

# *ASC SAFE HARBOR ISSUES*

Overview and Application to Physician/Hospital  
Joint Ventures

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# *ASC Joint Venture Legal Issues*

- ❑ Anti-kickback Statute
  - Safe harbor compliance
- ❑ Other issues include:
  - Stark Law
  - Hospital tax-exempt status if applicable
  - State licensure; anti-self referral laws

# *Anti-kickback Statute-ASC Joint Venture*

- ❑ Anti-kickback Statute is an intent-based statute
- ❑ Prohibits offer, solicitation, payment or receipt of remuneration if intent is to induce referrals of patients or other business paid for in whole or in part by a federal program
- ❑ For ASC, primary issue is whether return on investment constitutes an improper inducement for referral
- ❑ Contracts with referral sources or recipients can also raise Anti-kickback Statute issues if remuneration is not fair market value or is referral-based

# *OIG Fraud Alert and Recent Guidance on Joint Ventures*

- ❑ OIG has identified suspect features of a joint venture, including:
  - Investors chosen because they are referral sources
  - Disproportionate investment opportunity to physicians expected to make more referrals
  - Minimal capital investment by physicians, with extraordinary returns relative to risk
  - Tracking of referrals by venture
  - Loss of investment interests of physicians threatened if referral targets not met
  - Physicians able to borrow their capital investments from other venture participant(s)

# *OIG Safe Harbors-ASC Joint Ventures*

- ❑ OIG has published safe harbors to protect certain ventures
- ❑ Safe harbor protection available for ASCs if certain factors met
  - Intent of safe harbor is to protect investment by physicians who use ASC as an extension of practice
- ❑ Ventures not covered by safe harbor are not “per se” illegal, but must be analyzed based on the facts and circumstances of the particular venture

# *ASC Safe Harbor*

## □ Permitted investors:

- Physicians meeting “one-third” tests for physician investors
- Group practice solely composed of individual physicians who qualify to invest individually (exception only applies to group practices as defined in Stark Law and not to other investment entities)
- Physicians and others:
  - not employed by the entity or an investor
  - not in a position to provide items or services to the entity or investors
  - not in a position to make or influence referrals directly or indirectly to the entity or any of its investors

# *ASC Safe Harbor “One-third” Tests*

- ❑ At least one-third of annual practice income is from ASC-type procedures (“one-third income test”)
- ❑ **If a multi-specialty ASC**, at least one-third of each physician investor’s ASC-type procedures must be performed at the venture (“one-third procedures test”)
  - One-third procedures test does not apply to single-specialty ASC
- ❑ Safe harbors do not specify how to ensure compliance
  - Recommend annual representation by investors, with board discretion to require documentation of compliance

# *ASC Safe Harbor – Hospital Owner*

- Hospitals that are not in a position to make or influence referrals also permitted investors under safe harbor
  - Arguably, most hospitals are in a position to influence referrals of employed and independent contractor physicians and may be able to influence referrals of medical staff physicians
  - OIG advisory opinions identify factors reducing risk:
    - Hospital does not require or encourage affiliated physicians to refer to venture or investors
    - Hospital does not track referrals by affiliated physicians to venture or investors
    - Hospital compensation to affiliated physicians is fair market value and not related to referrals to venture or investors or business generated
    - Affiliated physicians informed annually of these measures

# *ASC Safe Harbor*

- Additional safe harbor requirements:
  - Patients referred by an investor must be fully informed of investor's interest
  - Operating and recovery room space must be dedicated exclusively to ASC (thus, other services cannot be provided within the ASC)
  - No loans of investment funds (or loan guarantees of such loans) from entity or other investors
    - Loans to Company not prohibited but must be on reasonable terms
    - Guarantees of Company debt should be pro rata or supported by adequate consideration
  - Investment terms cannot be related to volume or value of referrals
    - No obligation to offer to any qualified investor or to offer the same number of units to each investor, but differing offers cannot be based on referrals

# *ASC Safe Harbor*

- Additional safe harbor requirements:
  - Investment returns must be directly proportional to the amount of the capital investment (regulation does not contemplate investment at different times for different prices, but Advisory Opinion 01-21 viewed subsequent purchases at fair market value as reasonable)
  - No discrimination against governmental program beneficiaries by entity or any physician investor
    - Investors not required to accept new patients, but decisions must be made on a nondiscriminatory basis
  - Governmental program ancillary services must be directly and integrally related to primary procedures performed at the ASC and cannot be separately billed
    - Thus, ASC cannot provide separate imaging/independent diagnostic testing facility services

# *ASC Safe Harbor*

- ❑ Full compliance protects ownership in venture from Anti-kickback Statute challenge. Caveats:
  - A venture with subsequent investors purchasing at fair market value will fail to comply due to requirement that investment returns be directly proportional to the amount of the capital investment (Advisory Opinion 01-21 viewed subsequent purchases at fair market value as reasonable, but outside safe harbor)
  - Unclear when a hospital investor will be viewed as “in a position to make or influence referrals”
  - Investment through entity other than group practice (within Stark Law definition) made up solely of physicians who could invest individually is outside safe harbor
  - Investment by anesthesiologists generally outside safe harbor

# *ASC Safe Harbor*

- ❑ Substantial compliance is advisable to reduce Anti-kickback Statute risk but a venture not fully within safe harbor may be subject to Anti-kickback Statute challenge if it removes investors not meeting one-third procedures test
- ❑ In non-safe harbored joint venture, degree of risk presented by physician investors depends on extent to which they are likely to refer patients to other physicians who refer those patients to the venture

# *Anesthesiologists*

- ❑ Investment by anesthesiologists who are in a position to provide items or services to the entity or any of its investors takes the venture out of the ASC safe harbor
- ❑ Such investment generally does not in and of itself result in material risk, but because it takes the venture out of the safe harbor, it increases the risk of removing other investors for failing to meet safe harbor requirements
- ❑ Alternative: contract with anesthesiologists for clinical management services for fair market value compensation but do not permit them to invest unless they meet the requirements of the one-third tests (e.g. due to substantial pain practice)

# *Removal of Investors*

- ❑ Investors in safe-harbored entity may want to remove investors who do meet the one-third procedures test but do not refer as much as other investors
  - Such removal presents Anti-kickback Statute and litigation risk
- ❑ Investors in non-safe-harbored entity may wish to remove investors who do not refer as much as other investors
  - Such removal presents Anti-kickback Statute and litigation risk

# *Removal of Investors*

- ❑ Members may want to remove an investor for reasons unrelated to referrals
- ❑ Members may want venture documents to provide for removal of members who retire or otherwise cease to be in a position to perform services at the ASC
  - Defensible as ensuring participation in the ASC governance and management

# *Removal of Investors*

- ❑ Risks of removing investors:
  - Compliance risk if venture is not fully within safe harbor
  - Litigation risk--investors may assert that their removal was in violation of Anti-kickback Statute
    - Litigation risk increased if removal is at discretion of entity or members rather than automatic pursuant to agreed-upon terms
    - Litigation risk increased if removed investors receive less than fair market value
- ❑ Evaluation of these risks affected by a number of factors including
  - Whether venture fully complies with safe harbor
  - Whether there is evidence that physicians were removed due to insufficient referrals
  - Whether similarly situated investors in the venture who are not removed make referrals to other investors of patients likely to be treated in the ASC

# *Removal of Investors*

- ❑ Safest approach is full compliance with safe harbor
- ❑ Issues with full compliance:
  - Full compliance may not be possible if additional investors brought in after initial offering due to technical flaw in drafting of safe harbor
  - Safe harbor requires that hospital participant “not be in a position to make or influence referrals directly or indirectly to any investor or the entity”
  - Venture may fail to meet requirements despite best efforts (e.g., investors do not calculate percentage tests correctly)

# *Removal of Investors*

- ❑ Alternative approach is to require that one-third procedures test be met unless the board obtains an opinion of counsel that permitting the investor to remain does not result in a material compliance risk
  - Decision as to whether to seek an opinion should be at board's sole discretion
- ❑ Risk to this approach
  - Government may take the position that removal of an investor for failing to meet the one-third procedures test is impermissible if safe harbor not fully met (thus, legal opinion will not be a clean opinion)

# *Removal of Investors*

- ❑ Alternative--Do not require compliance with one-third procedures test, but require that physicians perform a minimum number of cases at the facility for credentialing purposes (probably a lower number than desired)
- ❑ Physician not meeting credentialing standard removed unless board obtains opinion of counsel that not removing such physician does not present a material compliance risk
  - Decision as to whether to obtain opinion should be at board's sole discretion

# *Automatic Removal Provisions*

## □ Examples

- Retirement/cease to be in a position to practice
  - Arguably, automatic removal when an investor ceases to be in a position to perform services is consistent with “extension of practice” rationale for ASC safe harbor and ensures that investors will be involved in governance/management of entity
- Competition
  - Arguably, not based on referrals, but on fiduciary duty to venture
  - Noncompetition agreement permitted in Advisory Opinion 03-2 (remedy for breach not addressed)
- Failure to meet one-third income test
  - Defensible as a compliance measure

# *Recommendations*

- ❑ If risk-adverse, comply fully with safe harbor
- ❑ Otherwise, be selective as to who is admitted, since removing investors from a non-safe harbored venture involves Anti-kickback Statute and litigation risk

# *Considerations Relevant to Whether to Combine ASCs in Single Entity*

- ❑ Anti-kickback Statute Safe Harbor Compliance - safe harbor contemplates single-entity ASC
  - More than one ASC in single entity risky if more than insubstantial cross-referrals between investors
- ❑ Ownership
  - Multiple entities gives flexibility to have different ownership or ownership proportions
- ❑ Governance
  - Multiple entities allows different governance at each site

# *Considerations Relevant to Whether to Combine ASCs in Single Entity*

## Economic integration

- Single entity permits integration of economic interests in entities

## Efficiencies

- Single entity may allow for management/operational efficiencies (e.g., consolidated operations, shared resources, group purchasing, insurance costs)

## Shared Risk and Liabilities

- Use of single entity means risks at each site would affect overall venture

# *Safe Harbor Analysis of Multiple ASCs in One LLC*

- ❑ Safe harbor contemplates that the investment entity would own a single ASC and does not address the concept of multiple ASCs in one entity
- ❑ OIG may take position that physician investment in an entity that owns and operates more than one multi-specialty ASC does not meet the safe harbor if a physician investor does not meet the one-third procedures test with respect to each ASC in the venture
- ❑ If not within the safe harbor, degree of Anti-kickback Statute risk depends on the extent of cross-referrals among physician investors (i.e. if a physician investor may refer ASC procedures to another physician investor)