



## Stark and the Anti-kickback Statute

### Overview of the Laws Governing Physician Financial Arrangements

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## Two Primary Statutory Schemes

- Medicare Anti-kickback Statute
- Stark Law self-referral prohibitions

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## The Laws

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## Anti-kickback Statute

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## Medicare Anti-Kickback Statute (“AKS”)

- AKS makes it illegal to offer or pay remuneration with the intent to induce referrals of government program business
- Prohibited Conduct
  - Knowing & willful
  - Solicitation or receipt *or* Offer or payment of remuneration
  - In return for referring a Federal Health Program patient, *or*
  - To induce the purchasing, leasing, or arranging for or recommending purchasing or leasing items or services paid by the Program
- Violation is a felony

## Anti-kickback Statute: Remuneration

- Anything of value
- Cash or in-kind
- Direct or indirect
- No “de minimus” exception

## Examples of Remuneration

- Medical Director payments
- Recruitment support/income guarantees
- Below market or free rent of space or equipment to physicians
- Above-market rent or space or equipment from physicians
- Loans/debt forgiveness
- Payments for call coverage

## More Examples of Remuneration

- Computers
- Palm Pilots/PDA's
- Printers/Office Equipment
- Billing and Collection Services
- Office Clerical Staff
- Nurse Practitioners/Physician's Assistants
- Answering Service

## More Examples of Remuneration

- Gift certificates
- Free goods
- Free medical waste disposal, office cleaning
- Trips
- Dinners
- Tickets to sporting events, concerts, entertainment
- Parties
- Cigars

## Anti-kickback Statute: To “Induce” Referrals

- Referral for beneficiaries of any Federal health care program
  - Medicare, Medicaid, TriCare, FEHB
- “To induce” -- To attempt to influence the physician’s or other party’s judgment on referral decisions
  - Does NOT require a bilateral agreement
  - Does NOT require that referrals resulted
  - Does NOT require that remuneration is actually paid
  - Does NOT require that intent be communicated to the physician or other referral source

## Anti-kickback Statute Safe Harbors

- Statutory and Regulatory “Safe Harbors” immunize from criminal and civil prosecution certain payment and business practices implicated by the Anti-kickback Statute
- Compliance voluntary, but all elements of safe harbor must be met to be protected
  - Specific safe harbor requirements apply to different types of arrangements
- Arrangements outside of safe harbor subject to examination of facts and circumstances
  - If improper intent, law is violated
  - If no improper intent, no violation

## General Requirements of Safe Harbors

- Fair Market Value paid in exchange for items or services
- Written agreement, signed by the parties, specifying items or services provided
- Aggregate compensation set in advance, not taking into account the volume or value of referrals

## Anti-kickback Statute: Penalties

- Criminal fines & imprisonment; up to
  - \$25,000 per count (each claim or payment)
  - 5 years imprisonment per count
- Administrative civil money penalty of \$50,000 *plus* 3X the amount of the remuneration paid
- Exclusion
- Civil False Claims Act liability
  - Mandatory Treble Damages
    - No court has addressed how civil FCA damages calculated for AKS violations
    - Government takes the position in settlement negotiations that damages are equal to amount paid on “tainted claims”
  - Mandatory penalties of between \$5,500 and \$11,000 *per claim*



## Stark Law

## Stark Law

- Prohibits referrals from physicians with financial relationships with providers unless an exception applies
  - Physician may not refer
  - Provider may not bill
- Compliance with an exception is MANDATORY
- All elements of exception must be met
- Civil penalties
- Intent is irrelevant

## Stark Sanctions

- Denial of payment
- Refund of amounts collected as a result of improper billing
- Civil Money Penalties of \$15,000 per item or service plus 2X the amount claimed if “knowing”
- Civil Money Penalties of \$100,000 for “Circumvention Schemes”
- Exclusion
- False Claims Act Liability
  - Mandatory damages of 3X amount paid on each claim
  - Mandatory penalties of \$5,500 to \$11,000 per claim

## Common Exceptions to Stark

- Professional Services Agreements (e.g., Medical Directors)
- Employment Agreements
- Space and Equipment Leases
- Recruiting Agreements
- Incidental Medical Staff Benefits (less than \$28/per occurrence)
- Non-monetary Compensation (less than \$329/year)
- Professional Courtesy
- Temporary non-compliance

## Common Requirements of Stark Exceptions

- Written agreement, signed by parties
- Sets out defined duties, items or services provided
- Compensation at Fair Market Value
- Compensation cannot take into account the volume or value of referrals or other business between the hospital and the physician

## Stark vs. Anti-kickback Statute

- Intent standard
- Definition of “referral”
- Compliance with exception/safe harbor
- Physician liability
- Stark applies only to financial relationships with physicians – not other referral sources

## AKS and Stark Enforcement Actions

- Criminal prosecution of AKS violations
- Civil enforcement of Stark and AKS violations under False Claims Act
  - Many initiated by whistleblowers under the *qui tam* provisions
  - Government participates vigorously
  - Settlement posture seeks reimbursement for value of claims paid by government on tainted referrals
- Growing number of Civil Money Penalty administrative settlements by OIG, most arising out of self-disclosures

## Civil False Claims Act Stark and AKS Settlements

- **Columbia/HCA**
  - Excessive directorship payments, leases to and from physicians, recruiting agreements, loans, uncollected debt, trips and entertainment
  - \$225 million to settle FCA AKS and Stark law claims
- **Tenet**
  - Recruiting agreements, directorships, leases
  - \$49.5 million to settle FCK AKS and Stark law claims
- **Erlanger Hospital**
  - Leases, directorships, sham teaching agreements
  - Settlement discussions leaked to the press within last two weeks
  - \$40 million to settle FCA Stark law claims

## Administrative CMP Stark and AKS Settlements

- **Lincare – DME supplier**
  - Gifts and entertainment, advertising expenses, office and medical equipment, sham consulting agreements
  - \$10 million administrative CMP settlement
- **Inova**
  - Below market and free rent to physicians
  - \$713,000 CMP included payments for Stark and kickbacks
- **2 South Florida Physicians**
  - Gifts, Miami Dolphins tickets, meals
  - \$65,000 and \$57,000 CMP included payments for Stark and kickbacks
- **New Jersey Physician**
  - Sham leases from physician
  - \$500,000 CMP included payments for Stark and kickbacks



## Practical Application

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## Written Contracts

- Question: Why do our contracts with physicians and other referral sources have to be in writing and signed before services are provided?
- Answer:
  - Required by most applicable Stark exceptions
  - Required for all applicable Anti-kickback Statute safe harbors
  - Required by company policy
  - If contract not signed and company has billed for Medicare referrals, may constitute an overpayment requiring a refund under the Stark law

## Written Contracts

- Question: What do I do if an old contract with a physician has expired, but the new one isn't signed yet?
- Answer:
  - Send the physician a letter telling him to stop providing services and that the hospital won't pay him for services provided prior to signing a new contract; **or**
  - Allow the physician to keep performing, and pay him, but hold all of the bills for his Medicare referrals during the gap period
    - If the physician signs a new contract within 90 days of the expiration of the old one, temporary non-compliance exception may be available. If so, bills on hold can be released
    - If physician does not sign a new contract within 90 days, bills on hold should be written off
  - If bills submitted without signed written contract, may be a violation of Stark requiring repayments of amounts billed

## Business Courtesies

- Question: Does the government really care about cookies, pizzas and cigars?
- Answer: Yes. Stark's non-monetary compensation exception applies to such courtesies
  - All non-monetary business courtesies to physicians must be logged and tracked on an annual basis, and reflected in the Database
  - Annual limit of \$329 per physician for 2007
  - Cannot be requested by physician or staff
  - Group gift cannot be split up "pro rata" among physician members
  - If send a gift to office staff, must credit physician

## Business Courtesies

- Question: Can we give members of our medical staff gift certificates?
- Answer: No
  - Stark non-monetary compensation exception prohibits cash or “cash equivalents”
  - Gift certificates are considered “cash equivalents”

## Business Courtesies

- Question: Can I give a member of the medical staff a voucher for a specific item?
- Answer: Yes, if the voucher can only be redeemed in exchange for the specific item, and it cannot be turned in for cash, and if the item is tracked in the non-monetary compensation database.
- Examples:
  - Voucher redeemable for one Honey Baked Ham – OK
  - \$50 Honey Baked Ham store gift certificate – not OK
  - Voucher for “Deluxe Car Wash” at Chevron OK
  - Chevron \$50 gas card – not OK

## Business Courtesies

- Question: Can I take a physician to dinner?
- Answer: Yes, but must either
  - Count the value of the meal toward the non-monetary compensation annual limit; *or*
  - Have a written agreement with the physician that contemplates that part of his compensation will include business meals.

## Business Courtesies

- Question: Are we permitted to invite physicians to sporting events, concerts, golf and other business entertainment?
- Answer: Yes, but the physician's share of the cost of the event must be included in the non-monetary compensation log. If the physician's spouse attends, too, his or her portion should be allocated to the physician as well.

## Business Courtesies

- Question: Do these same rules apply to physicians that are employed by the provider?
- Answer: No, these rules do not apply to employed physicians so long as their employment contracts reflect that their compensation includes certain incidental business courtesies.

## Business Courtesies

- Question: What happens if we go over the \$329 annual limit?
- Answer: You may have violated Stark and the company may have to repay any amounts that the government has paid on improper referrals. You should immediately contact your Legal Department for guidance.

## Recruiting Agreements

- Question: Are there new rules for recruiting physicians into groups?
- Answer: Yes, the Phase II Stark Regulations dramatically changed rules for recruiting into existing groups.
  - Limitation on allocated overhead to “actual incremental” costs
  - Open issues:
    - Can you avoid the incremental overhead restrictions by “expense sharing” instead of “joining” existing practice?
    - If replacing a retiring physician, can you claim pre-existing expenses as “incremental”?

## Recruiting Agreements

- Question: Why is “Community Need” important in recruiting agreements?
- Answer: To defend against Anti-kickback Statute liability
  - Many, if not most, communities do not qualify as “underserved” so safe harbor protection not available, intent at issue
  - Community need a surrogate for HPSA/MUA designation
  - Community need provides evidence of good intent
  - Historical inurement analysis/early tax cases looked to community need

## Proving Intent to Induce Referrals

- Question: How does the government try to prove intent?
- Answer: The government looks at every piece of paper related to the relationship
  - E-mails
  - Opinion letters
  - Audit/compliance reports
  - Accounting records
  - Business plans
  - Employee goals/evaluations
  - Referral data/tracking
  - Time records/work product
  - Staff interviews

## Volume or Value of Referrals

- Question: When is it appropriate to consider the amount of business a physician will/may refer to the hospital when deciding whether to enter into an arrangement with the physician and/or how much to pay?
- Answer: NEVER!!!!!!

## Advice of Counsel

- Question: All of our contracts must be reviewed by counsel. Doesn't that mean that we are all home free?
- Answer: No.
  - Attorney review does not absolve the rest of the organization from scrutiny (or even criminal prosecution)
  - Misstatements and mistakes in materials can be used to question validity of attorney's opinions and advice

## Advice of Counsel

- Question: What can we do to strengthen our position regarding attorney review and advice of counsel?
- Answer:
  - Don't just "check the boxes"
  - Make sure attorneys have all relevant facts
  - Demonstrate reasoned analysis of each relationship

## Enforcing Agreement Terms

- Question: Our contracts fulfill all of the Stark requirements, we don't have any bad intent evidence around, and the attorneys signed off on the agreements. Do we have anything to worry about?
- Answer: Yes, you still have to enforce the terms
  - Failure to require performance and/or enforce payment terms implicates FMV, intent
    - Failure to require performance/time records for payment under service agreements
    - Failure to require receipts for support/overhead
    - Failure to collect debt
  - Selective enforcement, especially with respect to big referral sources, can be construed as inducement to refer
    - No intent to require performance at the time agreement entered
    - Performance waived as a reward for past/future referrals

## Enforcing Agreement Terms

- Question: What do we do if a physician refuses to perform under the agreement?
- Answer: Act the same way you would act with a party who is not a referral source
  - Don't pay physicians when time logs/services not provided
  - Document collection efforts for debt
  - Pursue legal remedies
  - Obtain outside opinion on reasonableness based on litigation risk/likelihood of collection before compromising/forgiving obligations

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