Anti-kickback and Stark Law Developments

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Anti-kickback Guidance Update

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Heather Westphal

Anti-kickback Statute (AKS)

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b))

Criminal penalties for individuals or entities that:

- knowingly and willfully
- offer, pay, solicit, or receive remuneration
- to induce or reward the referral of business reimbursable under Federal health care programs.

Safe Harbors:

- payment or business practices that potentially implicate the AKS, but are not treated as offenses.

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New Safe Harbors
(December 7, 2016)

Section	Brief Summary
1001.952(f)	Technical correction to the referral services safe harbor.
1001.952(k)(3)	Interprets statutory exception to the anti-kickback statute permitting pharmacies to waive cost-sharing based on financial need or failure to collect.
1001.952(k)(4)	Protects certain waivers or reductions of cost-sharing by ambulance providers or suppliers owned and operated by a State or a political subdivision of a state.
1001.952(z)	Protects remuneration between a federally qualified health center (FQHC) and a Medicare Advantage organization pursuant to an agreement related to payment for certain FQHC services.
1001.952(aa)	Protects discounts on the price of certain drugs furnished in connection with the Medicare Coverage Gap Discount Program.
1001.952(bb)	Protects free or discounted local transportation services provided to Federal health care program beneficiaries.

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Local Transportation Safe Harbor

Protects from AKS sanctions free or discounted local transportation by Eligible Entities to established patients to obtain medically necessary items or services.

- **Local**: within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area
- **Eligible Entity:** any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items
- **Established patient:** a person who has selected and initiated contact to schedule an appointment with a provider or supplier to schedule an appointment, or who previously has attended an appointment with the provider or supplier

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Local Transportation (cont.)

Some Other Key Requirements:

- No luxury, air, or ambulance
- Uniform policy unrelated to referrals
- No marketing
- Separate protection for "shuttle service" with some requirements the same (e.g., still must be local) but others different (e.g., no "established patient" requirement)

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Advisory Opinions

OIG Advisory Opinion No. 16-10:

- Transportation program sponsored by two local healthcare districts to help get patients to a hospital or clinic in one of the districts
- Jointly hired a transportation coordinator and provided financial assistance for low-income patients to secure certain forms of public transportation

OIG Advisory Opinion No. 16-02:

- A state academic medical center (Hospital) that operates regional clinics that provide prenatal care for primarily low-income women to offer aid to qualified patients in the form of mileage reimbursement or fare reimbursement for public transportation to deliver at the Hospital
- Arrangement also had a lodging and meals component that could be included for patients with a physician's order justifying the stay (generally high-risk pregnancy)

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Alert: Improper Arrangements and Conduct Involving Home Health Agencies and Physicians

(June 22, 2016)

- Cautionary alert to home health agencies (HHAs) and physicians who refer to them about direct or indirect payments for referrals
- Must ensure arrangements and the payments under compensation arrangements between HHAs and physicians are fair market value and commercially reasonable in the absence of Federal health care program referrals

https://oig.hhs.gov/compliance/alerts/guidance/HHA_%20Alert2016.pdf

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OIG Self-Disclosure Protocol

- Benchmark 1.5 multiplier
  - Claims Calculation
    - All claims or statistical sample of 100 claims minimum
    - Use point estimate (not lower bound)
  - Excluded persons – salary and benefits-based
  - AKS – remuneration-based
- Presumption of no CIA
- Six-year statute of limitations
- Tolling of the 60-day period after submission
- Does not secure FCA release, but can help limit exposure
- More predictable process, but DOJ may become involved

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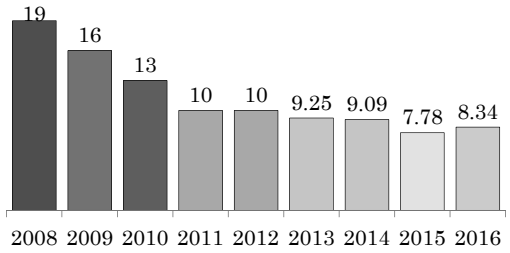
OIG Self-Disclosure Protocol: Average Time in Protocol (in months)



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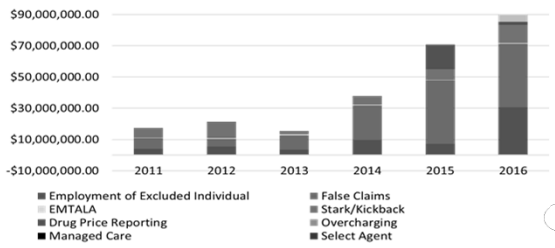
OIG CMP Recoveries



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Anti-kickback Enforcement Update

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Significant AKS Settlements

- 12/15/16: Forest Laboratories LLC
  - $38 M civil FCA settlement for kickbacks in the form of payments and meals to referring physicians related to speaker programs in exchange for prescriptions of drugs
- 12/2/16: Vitas Health Corporation Midwest
  - $200K civil FCA settlement for kickbacks in the form of contributions to cancer charity established by referring physician in exchange for hospice referrals; referring physician pled guilty and sentenced to 45 years
- 10/3/16: Tenet
  - $513M criminal and civil FCA settlement for kickbacks in the form of payments for various services to owners and operators of prenatal care clinics serving primarily undocumented Hispanic women in return for the referral of labor and delivery medical services at Tenet hospitals paid for by Medicaid; two individual pleas; one additional hospital executive recently indicted

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Significant AKS Settlements

- 3/23/16: Respironics
  - $34.8M civil FCA settlement for kickbacks in the form of free call center services to DME suppliers that bought its masks for patients with sleep apnea
- 3/1/16: Olympus Corp
  - $623.2M criminal and civil FCA settlement for kickbacks in the form of consulting payments, foreign travel, lavish meals, millions of dollars in grants and free endoscopes to physicians and hospitals

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AKS Focus on Individuals

- In recent years, DOJ has prosecuted or settled with a number of executives of healthcare companies in AKS matters:
  - W. Carl Reichel of Warner Chilcott
  - David Bostwick of Botswick Laboratories
  - Edward Novak, along with two other executives of Sacred Heart Hospital

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AKS Arrangements Under Scrutiny

- Joint Ventures
- Discounts
- Swapping
- Call Coverage
- Co-marketing/Practice Support
- Speaker Payments
- Grants
- Entertainment

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AKS: Are the Stakes Getting Higher?

- Increased public access to manufacturer payments to referral sources through Sunshine Act data
- Increasing involvement by Criminal Division
- Increasing focus on individuals
- More non-intervened civil FCA cases pursued by Relators
- More significant collateral consequences
  - Exclusion
  - Enhanced Corporate Integrity Agreement Provisions
  - Monitorships (OIG and DOJ)

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Stark Regulations Update

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New Stark Regulations: Key Changes
(October 30, 2015)

- Leniency on "written agreement" and "one-year term" requirements
- New exception for recruitment of mid-level clinicians
- New exception for timeshare arrangements
- Extensions on permitted "holdover" arrangements
- More latitude on missing signatures

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How The Stark Rules Have Changed – Written Agreement/Term

- Depending on the facts and circumstances, a collection of documents, e.g., e-mails, drafts, invoices, cancelled checks, timesheets, etc. can constitute a "written agreement"
- The "one-year term" requirement can be satisfied if the arrangement lasted one year, even if the written agreement does not specify a term
- These are both "clarifications" of existing law, meaning that they apply retroactively too

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How The Stark Rules Have Changed – Recruiting Mid-Levels

- Previously, there was just a "physician" recruitment exception
- Now, hospitals (and FQHC/RHC) can recruit mid-levels to provide primary care or mental health services to a physician's practice
- Covers PAs, NPs, clinical nurse, specialists, certified nurse, midwives, LCSWs and psychologists
- Up to 50% of compensation, once every 3 years (and other restrictions apply)
- What about 501(c)(3) hospitals?
- Effective as of January 1, 2016

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How The Stark Rules Have Changed – Timeshare Arrangements

- Protects certain "timeshare" arrangements (not leases, which are subject to a different exception) between hospital or physician organization and a physician or medical group
- Space, equipment and other items are predominantly for evaluation and management (E/M) visits
- Any equipment is in the same building as E/M visits and used for diagnostic imaging only if incidental to E/M visit, and not used advanced imaging, radiation therapy or clinical laboratory services (other than CLIA-waived tests)
- Could this be used in hospital-licensed or provider-based space?
- Effective as of January 1, 2016

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How The Stark Rules Have Changed – Holdovers

- The old rule allowed expired leases and personal services arrangements to continue after expiration on the same terms for up to 6 months, if exception otherwise satisfied
- Their new rule extends the 6 months to an unlimited period of time
- But, beware of fair market value issues and changes in services and/or compensation
- Effective as of January 1, 2016

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How The Stark Rules Have Changed – Signatures

- The old rule allowed arrangements where only a signature was missing, for up to 90 days if inadvertent and 30 days if advertent
- Now, all arrangements are allowed, when only a signature is missing, for up to 90 days
- This grace period is still limited to once per physician every 3 years
- Effective as of January 1, 2016

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Recent Cases and Settlements

How Should Compliance / Legal Respond?

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U.S. v. Bradford Regional Medical Center

- Two cardiologists, a hospital and an imaging camera
- The carrot, the stick and the carrot
- The $6,545/month sublease
- The non-compete
- What did we learn?

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U.S. v. Tuomey Healthcare System

- A hospital and its 18 part-time physician employees
- When is compensation fair market value?
- When does compensation take referrals into account?
- What is the moral of the story?

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U.S. v. Halifax

- Two Big Issues: Oncologists' Bonus Pool Included DHS and neurosurgeons compensation was "off the charts"
- What is the U.S. DOJ saying about physician compensation?
- "Given that each neurosurgeon was paid total compensation that exceeded the collections received for neurosurgical physician services, Defendants could not reasonably have concluded that the compensation arrangements in those contracts were fair market value for the neurosurgical services or were commercially reasonable."
- What does this mean?
- What are the lessons?

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Losses on Physician Services – OK?

- DOJ asserts that paying physicians more than the professional collections they generate exceeds FMV, is not commercially reasonable, and takes referrals into account.
- But, there is no requirement that providing physician services must be profitable:
  - If compensation is FMV and is not adjusted for referrals, it should satisfy the Stark Law
  - Some service lines have unprofitable payor mixes or low demand
  - CMS recognizes legitimacy of subsidizing physician compensation, *e.g.* in the Emergency Department
  - Likewise, call coverage and hospitalist services often require subsidies

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Stark Self-Disclosure

When, Why, How, What?

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Stark Law Self-Disclosure Protocol

- Should be used for "Stark only" self-disclosure
- Tolls the 60-day repayment obligation, but doesn't permit payment with the self-disclosure!
- Requires detailed submission, including:
  - facts and circumstances of violation
  - legal analysis of why it doesn't comply
  - calculation of financial damages
- What types of compromise might be available?

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Alternatives to Stark SRDP

- Report and Repay (in full) to Medicare Administrative Contractor (MAC)
- Use OIG Self-Disclosure (if colorable AKS violation)
- Others?
  - AUSA
  - DOJ
- Self-remedy?

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Case Studies On SRDP

- How did we decide there was a Stark violation?
- How did we decide there was no colorable AKS violation?
- Did the physician join the self-disclosure?

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Case Studies On SRDP (Cont'd)

- What is the settlement timeline?
- What is the settlement process?
  - Offer amount
  - Negotiable?
  - Timing?
  - Financial Distress?

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Compliance Tips

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Compliance Tips

- Contract management system, including database for tracking contracts, policies & procedures for entering into, renewing and monitoring contracts, etc.
- Maintain written agreements, signed by parties, and make sure they remain current (consider use of "evergreen" provisions and ways to ensure compensation remains fair market value and set in advance)
- Document the basis for determining FMV at the start of contract term
- Document services performed contemporaneously throughout term

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Compliance Tips (cont.)

- Document the reasons for the arrangement, especially if losses are anticipated (pre-transaction document)
- Assess potential consequences (cause and effect) and develop mitigation strategy, if applicable
- Document when you say "no" to physician compensation/deals
- Don't forget to check on physician ownership of vendors/suppliers!
- Don't forget that a physician's "immediate family members" financial relationships are attributed to the physician!

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The Trump Administration:
How Will It Impact Kickback and Stark Laws?

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Questions & Answers

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