Anti-Kickback and Stark Law Developments
Healthcare Enforcement Compliance Institute
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Anti-Kickback Statute

• Prohibits the knowing and willful
  – Offer or payment
  – Solicitation or receipt
  – Of remuneration
• In return for referring a federal health program patient or
• To induce the purchasing, leasing or arranging for, or recommending the purchasing or leasing
• Of items or services paid in whole or in part by a federal health care program

AKS Safe Harbors

• Statutory: discounts, employment, GPOs, certain copay waivers, certain managed care
• Numerous regulatory safe harbors
• Strict compliance with a SH “immunizes” the activity from the AKS.
Criminal AKS

- Warner Chilcott subsidiary
- Warner Chilcott individuals
- Olympus Corporation of the Americas
- Tenet/Clinica de la Mama
- Michael Rheinstein

Warner Chilcott

- Subsidiary of WC pled guilty to felony health care fraud and paid $125 million to settle criminal and civil charges arising from drug marketing programs
- Between 2009 and 2013, WC alleged to have directed employees to pay remuneration to physicians to induce them to prescribe WC drugs
- Payments consisted of meals and other remuneration for “medical education events” that often contained minimal or no education component
U.S. v. W. Carl Reichel

• Reichel was former president of WC subsidiary
• U.S. indicted Reichel for conspiracy to violate the AKS
• Reichel alleged to
  – Have established the sales strategy of free dinners
  – Sales people encouraged to take physicians out 2x week w/ $150 limit per person
  – Med education dinner speakers got $600-$1200 but for roundtables w/ no fixed presentation
  – Spouses welcome
• Reichel acquitted

U.S. v. W. Carl Reichel

• Court’s jury instruction on inducement:
  [i]n order to be a relevant inducement the remuneration must involve an intent to execute a quid pro quo transaction. A defendant cannot be convicted of violating the [AKS] merely because he sought to cultivate a business relationship or create a reservoir of goodwill that might ultimately affect one or more purchase or order decisions. ...However, a defendant may act with a mixture of motives and the Government’s burden is to prove that part of the remuneration is intended to compensate for past orders and/or induce future orders; but it is not required to prove that such compensation was the only reason for the remuneration.
U.S. v. W. Carl Reichel

- Jury instruction on “good faith”
  Since an essential element of the offense is that it be undertaken “knowingly” and “willfully,” it follows that good faith on the part of the defendant is a complete defense. ... The government has to prove intent, and that means overcoming any reasonable doubt regarding the defendant’s good faith. That is to say, however intentional the conduct may have been, the law is not violated if the defendant acted in good faith and held an honest belief that his actions were proper and not in furtherance of some illegal venture. The defendant has no burden to prove the defense of good faith. The burden is on the government to prove criminal intent and, consequently, to prove lack of good faith.

Other WC Individuals

- Rita Luthra, MD indicted for violation AKS by taking $23,500 in meals and speaker fees from WC
- Two former Warner Chilcott district managers, Jeffrey Podolsky and Timothy Garcia previously pled guilty to charges including conspiracy to commit health care fraud and violations of the Health Insurance Portability and Accountability Act (HIPAA).
- A third former district manager, Landon Eckles was criminally charged for alleged HIPAA violations relating to an alleged prior authorization scheme
U.S. v. Olympus Corp of the Americas

- OCA entered into deferred prosecution agreement paid criminal penalty of $312.4 million
- OCA entered civil FCA settlement of $310.8 million
  - Whistleblower was new compliance officer
- Criminal complaint charged that OCA won new business and rewarded sales by giving doctors and hospitals kickbacks, including consulting payments, foreign travel, lavish meals, millions of dollars in grants, and free endoscopes.
- OCA agreed the charges were true
- Unclear if any individuals will face prosecution

Tenet/Clinica de la Mama

- Tenet announced settlement of criminal and civil actions
  - Non-prosecution agreement
  - $146 million criminal penalty
  - $368 million civil settlement
- Allegations were that four Tenet hospitals in GA and SC paid kickbacks to obstetrics clinics and related entities known as Hispanic Medical Management d/b/a Clinica de la Mama (HMM) for referrals of patients, primarily undocumented women, for labor and delivery at the hospitals, which then billed Medicaid
- Two non-operating subs entered the plea
Michael J. Reinstein

- A Chicago psychiatrist pled guilty to AKS and sentenced to 9 months in prison and forfeited $592,000.
- Reinstein was alleged to have received approximately $600,000 in “consulting fees” and “entertainment expenses” in exchange for prescribing the anti-psychotic medication Clozapine to thousands of elderly and indigent patients in nursing homes and hospitals.
- He also settled a civil case with the US and Illinois for $3.8 million.

Biodiagnostic Laboratory Services

- BLS pled guilty to violation of AKS and the Travel Act in USDC NJ
- Straight forward payments for referrals scheme (blood draw payments, sham leases, consulting)
- Government has so far obtained over 40 guilty pleas, including 27 physicians
- More pleas are likely
AKS Civil FCA Case Trends

• Many more civil FCA cases based on alleged AKS violations
• Several of big criminal cases discovered through qui tams (Olympus, Tenet)
• More cases going forward even if DOJ declines
• Cases seem to be eroding safe harbors
• Courts skeptical of OIG guidance as law
• Unlike Stark, AKS cases are not easy cases to prove up

Pharma Continues To Be In Bullseye

• New wave of cases focus on three areas
  – Physician relationships (dining, consulting)
  – Discounts based on formulary compliance initiatives
  – Market share discounts generally
• Very disturbing judicial interpretations of the discount safe harbor
Pharma - Physician Relationships

  - $312 million
  - Giving key customers "permanent loans" of medical equipment at the request of Olympus sales and marketing personnel
  - Giving consulting contracts of up to $100,000 a year to certain "VIP" doctors at the discretion of Olympus sales and marketing representatives
  - Annual "grants" to fund educational or research programs made by a grant committee comprised solely of Olympus sales and marketing personnel
  - Funding luxury, all-expense paid vacations to Japan and other international destinations for "VIP" doctors and sometimes their spouses in exchange for purchases and promotion of Olympus medical products

Pharma - Physician Relationships

  - $102 million
  - Chilcott employees, at the direction of company management, provided payments, meals and other remuneration associated with so-called “Medical Education Events,” which included dinners, lunches and receptions.
  - Case also contained fraudulent prior authorization allegations
Pharma - Physician Relationships

- U.S. ex rel. Peikin v. Salix Pharmaceuticals, 12 Civ. 3870 (SDNY) and others
  - Salix paid $54 million and admitted the following
  - Speaker programs were an important part of Salix's selling strategy, with approximately 10,000 speaker programs conducted during that time.
  - Speaker payments ranged from $250 (for a doctor available on call to answer questions associated with a pre-recorded program) to $4,500 (for a doctor who spoke at an in-person program and had a specified level of experience and certain credentials).
  - Salix paid over 500 individual physicians such honoraria with dozens of physicians earning over $50,000, and several even earning over $100,000.

Salix Pharmaceuticals (cont’d)

- Salix employees held speaker programs that were primarily social in nature or did not otherwise comply with the company's internal policies.
- With respect to pre-recorded speaker programs, there were numerous instances where either: the Salix sales representative did not play the pre-recorded presentation; the Salix sales representative played the pre-recorded presentation but placed the laptop or other viewing device in a location where it could not easily be seen (or at a volume where it could not readily be heard); and/or the designated approved speaker was not called at the end of the pre-recorded presentation, but still received their honorarium payment.
Pharma - Physician Relationships

  – Ct. denied motion to dismiss AKS violations
  – Allegations that Medtronic hosted iPro clinics in physicians’ offices to fit patients with insulin pumps w/out physician involvement (services the physicians would otherwise have had to pay for), and
  – Medtronic paid above FMV for staff services

  – Ct. granted Pfizer summary judgement on off label mktg and AKS allegations.
  – AKS allegations involved a “sham speaker” program
  – “the record shows that the fees [paid to the physician speakers] were objectively calculated to provide fair market value,”
  – The court found it “unremarkable” that Pfizer tracked its return on investment from the series; “as a for-profit company, this is to be expected.” The court noted that while Pfizer tracked prescriptions written by attendees, the company didn’t track prescriptions written by speakers.

• See also, United States ex rel. King v. Solvay SA, No. H-06-2662 (S.D. Tex.)
• Recent SDNY investigation into Novartis physician speaker programs
Pharma Discount Cases

• Over last few years, DOJ has intervened and settled a number of FCA cases alleging that Pharma paid kickbacks to institutional pharmacies (Omicare, Pharmerica)
• Alleged kickbacks consisted of discounts on formulary preferred drugs for the pharmacies’ efforts to promote customer compliance
• Govt position is that discounts to buyers conditioned on their promotion of products to their buyers is not a discount
  – Ignores AO 98-2
  – Ignores exclusive contracts and similar arrangements
  – Ignores the text of the discount safe harbor which say only that a discount is “a reduction in the price of the product”

Representative Pharma Discount Cases

• United States ex rel. Richard Templin and James Banigan et al v. Organon USA Inc. et al., 1:07-cv-12153, (D. Mass)
• United States ex rel. Spetter v. Abbott Labs., et al., Case No. 10-cv-00006 (W.D. Va.)
• United States ex rel. McCoyd v. Abbott Labs., et al., Case No. 07-cv-00081 (W.D. Va.)
Pharma Discount Cases

• Relators are now pursuing declined cases alleging that market share discounts violate AKS and do not qualify for the discount safe harbor

• United States ex rel. Richard Templin and James Banigan et al v. Organon USA Inc. et al., 1:07-cv-12153(Dt. MA)
  – Judge denied Omnicare motion for summary judgment
  – Court held that discount safe harbor for charge based providers was only available IF THE GOVT HAD ACTUALLY ASKED FOR DISCOUNT INFORMATION AND BUYER HAD PROVIDED IT

• In other words, no one qualifies!!

The Relevant Language

“remuneration” does not include a discount ... as long as the buyer complies with the [following] standards

If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs ..., the buyer must comply with both of the following standards—

(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and

(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information [regarding the purchase price] provided by the seller ...
Next Pharma Targets?

• Patient assistance programs?
• Feds reported to have issued subpoenas to Giliead, Jazz Pharmaceuticals, and Biogen
• OIG spent much of last year, terminating and modifying numerous advisory opinions related to PAPs.

Other Cases of Note

• US ex rel. everybody v. Millennium ($ 256 million)(various false claims as well as free pee cups)
Other Cases of Note

- United States and State of Georgia ex rel. Adam Nauss v. Sweet Dreams Nurse Anesthesia, 5:14-CV-330 (M.D. GA) ($1 million) (free anesthesia drugs to ASCs)
- Swapping cases for ambulance services
- FL Anesthesia Society filed qui tam against several FL ASCs alleging ASC’s hiring of CRNAs violates AKS

OIG Developments

- New safe harbors pending at OMB
- No significant advisory opinions
  - Most revising old Patient Assistance Program opinions
  - Others on waiving inpatient copays in networks
- No significant new guidance
- Continued emphasis on affirmative CMP cases
Stark Law Developments

- 2016 Regulatory Amendments - Highlights
- Tuomey’s Legacy
- Stark/FCA Case Trends
- Stark Reform Developments

The Stark Law’s 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)
  - the DHS Entity is prohibited from submitting a claim or bill to any payor 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 prohibited from retaining the payments
The Stark Law & Financial Relationships

• 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
• Physician-owners of a practice are deemed to “stand in the shoes” of the practice, and non-owner physicians can elect to “stand in the shoes”
  – The practice is no longer an intervening entity
  – Compensation to the practice is deemed compensation to each physician standing in the shoes of the practice

The Stark Law’s Exceptions

• 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 and
  • other common arrangements
The Stark Law’s Exceptions

• 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”)
  – pursuant to a commercially reasonable arrangement

The Stark Law’s Exceptions

• Except for the employment exception, the compensation exceptions generally require that the arrangement
  – Be set forth in a writing signed by the parties before the arrangement commences
  – Have a duration of one year
  – Not change the compensation terms more frequently than once/year
The Stark Law’s DHS

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

2016 Stark Regulatory Amendments – Highlights

• Most significant revisions to the Stark regulations since 2008
• Generally, the amendments were effective

January 1, 2016

• Note: Certain amendments are “clarifications” of CMS’s interpretation of existing regulations; have retroactive effect
2016 Stark Regulatory Amendments - Highlights

• Changed the word “agreement” to “arrangement” in most of the compensation exceptions to clarify that the required signed writing does not have to be a single formal *agreement* or *contract* between the parties
  – Even where “written agreement” was retained, CMS does not interpret to require a single formal contract

• Confirms that the signed writing can be composed of more than one writing

• “Clarification” has retroactive effect

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2016 Stark Regulatory Amendments - Highlights

• “[T]here is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract. . . . a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing. “
2016 Stark Regulatory Amendments - Highlights

• Examples of individual documents that could be considered as part of a collection of documents satisfying the writing requirement:
  – Board meeting minutes authorizing payments for specified services
  – Written (including electronic) communication between the parties
  – Fee schedules for specific services
  – Check requests or invoices identifying items/services provided
  – Time sheets
  – Accounts payable data

2016 Stark Regulatory Amendments - Highlights

• Signatures must be on one or more of the contemporaneously prepared writings
  – Need not evidence intent to enter into an agreement or contract
  – “Clarification” has retroactive effect

• No guidance on what constitutes a “signature,”
  – Note that electronic communications can satisfy writing requirement
2016 Stark Regulatory Amendments - Highlights

- Increased the 30-day grace period for obtaining signatures to a 90-day grace period
  - Regardless of the reason for late signature
  - Clarifies that this is a signature grace period, not a signed writing grace period
- Signed writing requirement applies to all physicians “standing in the shoes” of practice
  - Can be satisfied by signature of duly authorized representative
- Can only be used once/3 years with same physician

2016 Stark Regulatory Amendments - Highlights

- One-year term requirement changed to one-year duration requirement
  - Amendments clarify that a signed writing does not need to state a term length, except the FMV exception still requires a stated term
  - Even “one year duration” requirement is misleading - requires a duration of one year, but early termination permitted so long as the parties wait until the anniversary of the arrangement to enter into new arrangement for the same or substantially similar services/items
  - One-year term requirement really a restriction on more than one arrangement for the same or substantially the same services/items in a year
2016 Stark Regulatory Amendments - Highlights

- If writing has a stated term length, the writing expires with the term; can use the holdover provisions for the space rental, equipment rental and personal services exceptions
- Increases the six-month holdover provision of space rental, equipment rental and personal services exceptions to an indefinite period of time, provided the terms of the arrangement do not change
  - Must continuously meet all of the requirements of the exception throughout the holdover other than the signed writing requirement, including the fair market value standard

Non-Physician Practitioner (NPP) Recruitment Assistance Exception

- What assistance can be provided?
  - Up to 50% of the NPPs salary, signing bonus and benefits
- Limitations on assistance
  - NP’s compensation and benefits must be fair market value
  - Assistance cannot be conditioned on referrals by practice or NPP
  - Dollar amount of assistance cannot take into account the volume or value of referrals by the practice or the NPP
  - Assistance can only be for up to 2 consecutive years
  - Assistance can only be provided to a practice once/3 years
Non-Physician Practitioner (NPP) Recruitment Assistance Exception

- Who can provide the assistance?
  - Hospitals, federally-qualified health centers and rural health centers (qualifying facilities)

- Which NPPs?
  - Nurse practitioners, physician assistants, clinical nurse specialists, nurse-midwives, clinical social workers and clinical psychologists (NPPs)
  - NPPs cannot have practiced, or been engaged by a practice located, in the geographic area served by the qualifying facility

- For what services?
  - Primary care and mental health services (at least 75% of the NPP’s services)

Timeshare Arrangements Exception

- Conveying the right to use premises, equipment, personnel, items, supplies or services on a limited or as-needed basis

- Does not preclude historical reliance on the space lease, equipment lease and FMV exceptions

- Benefit: Does not require exclusive use and control over non-common space
Timeshare Arrangements Exception

• Requirements:
  – By and between a hospital, physician organization and/or physician (with limitations)
  – Cannot confer “possessory leasehold interest” in space (for that, use space lease exception)
  – Equipment and other items and services must be used on same schedule as the use of space
  – Space and items must be used *predominantly* for evaluation and management (E/M) services
    • “Predominantly” not defined
  – Any DHS must be incidental to E/M services and furnished at the same office visit
  – Equipment must be located in the same building, and cannot be advanced imaging equipment or radiation therapy equipment, or used for clinical or pathology services (except CLIA-waived tests)

Tuomey’s Legacy

• Proof of intent for the compensation to take into account the volume or value of referrals is not enough to prove that the compensation took into account the volume or value of referrals
  – Following *Villafane v. Solinger*, key to preserving any semblance of a “bright-line” “volume or value” standard
Tuomey’s Legacy

• *Tuomey*’s “bad facts” are easily distinguishable from common productivity compensation to surgeons
  – Tuomey’s compensation to the surgeons for personally-performed surgeries was *conditioned on* the docs referring their *private practice patients* to Tuomey for the surgeries instead of a competitive ASC
  – But *Tuomey* has caused concern because the 4th Circuit’s reasoning was that just the correlation *alone* between a surgeon’s productivity compensation for personally performed services and the surgeon’s orders for the hospital operating room services was a “volume or value” problem, *apart from* whether the physician’s compensation was contingent on referrals *to Tuomey*

Tuomey’s Legacy (cont’d)

• *Tuomey* jury instructions and appellate decision support an argument that the Stark employment exception applies to an indirect compensation arrangement
  – Clear CMS guidance to the contrary
Stark/FCA Case Trends

- *Qui tam* (whistleblower) cases brought by physicians
  - E.g., Tuomey, North Broward Health Dist., Lexington Medical
- Physicians being held liable
  - E.g. Columbus Regional (Doc pays $425,000 to settle)
- Allegations that compensation to a physician that exceeds receipts from the physician’s personally-performed services net of costs (including the physician’s salary and benefits), by definition or default
  - is not fair market value; and/or
  - takes into account the volume/value of referrals; and/or
  - is commercially unreasonable
  - E.g., Halifax, Tuomey, North Broward, Schaengold, Columbus Regional & Adventist Health System
- Violations of the Stark law result in liability to State Medicaid programs
  - Halifax, Citizen’s Medical, All Children’s

Stark Reform Developments

- On June 30, 2016, the US Senate Committee on Finance (Committee) released a white paper titled *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models*
- Addressed suggestions for Stark law reform
- Summarizes comments and recommendations gathered during a roundtable discussion held by the Senate Finance Committee and the US House Committee on Ways and Means in December 2015, as well as written comments submitted by roundtable participants and other stakeholders
Stark Reform Developments

• Why now?
  – Intended to be a “bright-line” Medicare billing and payment rule, the Stark law has evolved into a byzantine and obscure law
  – Concerns that the Stark law is having the unintended consequences of chilling health care delivery and payment innovation, notwithstanding the regulatory waivers issued by CMS
    • Uncertain status of “gainsharing” and other hospital-physician alignment structures under the Stark law
  – The threat of draconian FCA liability for losing good faith disputes over vague and/or ambiguous standards such as “fair market value,” “volume or value of referrals” and “commercial reasonableness,” leaves defendants with little choice but to settle cases at extraordinary dollar amounts

Stark Reform Developments

Senate Finance Committee Chairman Senator Orrin Hatch:
“[T]he health care industry has changed significantly since Stark was first implemented, and while the original goals of the Stark law were appropriate, today it is presenting a real burden for hospitals and doctors trying to find new ways to provide high quality care while reducing costs as they work to implement recent health care reforms. . . [T]he paper reflects critical feedback from the stakeholder community on the law’s ambiguities, its unintended consequences and the need for reform, and I am hopeful it jumpstarts the discussion on how Congress can modernize the law to make it work for patients, providers, and taxpayers.”
Q&A

Thank you!