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The ASC Safe Harbors: An Overview and Key Considerations for Enforcement

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- I. Overview of Anti-Kickback Statute
- II. Overview of ASC Safe Harbors
- III. Monitoring and Enforcement Considerations
- IV. Special Considerations
- V. Questions



Why is this important?

- More aggressive government enforcement
- Increased enforcement in surgery centers (for both good and bad motives)
- Safe Harbor compliance is often tied to physician redemptions
- Frequent disputes
- Applicability outside ASC context



I. Overview of Anti-Kickback Statute

- Summary: Prohibits the knowing and willful solicitation, receipt, offer or payment of any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce the referral, arrangement or recommendation of Medicare or Medicaid business.
- Simply put, it prohibits directly or indirectly offering or receiving anything of value in exchange for or to induce referrals.



Anti-Kickback Statute Key Concepts:

1. Criminal statute.
2. Applies to all persons and all services, not just physicians
3. Applies to federal healthcare business, but many states also have similar laws that prohibit inducements for referrals regardless of payor.



Anti-Kickback Statute Key Concepts (continued):

4. Intent-based statute: “knowingly and willfully”
 - Remuneration and referrals alone do not violate the statute – there must be an intent to induce referrals.
 - If any one purpose is to induce referrals, then the intent requirement is satisfied
 - Practical Point – If prosecuted and you are arguing over “intent”, it will be an uphill battle. It is better to be safe harbor compliant.



Anti-Kickback Statute Key Concepts (continued):

5. Penalties for violation of the Anti-Kickback Statute
 - Fine of up to \$25,000 per occurrence
 - Imprisonment for up to 5 years
 - Suspension or exclusion from participation in Medicare and Medicaid programs
 - Civil and criminal penalties at stake.
 - Qui tam lawsuits



Government Enforcement and Guidance

1. Anti-Kickback Statute Enforced by the Office of the Inspector General

2. Forms of Guidance:
 - Advisory opinions – Can be costly and time-consuming
 - Special Fraud Alerts – Limited number



II. Anti-Kickback Statute Safe Harbors

Core Principles:

1. The Anti-Kickback Statute is very broad
2. Legislation has created certain “safe harbors” of conduct
3. Arrangements that satisfy all of the elements of a safe harbor are immune from both criminal prosecution and administrative enforcement
4. Unlike the Stark Law, failure to meet a safe harbor does not mean an arrangement automatically violates the Anti-Kickback Statute or is illegal
5. Compliance is not required, but affords protection under federal Anti-Kickback Statute
6. Requires adherence to both qualitative and quantitative standards



ASC Safe Harbors

- A. Physician investment in an ASC implicates the Anti-Kickback Statute

- B. Four slightly different ASC Safe Harbors:
 - A. Surgeon-Owned ASCs
 - B. Single-Specialty ASCs
 - C. Multi-Specialty ASCs
 - D. Hospital/Physician ASCs



Six Core Requirements of ASC Safe Harbors

1. Must not be related to volume or value of referrals
2. No loans or loan guarantees by other investors allowed
3. Distributions must be directly proportional to the amount of the capital investment of that investor



Six Core Requirements of ASC Safe Harbors (cont'd)

4. All ancillary services must be directly and integrally related to primary procedures performed at the ASC and none may be separately billed to Medicare
5. Must treat Medicare patients in a nondiscriminatory manner
6. Patients must be fully informed of the physician's ownership



The “One-Third” Tests

1. For Single-Specialty ASCs:
 - At least 1/3 of each physician investor’s medical practice income from all sources for the previous fiscal year or previous 12 month period must be derived from the physician investor’s performance of ASC procedures
2. For Multi-Specialty ASCs
 - 1/3 Income Test, PLUS
 - At least 1/3 of the ASC procedures performed by each physician investor for the previous fiscal year or previous 12 month period must be performed at the ASC



III. Monitoring and Enforcement Process

1. Assess Compliance: Annual Certification/Attestation Process
 - a. Voluntary
 - b. Compulsory per Operating Agreement or Partnership Agreement
 - c. Problem of Incorrect or False Responses
 - d. “Almost Compliant” Physicians

2. Enforcement:
 - a. Need contractual basis to redeem a physician owner in operating agreement
 - b. Redemption Price



III. Monitoring and Enforcement Process (continued)

3. Speak with Physician
4. Offer Chance to Cure (e.g., 1 year)
5. Monitor and Enforce all elements of safe harbor
6. Avoid selective enforcement



III. Monitoring and Enforcement Process (continued)

7. Attempt to negotiate a buy-out or settlement if desired
8. Intent for buying out should be compliance, not profitability
9. Consider offering full value for ownership and not discounted amount



III. Monitoring and Enforcement Process (continued)

10. Documenting the Redemption/Buy-Out

- a. Redemption Agreement
- b. Redemption Notice with Payment
- c. Payment Over Time vs. Lump Sum Payment



IV. Special Considerations

1. Failure to Satisfy One-Third Tests
2. Investment Considerations
3. Minimum Case Requirements
4. Indirect Referrals



IV. Special Considerations (continued)

5. Hospital Ownership and Hospital-Employed Physicians
6. Ownership by Group Practices
7. Ownership through Entity or Trust
8. Management Company Ownership



Questions

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