ANTI-KICKBACK STATUTE
AND
SAFE HARBORS

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MEDICARE AND MEDICAID
FRAUD AND ABUSE:
Overview

1. History and Development of the Anti-Kickback Statute 42 U.S.C. §1320a-7b

2. The Anti-Kickback “Safe Harbors” 42 C.F.R. §1001.952
DISMANTLING THE $70-$100 BILLION INDUSTRY

The Government’s Weapons:

- *Anti-Kickback Statute*
- False Claims Act
- Stark Acts
The History and Development of the Anti-Kickback Statute

A law that prohibits conduct that is commonly accepted and legal in businesses other than health care.
1965

- Medicare and Medicaid Created
- REIMBURSEMENT: Fee for Service
1972

Health care providers discover the federal deep pocket:
More Patients, More Revenue.

Congress passes the first anti-kickback provisions in the Social Security Act Amendments.
“Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any:

1) Kickback or bribe in connection with furnishing of such items or services or making or receipt of such payment; or

2) Rebate of any fee or charge for referring any such individual to another person for furnishing of such items or services,

shall be guilty of a misdemeanor and shall be fined not more than $10,000 or imprisoned for 1 year or both.”
The 1972 Amendments

Congress’ Goal: To prohibit by law certain practices that have long been regarded by professional organizations as unethical and that contribute to the cost of the Medicare and Medicaid programs.

Simply Stated: Congress made unlawful conduct that was already considered unethical.
Immediate Problems Arose in Courts Over How to Define *Kickbacks, Bribes and Rebates*

- *U.S. v. Porter, 591 F.2d 1048 (5th Cir. 1979)*

  First case prosecuted under 1972 amendments. Fifth Circuit reversed the convictions of physicians who had received ‘handling fees’ for referring blood samples to a laboratory.
Immediate Problems Arose in Courts Over How to Define *Kickbacks, Bribes and Rebates*

- **U.S. v. Hancock, 604 F.2d 999 (7th Cir. 1979)**
  - Rejected Porter and adopted a broad definition of *kickback*, upheld the indictments of a group of chiropractors who had referred blood and tissue samples to a laboratory in exchange for handling fees.
Health care fraud and abuse continues to grow.

Congress dreams of putting teeth into law so it enacts the Medicare and Medicaid Antifraud and Abuse Amendments.
The 1977 Amendments

- Broadens language of statute to prohibit solicitation, offer, payment or receipt of any “remuneration” given directly or indirectly, overtly or covertly, in cash or in kind, in return for patient, product, or service referrals or recommendations of business reimbursed through federal health care programs.

- Upgrades crime to a Felony.

- Punishable by up to 5 years imprisonment and/or $25,000 Fine.
UNTIL THIS TIME, THE ANTI-KICKBACK STATUTE CONTAINED NO "INTENT" OR STATE OF MIND ELEMENT
The Statute was amended to require that a person “knowingly and willfully” violate the law before he or she may be convicted.
Hoping for magical cure to spiraling costs of health care, the Medicare program implements DRGs. Affiliations and joint ventures between health care providers for outpatient services explode.

REIMBURSEMENT: DRGs
Affiliations and Joint Ventures

- Hospitals and other providers joint venture to form outpatient service entities.

- Motive: To maintain and maximize inpatient referrals and to tap into fee-for-service outpatient revenue streams.
If one purpose of the remuneration is to induce referrals, the statute is violated, even if the payment was also intended to compensate for professional services.
Responding to industry confusion and uncertainty regarding the application of the law, Congress passes the Medicare and Medicaid Patient and Program Protection Act of 1987.
Medicare and Medicaid Patient and Program Protection Act of 1987

- United the separate Medicare and Medicaid Anti-Kickback statutes into one statute.

- Created an intermediate sanction -- program exclusion.

- Directed HHS to develop “safe harbors” of protected conduct.
Litigating the *Anti-Kickback Statute*
What Constitutes “Knowing and Willful” Violation of the Law?

- **Hanlester Network v. Shalala** - the OIG tests the new remedy of program exclusion; providers win because they did not specifically intend to violate the Anti-Kickback Statute.

- **United States v. Jain** - rejected the Hanlester holding; “willfully means unjustifiably and wrongfully, known to be such by the defendant.” Specific intent to violate the Anti-Kickback Statute not necessary.
1991
Promulgation of the Federal Sentencing Guidelines for Organizations

- Imposes severe economic sanctions on corporations convicted of criminal wrongdoing.
- Eliminates most judicial discretion in sentencing.
- Allows for significant reductions in sanctions where organization has adopted effective compliance program.
• 1993 - IRS moves to rescind tax exempt status of organizations accused of health care fraud (i.e., Baptist Health System, Birmingham, Alabama).

• 1996 - *Health Insurance Portability and Accountability Act*
  
  - Increased penalties for some types of fraud.
  - Increased funding for enforcement.
  - OIG to issue advisory opinions and fraud alerts.
  - Authorized new exception to *Anti-Kickback Statute* for risk sharing arrangements.
• Under the Anti-kickback Statute, it is illegal to knowingly or willfully:
  - offer, pay, solicit, or receive remuneration;
  - directly or indirectly;
  - in cash or in kind;
  - in exchange for;
    • referring an individual; or
    • furnishing or arranging for a good or service; and
  - for which payment may be made under Medicare or Medicaid.
Fined not more than $25,000 or imprisoned for not more than five (5) years or both
THREE NECESSARY ELEMENTS

- Intentional Act
- Direct or Indirect Payment of Remuneration
- To *Induce* the Referral of Patients or Business
WHAT IS REMUNERATION?

• Extremely Broad Scope, whether in cash or in kind, and whether made directly or indirectly, including:
  - Kickbacks;
  - Bribes;
  - Rebates;
  - Gifts;
  - Above or below market rent or lease payments;
  - Discounts;
  - Furnishing of supplies, services or equipment either free, above or below market;
  - Above or below market credit arrangements; and
  - Waivers of payments due.
Almost Any Benefit by and Between Medical Providers Can Be Considered Remuneration
REAL LIFE EXAMPLES OF ILLEGAL CONDUCT

• Hospital paying staff physicians to attend conferences in their areas of specialty. (OIG Special Fraud Alert, May 1992)

• Contract between DME company and marketing company paid marketing company percentage of business it developed for DME company through its marketing program. (Medical Development Network, Inc. v. Professional Respiratory Care, 673 So.2d 565 (Fla. Ct. App. 1996))
REAL LIFE EXAMPLES OF ILLEGAL CONDUCT

- Physician or other supplier routinely waives coinsurance and deductible amounts for Medicare and Medicaid beneficiaries. (OIG Special Fraud Alert, May 1991; Preamble of Final Rule Governing Safe Harbors, 56 FR 35962)

- Hospital offers free training for physician’s office staff in CPT coding or laboratory techniques. (OIG Special Fraud Alert, May 1992)

- Company provides free surgical packs (sutures, gloves, etc.) with purchase of company’s intraocular lens. (Preamble of Final Rule Governing Safe Harbors, 56 FR 35978)
REAL LIFE EXAMPLES OF ILLEGAL CONDUCT

- Physician investors are offered shares in joint venture laboratory based on volume of referrals they could make; they know that if referrals from them decrease, they could lose their shares. *(Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995))*

- Pharmaceutical company offers 1,000 frequent flier miles every time physician starts patient on certain drug and completes a marketing questionnaire; after 50 patients, physician has free plane ticket anywhere in U.S. *(OIG Special Fraud Alert, August 1994)*
REAL LIFE EXAMPLES OF ILLEGAL CONDUCT

• Ambulance service seeking exclusive contract with city hires city employee who is part of bid committee to be a “consultant,” reimbursing him with cash, cars, and trips. (*United States v. Bay State Ambulance*, 874 F.2d 20 (1st Cir. 1989))

• Struggling hospital pays 2 physicians $70 for each patient they admit--payments are designated as “consulting fees.” (*OIG Special Fraud Alert, May 1992.*)
REAL LIFE EXAMPLES OF ILLEGAL CONDUCT

- Pacemaker Manufacturer offers doctor $250 for each of its pacemakers doctor implants; a competitor offers $400--in the end, doctor receives $238,000 from two firms and implants scores of unnecessary pacemakers. (Excerpted from Marc. A. Rodwin, Medicine, Money, and Morals, 57 - 63 (1993))
The First Eleven Safe Harbors Are Published In 1991
Two More In 1996
The Last Eight In 1999
SAFE HARBOR PROVISIONS
42 C.F.R. 1001.952

- If entity/person satisfies requirements of one or more of the following safe harbor provisions, otherwise suspect payment practices are NOT subject to criminal prosecution –
  - Investment interests for publicly traded companies and smaller entities;
  - Space and equipment rental agreements;
  - Personal services and management contracts;
  - Sale of a medical practice;
  - Employees;
  - Group purchasing organizations and Discounts;
  - Waiver of beneficiary co-insurance and deductible amounts;
  - Warranties; and
  - Health Plan/Managed care.
SAFE HARBOR PROVISIONS
42 C.F.R. 1001

- Investments in Ambulatory Surgical Centers (ASCs)
- Joint Ventures in Underserved Areas
- Practitioner Recruitment in Underserved Areas
- Sales of Physician Practices to Hospitals in Underserved Areas
- Subsidies for Obstetrical Malpractice Insurance in Underserved Areas
- Investments in Group Practices
- Specialty Referral Arrangements Between Providers
- Cooperative Hospital Services Organization
SAFE HARBOR COMPLIANCE

- Failure to comply with a safe harbor means either --

  The Arrangement Is Not Covered by the Statute (i.e., No Intent to Induce a Referral)

  or

  The Arrangement May Be a Criminal Violation Subject to Prosecution
Generally, Safe Harbor provides protection returns on “investment” in:

- Large publicly traded entities ($50 million+ in net assets) if certain criteria are met; and,
- Small entities if i) no more than 40% of investment interests are held by investors in a position to generate business to the entity and ii) no more than 40% of gross revenues for venture may come from investors (and if other criteria are met).
1) Investments

XYZ Physician Group

60% or Greater

Non Referrers

40% or Less
2) Health Care - Related Revenues

- Patients of XYZ Physician Group
  - 40% or Less
  - 60% or Greater

- Patients from other Referrers
INVESTMENT INTEREST SAFE HARBOR

- Investment offer must be same for referrers and nonreferrers.
- Terms cannot consider past volumes of referrals.
- No requirement that investor refer to entity.
- Cannot market to referrers and nonreferrers differently.
- Entity cannot loan funds to referrer to make investment.
- Return on investment must be proportionate to investment.
APPLICATION TO INTEGRATED DELIVERY SYSTEM (“IDS”) INVESTMENT INTEREST

• **Key Question**: Does the ownership structure affect the systems’ volume of business?

• **Physical Hospital Organizations (“PHO”) issues:**
  
  - If hospital and physician capitalize a PHO *in proportion* to benefits they receive from PHO, little risk.
  - If hospital provides *more* capital or resources to PHO, and physicians receive *equal* or *greater benefit* from PHO, risk that PHO treated as a guise to remunerate physicians.
TO LIMIT LIABILITY

- Ownership interest should be *proportionate* to capital contribution.
- Governance and control of entity should be *proportionate* to capital contribution.
- Right to participate in PHO should be offered both to physicians who refer and those who do not refer patients to hospital.
- No requirement that physician make referrals to hospital.
- Hospital or PHO should not loan or guarantee funds for physicians to invest in PHO, and amounts received by physicians should be proportionate to amount contributed.
SPACE AND EQUIPMENT RENTAL SAFE HARBOR

• Requirements for the space and equipment rental safe harbor:
  ➢ Written agreement signed by the parties;
  ➢ Lease describes premises covered;
  ➢ Term of at least one year;
  ➢ The aggregate payment must be set in advance; and
  ➢ All payments and services (including build-out amounts) must be reasonable and based upon fair market value.
  ➢ All arrangements between lessor/lessee must be in ONE Contract. Cannot have multiple overlapping contracts to circumvent the one year rule.
  ➢ The arrangement must serve a commercially reasonable business purpose.
  ➢ The specific schedule of intervals must be set out in advance.
Fair market value is not determined by what one lessor will offer, but is determined by looking at entire market.
CAUTION

Fair Market Value Cannot Be Adjusted Based Upon Close Proximity Or Convenience To Medical Provider
RENTAL FOR PERIODIC INTERVALS

Lease must specify:

- *Exact* schedule.
- *Precise* length.
- *Exact* rent for intervals.
REQUIREMENTS FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS

- Written agreement signed by parties.
- Term of at least one year.
- Agreement must specify aggregate payment and such payment must be set in advance.
- Compensation must be reasonable, fair market value and determined through arm’s length negotiations.
- Must set exact services required to be performed.
- Compensation must not be determined in manner that takes into account volume or value of referrals.
- All arrangements must be in ONE contract. Cannot have multiple overlapping contracts to circumvent the one-year rule.
- The arrangement must serve a commercially reasonable business purpose.
If Agreement does not contemplate full-time services, it must also specify:

- The *exact* schedule of intervals;
- Their *precise* length; and
- The *exact* charge for such intervals.
If hospital subsidizes MSO that provides services and/or assets to a physician group, may constitute an indirect payment in exchange for patient referrals.
To limit liability, ensure:

- Fee charged for each service is *reasonable*, based on *FMV* and constitutes an *arms-length transaction*;
- MSO compensation does not take into account volume or value of referrals or any other business between parties; and
- Obtain independent appraisal of fair rental value of premises or equipment prior to commencement of negotiations.
Payments made by employer to employee under bona fide employment relationship with employer for employment in furnishing of any item or service for which payment may be made under Medicare or Medicaid are excepted from statute’s prohibitions.
Compensation Must Be:

- Reasonable;
- Fair Market Value;
- Arm’s Length Negotiations; and
- Not based upon number or value of referrals.
SALE OF PRACTICE SAFE HARBOR

Elements:

- Maximum time of one year between date of agreement and effective date of sale.
- Seller *must not be in a position, post-sale to make referrals to purchaser.*
SALE OF PRACTICE SAFE HARBOR

- Reasonable
- Fair Market Value
- Arm’s Length Negotiations
- Amount Paid Not Based Upon Number or Value of Referrals by Physician
Remuneration does not include payments to Referral Service if:

- Medicare/Medicaid participants are included
- Payments based only on cost of operating Referral Service
  - *Not Volume*
  - *Not Value*
- Referral Service cannot impose service requirements on medical provider
Disclosures Must Be Made to Person Seeking Referral

- How it selects participants
- Whether fee paid to Referral Service
- How Referral Service selects participants
- Relationship between Referral Service and Participants
- Restrictions on Participants
WARRANTY SAFE HARBOR

Remuneration does not include payments under warranty obligations if:

- Buyer reports warranty payments on cost report
- Buyer supplies warranty information to DHHS upon request
- Seller:
  - Report Warranty item on invoice.
  - If cost of warranty replacement not known, must show warranty obligation on invoice and report amount when known.
Remuneration does not include discounts if *Buyer*: 
- Earns Discount in a single fiscal year.
- Claims Discount in year earned or following year.
- Reports Discount on cost report.
Remuneration does not include discounts if Seller:
- Reports Discount on invoice.
- If value of Discount not known at time of sale, existence of Discount must be reported on invoice.
A reduction in amount Seller charges Buyer (i.e., rebate check, credit or coupon) only if reduction in price is attributable to original good or service.
DISCOUNT DOES NOT INCLUDE

- Cash Payment

- Furnishing good or service without or at reduced charge for agreement to buy different good or service

- Price reduction not applicable to Medicare/Medicaid Programs
Cannot provide discount to private pay as condition to refer all Medicare/Medicaid patients.

Refer all Medicare Patients to me!

I will give you a discount

Medicare Pt.

Private Pay Pt.
Tying Arrangement Covered by Discount Safe Harbor **ONLY** if goods reimbursed by Federal Healthcare Program in the same manner.
DISCOUNT

Permitted Tying Arrangement

Covered by same DRG.
Tying Arrangement Not Covered

DRG Reimbursed

Cost Report Reimbursed
DISCOUNT EXAMPLES-YOU DECIDE

- Buy 10, get 1 free
- Buy monitors, get service agreement free (Warranty?)
- Buy insulin, get syringes free
- Buy 100 hearing aids in 6 months, get $500 travel fee for seminar
PRICE REDUCTIONS TO HEALTH PLANS

Remuneration does not include price reductions offered to health care providers:

• If Medicare/Medicaid plan:
  ➢ Written Agreement for not less than 1 year
  ➢ Covered items/services and payment requirements must be set out in advance
  ➢ Fee schedule must remain in effect throughout term of agreement unless updated by Medicare/Medicaid
  ➢ Cost Report must show amount paid
PRICE REDUCTIONS TO HEALTH PLANS

• If not a Medicare/Medicaid plan:
  ➢ Written Agreement for not less than 1 year
  ➢ Covered items/services and payment must be set out in advance
  ➢ Fee schedule must remain in effect throughout term of agreement
  ➢ Upon request, plan must be reported to Medicare/Medicaid
Four Types of ASCs:

1) Surgeon-owned ASCs
2) Single-specialty ASCs
3) Multi-specialty ASCs
4) Hospital/physician ASCs
ASC
SAFE HARBOR

Surgeon-owned ASCs:
To qualify for this Safe Harbor, the following seven factors must be met:
1) All investors must be general surgeons or surgeons engaged in the same surgical specialty.
2) The investment terms must not be related to previous or expected volume of referrals to be generated from investor.
3) At least one-third of surgeons/investors’ medical practice income from all sources must be derived from surgeons’ procedures.
Surgeon-owned ASCs:

**To qualify for this Safe Harbor, the following seven factors must be met:** (Continued)

4) The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.
5) The return on investment must be directly proportional to the amount of capital investment.
6) All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.
7) The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.
ASC SAFE HARBOR

Single-specialty ASCs:

To qualify for this Safe Harbor, the following seven factors must be met:

1) All investors must be physicians engaged in the same medical practice specialty.

2) The investment terms must not be related to previous or expected volume of referrals to be generated from investor.

3) At least one-third of surgeons/investors’ medical practice income from all sources must be derived from surgeons’ procedures.
ASC
SAFE HARBOR

Single-specialty ASCs:

To qualify for this Safe Harbor, the following seven factors must be met:

(Continued)

4) The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.
5) The return on investment must be directly proportional to the amount of capital investment.
6) All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.
7) The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.
ASC
SAFE HARBOR

Multi/specialty ASCs:

To qualify for this Safe Harbor, the following eight factors must be met:

1) All investors must be physicians who are in a position to refer patients directly to the ASC and perform procedure on such referred procedures.

2) The investment terms must not be related to previous or expected volume of referrals to be generated from investor.

3) At least one-third of surgeons/investors’ medical practice income from all sources must be derived from surgeons’ procedures.
ASC
SAFE HARBOR

Multi-specialty ASCs:
(Continued)

4) At least one-third of the procedures performed by each physicians must be performed at the ASC.

5) The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.

6) The return on investment must be directly proportional to the amount of capital investment.

7) All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.

8) The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.
ASC SAFE HARBOR

Hospital/physician ASCs:
To qualify for this Safe Harbor, the following Nine factors must be met:

1) At least one investor must be a hospital and all of the remaining investors must be physicians who meet the requirements of the surgeon-owned ASC, single-specialty ASC or multi-specialty ASC.

2) The investment terms must not be related to previous or expected volume of referrals to be generated from investor.

3) The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.
ASC SAFE HARBOR

Hospital/physician ASCs:

To qualify for this Safe Harbor, the following Nine factors must be met:

(Continued)

4) The return on investment must be directly proportional to the amount of capital investment.
5) All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.
6) The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.
7) The ASC may not use space or equipment owned by the hospital unless such space/equipment meets the Equipment/Leased Space Safe Harbor.
Hospital/physician ASCs:

To qualify for this Safe Harbor, the following Nine factors must be met:

(Continued)

8) The hospital investor may not include any cost related to the ASC on its cost report or any other claim for payment from Medicare/Medicaid.

9) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the ASC.
HOSPITAL/PHYSICIAN ASC
SAFE HARBOR

Can a hospital comply with the requirement not to make or influence referrals, directly or indirectly?
JOINT VENTURES IN UNDERSERVED AREAS
SAFE HARBOR

This safe harbor expands the Small Investment Safe Harbor for underserved areas by:

1. Permitting up to fifty percent of investors to be referring investors; and

2. Unlimited revenues from referral investors.
Payments to physicians being recruited to an underserved area will qualify for Safe Harbor if:

1. The arrangement is set forth in a written agreement.
2. At least 75% of the revenues of the new practice must be generated from new patients.
3. The benefits cannot exceed three years.
4. There is no requirement that the physician make referrals to the hospital.
5. The physician is not restricted from referring to any provider of his/her choosing.
6. The value of the benefits paid by the hospital may not be based upon the volume or value of referrals.
Payments to physicians being recruited to an underserved area will qualify for Safe Harbor if: (Continued)

7) The physician must treat Medicare/Medicaid patients in a non-discriminatory manner.
8) At least 75% of the revenues of the new practice must be from patients from the underserved area.
9) The payment may not benefit any other referral source except for the recruited physician.
To qualify for this safe harbor, the following four factors must be met:

1. The time from the signing of the contract to the completion of the sale must not exceed three years;
2. The selling physician will not practice after completion of the sales;
3. The physician's practice must be in an underserved area; and
4. After the first agreement is signed with the physician, the hospital must engage in recruitment activities.
COOPERATIVE HOSPITAL SERVICES ORGANIZATIONS ("CHSO")
SAFE HARBOR

Payments made by CHSOs and patron hospitals qualify for a safe harbor if:

1. Payments by patron-hospitals are for bonified operating expenses of the CHSO; and

2. Payments by the CHSO to the patron hospital must be a distribution of net earnings required to be paid by the IRS under Section 501(a) (2).
INVESTMENTS IN GROUP PRACTICES
SAFE HARBOR

Payments made to physicians investing in group practices qualify for a safe harbor if:

1. The equity interest in the practice is held by licensed health care professionals who practice in the group;
2. The equity interest must be in the practice, not some subdivision of the practice or group;
3. The practice must meet the “group practice” definition under the Stark Act; and
4. Ancillary revenues must be derived from “in office ancillary services” as defined in the Stark Act.
Agreements among providers to refer a patient to the other party if the other party in return agrees to refer the patient back to the referring physician complies with the Safe Harbor as long as:

1. The agreed time or circumstances for referring the patient must be clinically appropriate;
2. The physician to whom the patient is referred has special expertise required by the patient;
3. The parties receive no payment for the referral and do not split the fees paid; and
4. The only compensation received by the parties is for services actually rendered by the parties.
ANTI-KICKBACK STATUTE AND SAFE HARBORS