a Stark exception
    - CMS clarified that per-click is permitted for litho provided “under arrangements” to a hospital, so long as all of the requirements of a relevant exception are satisfied

- Fraud and abuse concerns remain (see United Shockwave)
  - FMV highly recommended (AKS applies regardless of litho not being DHS)
  - Often difficult to fully satisfy exception/safe harbor due to challenges establishing set intervals for use or having compensation set in advance
Lithotripsy – Recommendations for Arrangements

- Structure arrangement to comply with a Stark exception
  - Personal Services, FMV, Indirect Compensation
  - *Not* rental of equipment if want to use per-click
- Determine whether urologist has relationship with hospital other than referring litho patients (e.g., refers other DHS to hospital, part owner in hospital)
- Assess commercial reasonableness of hospital renting versus owning the lithotripter
- Carefully assess compensation structure
  - Obtain FMV (see next slide)
  - Establish flat, blended rate that applies to all payor types
  - Consider volume discounts
  - Consider an annual cap
Lithotripsy – FMV Considerations

- Wide range of rates ($1000 to $3500)
- Varying rates for payor type
- Technical component reimbursement for litho is often attractive for hospitals, so hospital may be able to “afford” rate above FMV, but does not mean it should

- Aspects which may affect FMV
  - Unique market (e.g., rural)
  - One provider dominating a market
  - All providers in a market being physician-owned and controlling volume of patients
  - Ensure arms-length negotiations; do not just pay what facility down the street pays
Neuromonitoring
Neuromonitoring – What is it?

- Sometimes referred to as “intraoperative neuromonitoring” or “intraoperative monitoring” (IOM) or “intraoperative neurophysiological monitoring” (IONM).

- Involves stimulating nerves and muscles and using electrophysiological methods (i.e., EEG, EMG, etc.) to monitor patient’s nervous system during surgery.

  - Typically involves neuromonitoring equipment, technician, and neurophysiologist (often remotely monitoring) to interpret signals.

  - Surgeon often requests neuromonitoring service.
Neuromonitoring – Benefits/Potential Issues

- **Benefits**: Provides real-time feedback during surgery, allowing opportunity for the surgeon to intervene and potentially avoid or mitigate neurological damage.

- **Potential Issues**: Could involve billing patients and insurers at higher, out-of-network charges; could have potential for overuse; typical fraud concerns (e.g., billing for services that are not provided, or billing for monitoring multiple patients at same time).
Neuromonitoring – Significant Stark Law Changes

- **Stand in the shoes rule (42 C.F.R. 411.354(c)(3)(i))**
  - Physician owner of a medical practice stands in the shoes of the practice itself, so that any financial relationship between the practice and another DHS entity is attributed to the individual physician owner.
  - Practical effect is that arrangements (e.g., Hospital > Practice > Physician Owner) that were previously considered potential indirect arrangements could now be considered direct arrangements with the physician owner and would have to meet a direct compensation arrangement exception.

- **Definition of DHS entity (42 C.F.R. 411.351)**
  - Includes entity that performs the DHS (not just entity that submits claim).
  - Practical effect is that under arrangements become problematic. For example, if a hospital contracts with a physician-owned entity to perform a service that the hospital bills for under arrangement, the physician-owned entity could be considered a DHS entity. If the physician owner makes a referral for DHS to the entity, there is potentially no applicable Stark exception (e.g., there is no small investor safe harbor under Stark).
Neuromonitoring – Significant Billing Changes

- **CPT Codes**
  - 95940 - used to report time for one-on-one patient monitoring when the provider is physically present in the operating room.
  - 95941 - for simultaneous monitoring of multiple patients by a single provider in connection with non-Medicare cases in which the monitoring provider is not in the operating room or monitoring more than one case (note that this is not billable to Medicare).
  - G0453 – similar to 95940, but used when IOM is provided outside the operating room (i.e., remotely).
Neuromonitoring – Applicability of Stark

- Inpatient hospital services are DHS

- Physician financial relationship with IOM entity or management company for IOM entity may be problematic under the Stark Law
  - E.g., surgeon owns IOM entity that provides services to hospital and contracts with neurophysiologist for interpretation services
  - E.g., surgeon owns management company that provides services to an IOM entity
Neuromonitoring – Applicability of Stark (cont’d)

Surgeon owns IOM entity that provides services to hospital

- Is the IOM entity the DHS entity? If so, limited exceptions for physician ownership (e.g., in-office ancillary services).
- Is the IOM entity a “physician organization” so that surgeon owner must stand in the shoes (i.e., direct compensation relationship with hospital)?
Indirect Compensation Arrangement Definition (42 C.F.R. § 411.354(c)(2)):

- **Unbroken chain of financial relationships;**
- Referring physician receives aggregate compensation from the person/entity in the chain with which the physician has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS; and
  - If the direct financial relationship is ownership/investment interest, look to nonownership/noninvestment interest closest to the referring physician.
- Entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.
Neuromonitoring – Applicability of Stark (cont’d)

- Indirect Compensation Arrangement Exception (additional requirements for specific types of arrangements, i.e., rental of office space/equipment) (42 C.F.R. § 411.357(p)):
  - The compensation received by the referring physician is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS;
  - The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement; and
  - The compensation arrangement does not violate the federal anti-kickback statute, or any federal or state law or regulation governing billing or claims submission.
Neuromonitoring – Applicability of Stark (cont’d)

Surgeon owns management company that provides services to IOM entity that provides services to hospital

- Payment for IOM services
- Referrals to hospital for DHS
- Ownership in management entity
- Payment for management services
Pathology
Pathology – What is it?

- Definition -- Laboratory examination of samples of body tissue for diagnostic or forensic purposes

- Process (generally)
  - Treating physician performs procedure (often outpatient) to obtain a tissue specimen from a patient
  - Facility labels and transports specimen to lab for processing and analysis
  - Lab processes specimen
  - Pathologist analyzes specimen and generates reports

- Billing (the “Traditional” approach)
  - Treating physician bills pro fee for procedure to obtain the specimen.
  - Facility may bill tech/facility fee related to procedure performed.
  - Commercial Lab bills tech component of processing the specimen.
  - Pathologist (may be employed by and/or owner of commercial lab) bills professional component for analyzing the specimen.
Pathology – What has changed?

Non-pathologist owning a “lab” and being the treating physician who uses such lab for his/her own pathology specimens

- Popular specialties – urology, gastroenterology, dermatology
- “POL” = physician-owned lab, with the physician owner being a specialty other than pathology
- Sometimes the “lab” is not a physical building (and not CLIA-certified), but is simply a corporate entity set up by the specialist separate from his/her medical practice (a “Pass-Through Lab”)
- Specialist may be able to bill for portions of the pathology lab
Pathology – Sample Structures

**Less Concerning**

- ASC
- Specimens obtained at facility
- Transport Own Specimens
- Part Owner and Provides Services
- Gastroenterologist

**More Concerning**

- POL
- Specimens sent by Courier
- Part Owners

- INDEPENDENT PATHOLOGY LAB
  - Work together for processing and analysis
  - Sends Path Specimens for Analysis
  - Part Owners

- SPECIALIST
  - Part Owners

Other Physicians Only Use Independent Lab
Pathology – Why has this become popular?

- **Rationale** - close working relationships between Specialists and Pathologists and understanding each other’s language aids in early detection of illnesses, faster processing times between biopsy and reporting to the patient, and overall improved patient care.

- **Billing (the “Creative” approach)**
  - Specialist prepares the specimen to earn the tech fee, but has an outside pathologist read the specimen and earn the pro fee.
  - Outside lab prepares the specimen and earns the tech fee, then Specialist reads the specimen to earn the pro fee.
  - Specialist performs both the preparation and read of the specimen and collects a global fee.
Pathology – Applicability of Stark

- Are pathology lab services subject to Stark?
  - Clinical Lab Services = DHS, but anatomic pathology exempted from DHS
  - Pathologist = not a referral source
  - Specialist = is a referral source

  - Self-referred pathology services more than doubled from 2004-2010
  - Financial incentives “likely a major factor driving the increase”
  - Recommended CMS analyze the self-referral trend and take action to limit such self-referrals
  - CMS did not implement the GAO’s recommendations (CMS had previously lowered reimbursement for certain CPT codes and felt that was sufficient to deter abuse of self-referred pathology service)

- Conclusion = Stark does not apply to most pathology arrangements...
Pathology – Other Laws and Rules at Issue

- **CMS**
  - Interpretive guidelines for ASCs indicate well-defined contractual agreements should be used
  - If physician has ownership in both the facility and a lab, need to ensure all arrangements with that physician comply with Stark (not just the pathology arrangement)
  - Use caution if lab providing supplies to facility

- **Federal laws**
  - AKS
  - CLIA

- **State law obligations on facility**
  - Utilizing certified lab
  - Protecting patient, specimens, and records
  - Having written agreements with outside labs (not required in Tx)
Pathology – Other Laws and Rules at Issue (cont’d)

- Facility not interfering with a physician’s ability to treat its patient
- Facility’s liability for specimens obtained from patients treated at the facility
  - Negligence – in procuring, labeling, transporting, processing, analyzing
  - Control –
    - Between facility, physician, and insurer, who decides which lab to use for a specific patient or specific specimen?
    - Who was in “control” at the point in the process when an error occurs?
- **Example** – Urologist obtains prostate biopsy specimen from patient at an ASC, then urologist uses his own vehicle to transport specimens to “lab” urologist owns
  - Is ASC liable at any point?
  - How does ASC protect itself?
Pathology – Considerations

- What do state laws and licensure rules require of the ASC?
- Confirm the POL is a CLIA-certified/Medicare-approved lab.
- Inquire as to the structure/ownership of the POL.
- Determine if the POL will be performing preparation, reads, or both, of the specimen, and which components the POL will bill and collect?
- How are specimens collected, labeled, and transported to the POL?
- Decide the extent of engagement ASC wants to have with the POL.
- Ensure ASC takes all of the steps within its control to make its own operations compliant.
- Enter into written agreements with labs (see next slide).
Pathology – Recommendations for Written Agreements

- Describe each parties’ duties and obligations.
- Clearly explain which party is responsible for different phases (e.g., physician obtaining specimen, ASC packaging/labeling, courier transporting, POL preparing the specimen and ensuring ASC receives copy of the report).
- Establish which party will be deemed to be in “control” of the specimen at various phases.
- If the POL is providing supplies to the ASC, document such and specify that such supplies are of low value and integrally related to the services.
- Include indemnification and limitation of liability provisions to protect the ASC from improprieties of the POL.
- Require that POL represent and warrant that it is operating in compliance with all fraud and abuse laws (e.g., specify that POL is not performing any service which would constitute DHS).
- Consider specifically listing which physicians will utilize that particular POL.