Kickback and Stark Law Developments

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Topics

• Stark Law Regulatory Developments
• Anti-Kickback Statute Caselaw Developments
• Recent OIG Enforcement Priorities
• Stark Caselaw Developments

Stark Law Regulatory Developments

• July 15, 2015 CMS Issued Guidance and Proposed Rule Changes
• First Important Published Guidance and Updates from CMS for Hospitals (Not Owned by Physicians) Since 2008
The Stark Law – Basic Terms

• The Prohibitions
  • Unless an exception applies
    — if a physician (or an immediate family member) has a financial relationship with an entity that furnishes designated health services (DHS Entity), the physician is prohibited from making a referral to the DHS Entity for designated health services (DHS)
    — a DHS Entity may not submit a claim or bill any payer for DHS furnished pursuant to a prohibited referral
    — no claim may be paid by Medicare that is for DHS furnished pursuant to a prohibited referral
    — if the claim is paid, the DHS Entity is required to refund the payments

The Stark Law – Basic Terms

• Financial relationships can arise from ownership/investment or compensation arrangements
  — Compensation arrangements arise from any remuneration to or from a physician, subject to certain exceptions
• Financial relationships can be direct or indirect
• The Stark Law has many exceptions, including 24 compensation exceptions
• There are compensation exceptions for:
  • space leases
  • equipment leases
  • employment compensation
  • personal services arrangements
  • physician recruitment incentives and physician retention incentives
  • other common arrangements

The Stark Law – Basic Terms

• Most of the compensation exceptions require that the compensation to the physician be
  — set in advance
  — fair market value
  — not be determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the DHS Entity (“volume/value standard”)
• Generally, the compensation exceptions require that the arrangement
  — be set forth in a writing signed by the parties
  — have a term of at least one year
The Stark Law – Basic Terms

The 10 "designated health services" or "DHS" are:

1. Clinical laboratory services
2. Physical and occupational therapy services
3. Radiology and other imaging services
4. Radiation therapy services and supplies
5. Durable medical equipment and supplies
6. Parenteral and enteral nutrients, equipment and supplies
7. Prosthetics, orthotics, and prosthetic devices and supplies
8. Home health services
9. Outpatient prescription drugs
10. Inpatient and outpatient hospital services

CMS's July 15, 2015 Clarifications and Proposed Amendments

- Extends the 30-day grace period for the signature requirement of various compensation exceptions to a 90-day grace period
  - Clarifies that this is signature grace period, not a signed writing grace period
  - Does not comment on whether a signature must be a person’s handwritten signature

- Extends the six-month holdover provision of various compensation exceptions to an indefinite period of time, provided the terms of the arrangement do not change
  - Requests comments on whether it should specify a time period, e.g. 2 years
  - Must continuously meet all of the requirements of the exception throughout the holdover, including the fair market value standard
CMS’s July 15, 2015 Clarifications and Proposed Amendments

- Changes the word “agreement” to “arrangement” throughout the compensation exceptions to clarify that the required signed writing does not have to be a single formal agreement or contract between the parties
- Confirms that the signed writing can be composed of more than one writing

CMS’s July 15, 2015 Clarifications and Proposed Amendments

- Clarifies how the signed writing requirement applies when direct compensation arrangements arise from the “stand in the shoes” (SITS) rule
  - Does the signed writing requirement apply to all of the physicians’ affiliated physicians?
    - No, only the physicians standing in the shoes of their group practice, and a signature by a duly authorized representative of the group is imputed to all of these physicians

CMS’s July 15, 2015 Clarifications and Proposed Amendments

- Clarifies that the one-year term requirement of certain compensation exceptions does not have to be stated in a formal agreement
- Articulates position that the one-year term requirement is satisfied when there is documentation that an arrangement, in fact, lasted for at least one year
- Note: FMV exception still requires that the term be stated in the writing(s)
CMS’s July 15, 2015 Clarifications and Proposed Amendments

• Responds to the 3rd Circuit’s position in Kosenske that a pain management physician’s use of a hospital’s outpatient facility and staff without compensating the hospital constitutes remuneration to the physician
• CMS: No, only when the hospital and the physician do not split-bill for the professional and facility components of the services would one of the parties have benefited from the resources of the other

CMS’s July 15, 2015 Request for Comments (Due September 8, 2015)

• Makes multiple and detailed requests for comments on a range of topics:
  – Asks whether the Stark Law is interfering with the development of alternative delivery models, and, if so, what Stark amendments CMS should consider
  – Asks whether the Stark Law, most notably its “volume or value” standard, is interfering with gainsharing arrangements, and, if so, what Stark amendments CMS should consider
  – Asks whether, in light of judicial decisions or other developments, CMS needs to provide more guidance on the applicability of the Stark Law to physician compensation models, most notably, more guidance on the fair market value, volume/value and commercial reasonableness standards

AKS Caselaw Developments

• Ameritox v. Millennium Laboratories, (M.D. Fla. 2014)
• Ameritox brought suit opposing provision of free “point of care” specimen cups
  – Millennium handed out 750,000 point of care cups in 2013, worth millions
  – Ameritox brought Lanham Act, Stark, AKS, and unfair competition and tortious interference claims
• Court dismissed Lanham Act claim, but exercised supplemental jurisdiction
• Jury was permitted to conclude that AKS and Stark Law violations supported state law violations
• Court entered $15 million judgment in favor of Ameritox
AKS Caselaw Developments

- *Millennium Laboratories v. Ameritox*, (11th Cir. 2015)
- Eleventh Circuit vacated judgment, finding that there was no basis for federal jurisdiction
  - Purely procedural decision; no analysis of substantive legal claims
- No private right of action under AKS or Stark
- Once Lanham Act claim was dismissed, no basis to exercise supplemental jurisdiction over state law claims
  - No legal basis to conclude that Stark and AKS violations stated state law cause of action
  - Relevant state courts had not considered the issue

AKS Caselaw Developments

The Eleventh Circuit was not impressed:
- “In other words, Ameritox’s attorneys wasted both judicial resources and Ameritox’s money.”
- “Ameritox advanced outlandish legal theories and Millennium went along with it.”
- “Millennium has certainly suffered insofar as it massively wasted resources arguing that it did not violate Stark or AKS when it could have moved to dismiss Ameritox’s various theories for failure to state a claim.”
- “At the end of the day, the attorneys here left their clients with gargantuan legal bills and “a tale/Told by an idiot, full of sound and fury,/Signifying nothing.”

AKS Caselaw Developments

*Ameritox v. Millennium Laboratories* (M.D. Fla.)
- OIG Special Fraud Alert
- Laboratory Payments to Referring Physicians (June 2014)
  - Specimen Collection and Processing
    • Double payment
    • Above-FMV payments
    • Other factors
  - Registry Arrangements
    • Volume
    • Duplicative or unnecessary tests
AKS Caselaw Developments

Fraud Alert Supports Ameritox Argument

• Footnote provides:
The same principles described in this Special Fraud Alert apply to arrangements that are similar or analogous to Specimen Processing Arrangements, including arrangements under which clinical laboratories pay physicians to collect and package patients’ buccal swabs or urine specimens or provide free or below-market point of care urine testing cups to health care providers who use the cups to perform billable in-office testing.

AKS Caselaw Developments

Ameritox Reaction to 11th Circuit Decision

• We initially brought this case in hopes of putting a stop to Millennium Health’s anti-competitive behavior, and in the past year it has become apparent that the Department of Justice is pursuing a $250 million settlement from Millennium Health for similar conduct. At this time, we’re happy to let federal regulators hold Millennium Health accountable.

AKS Caselaw Developments

• United States ex rel. Riedel v. Health Diagnostic Laboratory, Inc., et al., Case No. 1:11-CV-02308 (D.D.C.) (consolidated with two cases from D.S.C.)
• Government investigated “long-standing, industrywide practice” of paying fees to doctors in connection with drawing blood and processing and handling blood samples sent to HDL for testing
• HDL settled for $50 million
• Company filed for Chapter 11 protection in April 2015
AKS Caselaw Developments

• U.S. ex rel. Simmons v. Meridian Surgical Partners, LLC, 11-cv-00439 (M.D. Tenn.)
  - Relator was former manager of ASC
  - Former manager claimed that Meridian bought out doctors’ interest in ASC at inflated value to obtain majority interest
  - Whistleblower alleged that Meridian then offered minority ownership shares in exchange for referrals
  - Case settled for $5.1 million on eve of trial (Sept. 2014)
  - Government did not intervene

AKS Caselaw Developments

  - Relators alleged that DaVita identified providers with patient populations suffering renal disease and offered them lucrative opportunities to partner with DaVita by acquiring and/or selling an interest in dialysis clinics to which their patients would be referred for treatment.
    - DaVita allegedly ensured referrals through a series of secondary agreements with the physicians, including non-compete and non-disparagement agreements that would have prevented the physicians from referring their patients to other dialysis providers.

AKS Caselaw Developments

• U.S. ex rel. Ruscher et al. v. Omnicare Inc. et al., No. 08-cv-03396 (S.D. Tex. 2015)
  - Court granted summary judgment to Omnicare on conspiracy claim for allegedly writing down debt owed by eight skilled nursing facilities in exchange for referrals
    - Court stated that multi-million dollar fraud claims must be supported by more than “a few ambiguous emails”
    - Despite 4 million emails and 25 depositions, no evidence of quid pro quo based on forgiveness of debt
  - Omnicare filed counterclaims against relator for breach of fiduciary duty, breach of implied contract, and misappropriation of trade secrets
AKS Caselaw Developments

• **U.S. ex rel. Kester v. Novartis, No. 11-8196 (SDNY)**
  – Filed in 2011 by former sales manager; pre-trial filing identified potential damages of $3.35 billion
  – Government settled with Accredo and BioScrip
  – Accredo (April 2015; $45 million) – One of three specialty pharmacies permitted to dispense Exjade as part of Novartis’ network. Novartis allegedly distributed undesignated prescription referrals based on performance in marketing activities, including a therapy “adherence” program
  – BioScrip (January 2014; $15 million) – Allegations that BioScrip received rebates and referrals in exchange for participation in refill and promotion campaigns

AKS Caselaw Developments

• **U.S. ex rel. Kester v. Novartis, No. 11-8196 (SDNY)**
  – Filed in 2011 by former sales manager; pre-trial filing identified potential damages of $3.35 billion
  – Myfortic is an immunosuppressant used to prevent organ rejection following transplant surgeries
  – DOJ alleges that Novartis offered kickbacks in the form of “market share rebates” in exchange for commitment to recommend (1) switching patients to Myfortic, and (2) keeping existing patients on Myfortic even when cheaper generics became available

AKS Caselaw Developments

**U.S. ex rel. Kester v. Novartis, No. 11-8196 (SDNY)**

“As alleged, using the lure of kickbacks disguised as rebates, Novartis co-opted the independence of certain pharmacists and turned them into salespeople for one of its drugs. And by allegedly hiding this illegal quid pro quo from physicians, patients, and federal healthcare programs, Novartis caused the public to pay tens of millions of dollars for kickback-tainted drugs that were dispensed by pharmacists who were in cahoots with the company.”

- United States Attorney for the Southern District of New York
AKS Caselaw Developments

  - Whistleblower alleged that Organon paid kickbacks to Omnicare and PharMerica, disguised as market share discounts and rebates, to induce them to promote the switching of patient prescriptions to Organon’s preferred drugs, Remeron Tablet and Remeron SolTab
  - Omnicare argued that the market share discounts and rebates included in the purchasing agreements satisfied the discount safe harbor.
  - The relators argued – as did the government in its SOI – that the discounts and rebates did not satisfy the discount safe harbor because they were contingent on Omnicare’s participation in drug switching programs designed to promote Organon’s drugs.
  - The Court ruled that the price concessions were not protected by the safe harbor because they were allegedly hidden from the Medicaid “Best Price”
    - “And the term ‘discount’ does not embrace collateral kickbacks or reductions in price which are not passed on to Medicaid, as alleged in the [Complaint].”
  - Organon and Omnicare ultimately settled for $31 million

Recent Enforcement Priority

- Physician Practice Building
  - Government has taken the position that joint marketing arrangements may provide improper inducement
    - Physician-led patient seminars
    - Physician referral events
    - Practice assessments
    - Co-branding
    - Cooperative Advertising

Recent Enforcement Priority

- Joint Marketing Between Manufacturers and Providers
  - Government has taken the position that joint marketing arrangements may provide improper inducement
    - Formulary arrangements
    - Marketing funds
    - Volume based discounts, when combined with cooperative marketing
AKS/Stark Caselaw Developments

- U.S. ex rel. Reilly v. North Broward Health Dist., No. 0:10-cv-60590 (S.D. Fla. 2015)
  - Defendant paid $69.5 million to settle whistleblower complaint
  - Example of how NOT to structure physician comp
  - Each of nine physicians received salary in 7 figures
    - Some practices operated at a loss
    - “District lost $150 million between 2004 and 2011
  - “Contribution Margin Report” tracked and rewarded referrals for services such as radiology and PT
    - System penalized physicians for taking on low-paying cases
  - One of the physicians showed the contract to his attorney

AKS/Stark Caselaw Developments

  - Held that Patel’s signed medical necessity certifications were referrals to Grand, a HHA, even though the patient had chosen Grand from a wide selection of HHAs
    - Rationale: By demanding a payment by Grand for the certification, Patel’s medical necessity certification amounted to a referral to Grand; without it, Grand would not get the patient
    - “Without [Patel’s] permission, his patient’s independent choices were meaningless.”
  - Note: This was an anti-kickback case; Patel charged Grand $400 for certifications and $300 for re-certifications of medical necessity
  - Both parties cited the Stark definition of a “referral” as support for their interpretation of “referral” under the AKS
  - Stark issue: Does a “referral” require a referral “to” a DHS entity, or is a “referral” simply an order or request by a physician that could be filled by multiple DHS entities

Stark Caselaw Developments

  - Urologists sued to overturn CMS’s 2008 rule changes that prohibited:
    - Referring physician-owned JVs from selling hospital facility-component services to hospitals (“under arrangements” transactions); and
    - Per unit (or “click”) equipment rentals from referring physician-owned leasing companies
  - Court upheld the prohibition on “under arrangements” transactions with referring physician-owned JVs
  - Court struck down prohibition on “per click” equipment rentals with physician-owned equipment leasing companies
    - Reason: CMS did not address legislative history approving of per unit rentals
  - Will CMS try again? Probably not.
  - OIG can regulate; has not taken position that “per click” equipment rentals are automatically kickback schemes, but there is a anti-kickback risk
Stark Caselaw Developments

  — Case settled for $88M before trial, but court entered important rulings
  on pre-trial motions

• Stark's Applicability to Medicaid
  — Stark's prohibitions do not apply to Medicaid-covered DHS, but there
    is no federal financial participation for DHS claims that would be
    prohibited if covered by Medicaid to the same extent as Medicare
    (SSA, § 1903(g); 42 U.S.C. § 1396a(u))
  — Halifax asked the court to dismiss United States’ Stark claims as
    applied to Medicaid; court denied the motion
  — Rationale: Because the State is not entitled to Medicaid financial
    participation payments for DHS furnished pursuant to a referral that
    would have been prohibited had the DHS been covered by Medicare,
    the DHS Entity has caused the State to submit a false claim to the
    federal government for subsidies when it submits a claim to the State
    for such DHS.


Stark Caselaw Developments

• Stark’s Applicability to Medicaid (cont’d)
  — See also
    • United States ex rel. Parikh v. Citizens Med. Ctr., 2013 WL 5304057,
      at *8 (S.D. Tex. Sept. 20, 2013)
    • United States ex rel. Schubert v. All Children’s Health Sys., No.
      15, 2013)
  — Halifax and Citizens Medical stand for proposition that
    claims for the federal share of Medicaid implicate the Stark
    Law & False Claims Act.
  — Only All Children’s stands for proposition that claims for the
    state share implicate the Florida false claims act
    (without even violating the Florida self-referral law)

Stark Caselaw Developments

Halifax (cont’d)

• Stark and Employment Productivity Bonuses
  — Stark employment exception prohibits compensation
    that is determined in a manner that takes the
    volume/value of referrals into account, except
    productivity bonuses for personally performed
    services (Productivity Bonus Exception)
  — In Halifax, oncologists could earn bonuses in the form
    of a share of a bonus pool funded by the hospital’s
    outpatient cancer services
      • the size of the pool varied with the oncologists’ referrals
        for outpatient cancer services, but each oncologist’s share of
        the pool was based on his personal clinical productivity
        relative to the clinical productivity of the other oncologists
Stark Caselaw Developments

Halifax (cont’d)

• Stark and Employment Productivity Bonuses
  - United States moved for summary judgment that Halifax’s compensation to oncologists failed the volume/value element of the Stark employment exception, and was not saved by the Productivity Bonus Exception
  - Court agreed, holding that the Productivity Bonus Exception permits a physician to receive a bonus that takes into account the volume/value of the physician’s referrals for DHS that are personally performed by the physician:
    - the hospital outpatient cancer services referred by the oncologists and funding the pool were not personally performed by the oncologist

Stark Caselaw Developments

  - Two federal court jury trials, two 4th Circuit appeals
  - 4th Circuit upholds $237M judgment against Tuomey
  - Tuomey appealed, raising
    • Volume/value issue
    • Scienter issue
    • Jury instructions issue
    • Size of the award unconstitutional - Eighth Amendment (Excessive Fines) and Fifth Amendment (Due Process)
  - Tuomey lost its appeal

Stark Caselaw Developments

• Tuomey (cont’d)
  - Tuomey had bad facts, but court’s analysis raises concerns
  - 4th Circuit handling of the volume/value issue means a hospital can’t pay even an employed surgeon a percentage of the physician’s professional collections if the surgeries are performed in the hospital-employer’s facilities
    • Court did not recognize the true nature of Tuomey’s volume/value problem; this absurd outcome was avoidable
Stark Caselaw Developments

• Tuomey (cont’d)
  – Tuomey’s guilt/innocence turned on whether it knew or should have known that its compensation to the surgeons varied with or took into account the volume/value of referrals
  – Court held Tuomey had requisite scienter because of one attorney’s negative opinion even though that attorney did not comment on the volume/value issue
    • Court should have focused on what Tuomey knew or should have known about whether the compensation offended the volume/value standard

• Tuomey (cont’d)
  – 4th Circuit’s constitutional analysis turned on a finding that the Tuomey’s conduct was “reprehensible,” claiming payment from Medicare for services that Congress deemed to be medically unnecessary and “worthless”
    • Nothing in the Congressional Record supports the notion that Congress thought that services furnished to Medicare beneficiaries per Stark-prohibited referrals were worthless and medically unnecessary
    • CMS commentary indicates CMS does NOT take the position that services furnished to Medicare beneficiaries per Stark-prohibited referrals are medically unnecessary

Stark Caselaw Developments

• Key lessons from Tuomey
  – Stark/FCA cases involve dangerously high financial liability, perhaps too dangerous to litigate unless settlement demand would put hospital out of business
  – Even a simple refund of Stark-based Medicare overpayments can be Draconian
    • Err on the conservative side; or
    • Get CMS advisory opinion (but note CMS will not opine on FMV)
  – Assure that all attorneys consulted get all the relevant facts, including the opinions and fact-finding of other attorneys
  – Fully account for and address, in writing, negative opinions of counsel that are not being followed (jury and court thought Tuomey too dismissive of one attorney’s negative opinion)
  – Fully inform the Board or applicable committee of all points of view on an important legal issue raised by a transaction brought to them