OIG Approves Sole Physician’s Investment Interest In Single-Specialty ASC

On June 21 the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) released an Advisory Opinion approving a proposed investment interest by a single physician in an ambulatory surgical center (ASC) where only endoscopic procedures were performed (the Proposed Arrangement). The OIG determined that the Proposed Arrangement, while subject to the Federal Anti-kickback Statute, fully satisfied the safe harbor for investment interests in single-specialty ASCs and thus posed little threat of fraud and abuse. As such, imposition of civil monetary or exclusion sanctions was unwarranted. The Advisory Opinion was limited solely to the physician’s investment interest in the ASC and not to any other financial arrangement of the physician. The OIG’s determination was based largely on certifications by the physician that provisions of the safe harbor were met.

Recommendations for Health Care Entities

This Advisory Opinion involves a straightforward application of one of the newer safe harbors for ASCs promulgated by the OIG in November 1999. The single-specialty ASC safe harbor (applicable when all of the investors practice in the same medical specialty) requires compliance with eight criteria designed to protect Federal health care programs and their beneficiaries. If all of the criteria are fully satisfied, no sanctions will be imposed under the Federal Anti-Kickback Statute.

Here, the Proposed Arrangement was structured to meet most of the financial requirements of the safe harbor (e.g., physician income, profit/loss distribution and terms of investment requirements). The OIG conducted little analysis of the Proposed Arrangement beyond acknowledging that the safe harbor appeared to be met by the physician’s certifications with respect to other financial and operational safe harbor requirements (e.g., space, nondiscrimination and provision of service operational requirements and financial requirements related to disclosure of the interest and use of loans). Health care entities wishing to make investments in ASCs should consult with counsel to determine whether such investments can be structured to satisfy all of the requirements of the ASC safe harbor and whether all necessary certifications can be made.

Strict compliance with all elements of the safe harbor is required for safe harbor protection.
Single-Specialty ASC Safe Harbor

The safe harbor for single-specialty ASCs provides that “remuneration” under the Federal Anti-kickback Statute does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as:

- the investment entity is a certified ASC whose operating and recovery room space is dedicated exclusively to the ASC;
- patients referred to the investment entity by an investor are fully informed of the investor’s investment interest;
- if all of the investors are physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients, all of the following six standards must be met:
  - the terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity;
  - at least one-third 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 surgeon’s performance of procedures;
  - the entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest;
  - the amount of payment to an investor in return for the investment must be directly proportional to the amount of capital investment (including the fair market value of any pre-operations services rendered) of that investor;
  - all ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs;
  - the entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

Under this safe harbor, “procedures” means any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers in accordance with regulations issued by HHS.

The Proposed Arrangement

With respect to the Proposed Arrangement, the physician derives at least one-third of his medical practice income from endoscopic procedures he performs within his office or at one of the local hospitals. The physician also has certified that these endoscopic procedures meet the definition of “procedures” set forth in the ASC safe harbor.

Under the Proposed Arrangement, the physician will be the sole investor in and owner of a new, freestanding, Medicare-certified, single-specialty (in endoscopy) ASC. The physician will perform endoscopic procedures at the ASC and the ASC will bill and collect facility fees related to such procedures. As ASC’s sole owner, the physician will receive all distributions of profits and losses. With respect to the ASC, the physician has certified that:

- ASC’s operating and recovery room space will be dedicated exclusively to ASC;
- All ancillary services for Federal health care program beneficiaries performed at ASC will be directly and integrally related to primary procedures performed at ASC and none will be billed separately to Federal health care programs; and
ASC and the physician will treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

The physician will also continue to practice medicine as a member of a two-person group practice (Group Practice) equally owned by the physician and another physician. Group Practice will continue to bill and collect the physician’s professional fees, including those for endoscopic procedures performed at ASC. The physician has certified that professional fees for procedures performed at ASC will be distributed solely to the physician.

The physician also has certified that:

- Patients referred to ASC by the physician will be fully informed of the physician’s investment interest; and
- Neither ASC, Group Practice or anyone acting on their behalf has or will loan funds to or guarantee a loan for the physician if any part of such loan will be used to obtain his investment interest in ASC.

**ASC Safe Harbor Satisfied**

The broad language of the Federal Anti-kickback Statute prohibits any remuneration offered, paid, solicited or received for the purpose of inducing or rewarding referrals of items or services reimbursable under Federal health care programs. Arrangements that meet safe harbors, however, are not subject to the Anti-kickback prohibition because such arrangements are not likely to result in fraud and abuse. Strict compliance with all elements of the safe harbor is required for safe harbor protection.

Here, the OIG offered little analysis, simply concluding that, based upon the physician’s certifications, the Proposed Arrangement fit within the safe harbor for single-specialty ASCs, making sanctions under the Federal Anti-kickback Statute unnecessary.

**Conclusion**

Given its strict compliance with the safe harbor for single-specialty ASCs, the OIG determined that the Proposed Arrangement presented low Anti-kickback risk. As such, it declined to impose civil monetary penalties or exclusion sanctions on the physician.

**Endnotes**

3. This safe harbor also applies to group practices composed exclusively of such single-specialty physicians and to investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors. See 42 CFR 1001.952(r)(2).
5. 42 CFR 1001.952(r)(5).
6. 42 USC 1320a-7b(b).
If you have any questions about this Client Alert, please contact any of the following attorneys.

**CHICAGO**
James A. Cherney
(312) 876-7700

**LOS ANGELES**
Daniel K. Settelmayer
L. Susan McGinnis
(213) 485-1234

**SAN DIEGO**
Katherine A. Lauer
(619) 236-1234

**SAN FRANCISCO/SILICON VALLEY**
Paul R. DeMuro
Jerry Peters
(415) 391-0600

**WASHINGTON, D.C.**
Stuart S. Kurlander
(202) 637-2200

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