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Anti-Kickback Statute Compliance in Healthcare Transactions

Navigating Safe Harbors, Identifying Transactions That Implicate AKS, Limiting Civil Monetary Penalty Exposure

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Anti-Kickback Statute Compliance in Health Care Transactions

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Understanding the AKS

Anti-Kickback Statute, Section 1128B(b) of SS Act, 42 USC 1320a7-b(b)

- Criminal statute - requires intent of an illegal inducement
  - DOJ, not OIG, is responsible for prosecutions
  - Government must prove guilt beyond a reasonable doubt
  - “Specific Intent” (intent to violate the AKS) is NOT required
- Prohibits the knowing and willful offer, solicitation, payment or receipt of anything of value that is intended to induce the referral of an individual for which a service may be made by Medicare and Medicaid or certain other federal and state healthcare programs or to induce the ordering, purchasing, leasing or arranging for, or recommending the purchase, lease or order of, any service or item for which payment may be made by such federal healthcare programs (collectively referred to as an illegal inducement)
- Covers referrals for any item or service that might be paid for by Medicare or any other federal health care program

Anti-Kickback Statute, Section 1128B(b) of SS Act, 42 USC 1320a7-b(b)

One-Purpose Test (Majority in case law)

- Ascribes criminal liability to both sides of an impermissible "kickback" transaction, and has been interpreted to apply to any arrangement where even one purpose of the remuneration offered, paid, received, etc., is to obtain money in exchange for referrals or to induce referrals

Statutory Exceptions and Safe Harbors

- Statute prescribes exceptions, and also allows OIG to issue additional exceptions (commonly known as "safe harbors") through regulations (codified at 42 CFR 1001.952). Where all requirements of safe harbor are met, AKS will not apply, regardless of intent

AKS – Advisory Opinions from OIG

HHS OIG is tasked by Statute to Issue Advisory Opinions

- Because of risk of violation (or risk of costly investigation) for even non-abusive arrangements, OIG issues Advisory Opinions.
- A favorable AO means that the arrangement will not be subject to sanctions under the AKS (regardless of intent) because OIG believes it is not abusive
- A favorable AO technically binds OIG only as to the requester of the AO, but as a practical matter, other parties to the subject arrangement, or parties to the very same type of arrangement, bear very little risk of prosecution

AKS – Other Guidance OIG

OIG issues other guidance, available on its website

- Special Fraud Alerts
  - 1994 SFA on Suspect Joint Ventures
  - 2013 SFA on Physician Ownership
  - 2015 SFA on Medical Directorships and Office Staffing
- Special Advisory Bulletins
  - 2003 SAB on contractual joint ventures
- Other Guidance
  - 1992 Letter to IRS on Application of AKS to Acquisition of Physician Practices

Civil Monetary Penalty Statute, Section 1128A of SS Act, 42 USC 1320a7-a

- Civil/Administrative Analog to the AKS
- Statute gives Secretary the authority to issue CMPs and "assessments" for (among many other things):
  - illegal kickbacks
- OIG delegated authority to administer
- "Knows or should know" standard for liability
- Gov't has burden or proof under preponderance of evidence standard; appeals are to ALJ and HHS DAB
- Vicarious liability
- 6-year Statute of Limitations
- CMP Statute also authorizes exclusion from Federal and State healthcare programs

State Kickback Laws

- Many States have their own anti-kickback statutes
  - Some apply to Medicaid only
  - Some are “all payor” statutes (i.e., cover claims paid by commercial payors)
- State anti-kickback laws can be styled as anti-kickback statutes, false claims acts or fee splitting statutes
  - Some contain provision that conduct is not illegal if it is not illegal under the Federal statute

CMP Statute, Section 1128A(b) of the SS Act, 42 USC 1320a-7a(b)

- As amended by MACRA*, prohibits a hospital (or CAH) from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit *medically necessary* services to a Medicare or Medicaid beneficiary who is under the direct care of the physician
  - Note that paying a physician to design a plan or to oversee its implementation would not violate the CMP statute if the physician is not directly providing care to Medicare or Medicaid beneficiaries
- CMP of not more than $2,000 for each such individual with respect to whom the payment is made
- A physician who knowingly accepts payment subject to a CMP of not more than $2,000 for each individual with respect to whom the payment is made
- Potential for exclusion from Federal and State Healthcare programs (see 1128(b)(7) of the SS Act)

* Medicare Access and CHIP Reauthorization Act of 2015, section 512

Statutory Exceptions and Safe Harbors

Statutory Exceptions and Regulatory Safe Harbors

- The AKS contains exceptions, which are called "exceptions," and the OIG's regulations contain exceptions, which are called "safe harbors"
  - Difference in terminology is just a matter of convenience and common parlance
  - Statutory exceptions are included in the regulatory safe harbors, but there are many additional regulatory safe harbors
- Some regulatory safe harbors (e.g., discount) have noticeably more requirements than their statutory counterpart
  - OIG takes the position that it has legal authority to add conditions and that parties must meet the regulatory version
  - At least one case (*U.S. v. Shaw*) is contrary to OIG view (parties can choose to meet statutory exception for discounts or regulatory safe harbor)

Common Safe Harbors, and some of their Requirements -- 42 C.F.R. 1001.952

- Employee
  - Must be for a bona fide employer/employee relationship
    - IRS test for employment
    - FMV is NOT required (neither is absence or relation to V or V of referrals)
    - Compensation must be for the furnishing of any item or service for which payment may be made in whole or in part under Federal Healthcare Program– what does this mean?
- Personal Service Arrangements and Management Contracts
  - Used for call arrangements, medical directorships, professional services, management contracts
    - Signed written agreement, with term of 1 year or more
    - FMV, Set in Advance, Not related to V or V of Referrals, commercially reasonable

Common Safe Harbors, and some of their Requirements -- 42 C.F.R. 1001.952

- Space and Equipment Leases
  - Same basic requirements as in PSA safe harbor
- Discounts
  - Easy to meet (except for bundled discounts) – essentially just documentation of discount
  - Special problem and uncertainty surrounding bundled discounts
  - Tacks on requirements to the statutory exception

Common Safe Harbors, and some of their Requirements -- 42 C.F.R. 1001.952

- Ownership in ASC
  - Four separate safe harbors (surgeon owned; single specialty owned; multi-specialty owned; and hospital/physician owned)
  - 1/3 tests
- Managed Care (“EMCO”)
  - Broadest of the managed care safe harbors
  - Technical requirements and prohibition on swapping

Difficult-to-Meet Safe Harbors

- Small Investment
  - the 40/40 tests are exceedingly difficult to meet
- Sale of Practice to Hospital or Other Entity
  - practitioner must not be in position after sale to make or influence referrals to, or otherwise generate business for, the purchaser
  - Acquired practice must be in a Health Professional Shortage Area (HPSA) and must try to recruit a practitioner to take over acquired practice within 1 year
- Practitioner recruitment
  - Practitioner must relocate into HPSA

Transactions that can Implicate the AKS

Typical Transactions that Involve the AKS

- Employment of Physicians by Hospitals (and their related entities), and (in States with corporate practice of medicine prohibition) by Friendly PCs or Foundations
- Personal service arrangements between physicians and hospitals
  - Call
  - Medical directorships
  - Professional services

Typical Transactions that Involve the AKS

- Joint Venture between physicians and non-physicians
  - physician owned hospital or ASC
  - Physician-owned distributorship
  - Private Equity Company purchase of or investment into physician practice
  - Clinical integration agreement

Typical Transactions that Involve the AKS

- Hospital purchase of physician practice
- Management Contracts between physician-owned management company and health care provider
- Sales and Marketing arrangements
- Leases between physicians in hospital-owned MOBs
- Gainsharing and Co-Management Arrangements
  - Many favorable Advisory Opinions on Gainsharing
    - Not much of an issue given amendment to prohibition in MACRA
  - 2013 favorable Advisory Opinion on Co-Management Agreement

Typical Transactions that Involve the AKS

Bundled Payment Arrangements

- CMS has used its demonstration authority in section 1115A of the SS Act, as added by PPACA for several bundled payment models
  - Accountable Care Organization/Medicare Shared Savings Programs
  - Bundled Payment for Care Improvement Models
  - Comprehensive Joint Replacement
- OIG/CMS have issued various waivers, including waivers of the AKS if certain conditions are met
- Commercial Payor bundled payment arrangements
  - May not implicate the AKS, but will implicate State “all payor” aks if applicable

Common Pitfalls and Ensuring Compliance

Considerations and Risk Factors in Transactions

1. Employment of Physicians

- Is compensation for the furnishing of items or services?
- If employed by related entity, will hospital get the benefit of the safe harbor?

2. Purchase of Physician Practices

- Fair Market Value
  - Is any portion of the payment for intangibles such as “goodwill”?
  - In the context of discussing the small investment interest safe harbor the OIG stated:

> We are excluding all intangible assets such as the company's valuation of its name recognition and stock and other forms of goodwill. We are excluding such assets because their valuation is too subject to "creative" accounting or appraisal techniques. 56 Fed Reg. 35965 (July 29, 1991)

Considerations and Risk Factors in Transactions

3. Medical Directorships

- Fair Market Value
- Commercial Reasonableness
  - Are there multiple medical directors, and are they needed?
  - Is the number of hours reasonable?

4. Co-management agreements/gainsharing arrangements/bundled payment arrangements

- Fair Market Value
- Volume or Value of Referrals
  - Are the metrics of the incentive compensation related to increase in volume

Considerations and Risk Factors in Transactions

5. Physician Joint Ventures

- Are suspect characteristics in 1999 and 2013 Special Fraud Alerts present?
- If a contractual joint venture, are suspect characteristics of 2003 Special Advisory Bulletin present?

6. Management/Billing Agreements

- Are there physician owners of management company who refer to the managed entity? If so, is the compensation paid to the management company fixed or is it percentage based?
- If management company is also paid for billing, is the percentage paid to billing company FMV?

Considerations and Risk Factors in Transactions

7. Call Arrangements

- FMV? Is physician being paid a per diem amount? What is the payor mix?

8. Professional Services Arrangements

- Is physician billing for his/her services or reassigning to entity?
- Commercially Reasonable? Are physicians being paid so much that hospital or other entity is taking a loss? Of taking a loss, are there factors (e.g., mission to serve low-income, uninsured) that satisfy CR concerns?
- Volume or Value Concerns? Are physicians being paid on a percentage comp or per click basis?

Considerations and Risk Factors in Transactions

8. Leases

- FMV? Are physicians paying enough rent? If physicians are lessor, are they getting too much rent? Are there appropriate escalators to keep rent at FMV?
- Commercially Reasonable? If physicians are lessee are conditions in lease being enforced? If physicians are lessor, is entity/lessee leasing more space than it needs??

Transaction Document Preparation

- Representations and Warranties
- Escrow and Indemnity Funds
- Fraud and Abuse Insurance
- Guaranties and other Security
- Addressing the Relevant Time Periods

Representative Clauses

- Representative clauses are very comprehensive
- They may be an alternative to very consuming due diligence
- The challenge then, is how much due diligence to do
- The cost and timing of diligence vs. the indemnity periods and escrow or holdback sizes is key to the negotiation

Indemnity and Holdback Periods

- Are compliance with healthcare laws fundamental representations
- How much time is enough?
  - Statute of limitations?
  - Agreed periods, e.g. 4 years (other mid – market non-heathcare transactions are trending toward less)
  - Are there exceptions for pending matters?

What is the size of the bucket?

- Is there a separate bucket for healthcare laws compliance?
- What is a realistic size of this bucket?
- Core range in surveys looks like 7-15%
- As high as 20% is not a shock
- Negotiating partial release periods with higher numbers
- Whose money is it – interest on the funds, control, investment,bankruptcy

Representative Cases

Hospital Purchase of Physician Practice

- Perales ex re. St. Margaret's Hospital, 243 F.Supp.2d 843 (C. D.Ill. 2003)
  - Relator contended that by paying more than fair market value for the practice purchases noted above, SMH paid remuneration for referrals and therefore violated AKS (and Stark)
  - Court held Relator failed to show that price was more than FMV
    - Relator did not prove allegation that price was inflated by payment for good will

Sacred Heart Hospital (2015)

- Three executives of Sacred Heart Hospital in Chicago charged with violations of AKS
- Allegations of kickbacks to physicians in exchange for referrals,
  - The alleged payments for referrals were alleged to have been nominally payment for sub-leasing space from physicians (with no actual use of the space)
  - Sham medical directorships
  - Spreadsheets tracked referrals
- 7 other officials chose to plead rather than face trial

Non-Competes

Bradford (*U.S. ex rel. Singh v. Bradford Regional Medical Center*, 752 F. Supp. 2d 602 (W.D. Pa. 2010)

- Physicians lease nuclear camera, stop referring to hospital
- Hospital and physicians subsequently enter into a sublease. Under sublease agreement, Hospital leases the camera from the physicians, and physicians agree to a noncompete for the term of the sublease
  - Physicians provide Hospital with data on use of GE nuclear camera

Non-Competes

Bradford, cont'd

- Hospital has FMV analysis performed by accountant, who compares Hospital's expected revenues with sublease in place to expected revenues without sublease in place
- Hospital estimates would generate $402,000 in profit from referrals from Group Practice if parties entered into sublease
- Parties enter into Sublease Agreement. Hospital pays physicians a monthly fee to cover the cost that the physicians owe under the lease, plus $23,655 per month for all other rights under sublease including covenant not to compete.
- Gastroenterology Specialists (GSI)

Non-Competes

Bradford, cont'd

- Sublease provides that Physicians would not own or operate competing nuclear imaging equipment w/in 30 miles of Hospital, and would not provide other outpatient diagnostic imaging w/in 30 miles of Hospital while proposed JV is under consideration.
- Hospital executive says he would not have entered into Sublease if he knew that Hospital would not receive any referrals from Physicians
- Sublease provides that camera would be delivered to Hospital, but camera stayed in Physicians' space. Hospital paid $2500 month rent, and payments for secretarial and other admin expenses.

Non-Competes

- Gastroenterology Associates, Inc. (GSI) – Settlement 2013
- GSI advises Hospital that it plans to open its own outpatient surgery center
- Hospital and GSI enter into 10-year non-compete, whereby Hospital Pays GSI $50,000 per month for the first 5 years, and $60,000 per month for the next 5 years, subject to reductions if usage of Hospital's surgery suites declined

Non-Competes

OIG Advisory Opinion 03-02

- Hospital would purchase an ownership interest in Surgeons' Surgical Center in exchange for certain capital contributions and loans
- Non-competition would prohibits Hospital and Surgeons from developing, managing, or investing in any ASC offering orthopedic services
  - Non-compete would not prohibit referrals to, or use of, any other ASC

Non-Competes

OIG Advisory Opinion 03-02

- OIG said:

the restrictions in the Noncompetition Agreement appear to be narrowly tailored to achieve a legitimate business purpose. In particular, the Group Shareholders and the Hospital-Affiliated Physicians are free to use other ASCs or hospitals. In these particular circumstances, we do not believe that the Noncompetition Agreement is objectionable under the anti-kickback statute, although such agreements require close scrutiny and a full analysis of the facts and circumstances.

Responding to Potential AKS Problems

Responding to Subpoenas

- OIG has broad statutory authority for subpoenas
  - Compare with ZPICs, which sometimes assert authority where there is none
- Work with the OIG if you believe subpoena is overly broad, or time period for responding is too short
- Counsel Clients that they must notify you immediately if served with a subpoena
- Place Litigation Hold on Documents
- CMP and Exclusion authority for failure to grant access to OIG

Presenting Your Case to the OIG

- OIG is usually amenable to meeting with counsel
  - to discuss its concerns
  - to potentially narrow scope of document production
- You may wish to prepare powerpoint or other materials
  - May not be a good idea to distribute copies

OIG Voluntary Self-Disclosure Protocol

- Because OIG has authority for enforcing penalties under the CMP Statute, and because the CMP Statute provides for penalties of "not more than" a certain amount, OIG has authority compromise violations, including violations that involve kickbacks
- Intended to facilitate the resolution of only matters that, in the provider's reasonable assessment, potentially violate Federal criminal, civil or administrative laws.
- March 2009 Letter – OIG focusing its resources on AKS disclosures
  - "*OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation*."

OIG Voluntary Self-Disclosure Protocol

- Initial Information Submission
  - Written
  - Basic Information:
    - Name, address, provider identification number(s) and tax identification number of disclosing provider
    - Indicate whether the provider has knowledge that the matter is under current government inquiry
    - A full description of the nature of the matter being disclosed
    - The type of healthcare provider implicated and any provider billing numbers associated with the matter disclosed
    - The reasons why the disclosing provider believes there is a violation
    - Certification of that the submission is truthful and submitted in good faith

OIG Voluntary Self-Disclosure Protocol

- Basic Information (Cont'd.)
  - A complete description of the conduct being disclosed
  - A description of the provider's internal investigation or a commitment regarding when it will be completed
  - An estimate of the damages to the Federal healthcare programs and the methodology used to calculate that figure or a commitment regarding when the provider will complete such estimate
  - A statement of the laws potentially violated by the conduct

OIG Voluntary Self-Disclosure Protocol

- *Potential* benefits of self-disclosing:
  - Avoiding criminal liability
  - Minimizing civil exposure
  - Avoiding Corporate Integrity Agreements
  - Neutralizing *qui tam* suits
- ***Tolls the time for Reporting and Refunding Medicare Overpayments*** (60-Day Rule)– When a provider enters into a self-disclosure process, the overpayment disclosure/refund time-frame is tolled with respect to any overpayments that are associated with the violation

Disclosing Under the OIG SDP

- Big risks in disclosing or not disclosing under the SDP
  - If disclosed, likely to be very expensive
    - Usual and basic formula is 1.5 times the amount of damages, but OIG cautions it could be more
    - In any event there is a $50K minimum for AKS violations
  - If “potential” violations are disclosed, unlikely that OIG will find that there are no violations in fact
  - If disclosed, unlikely to have Corporate Integrity Agreement (CIA) imposed
  - If not disclosed, may escape any payment, or if conduct discovered by or reported to Gov’t liability could be staggering under CMP Statute and FCA, with likelihood of CIA (or no release from exclusion if CIA is not accepted) and possibility of exclusion
  - 6 year statute of limitations in CMP Statute