Imagine the following scenario. It was a big day for “XYZ Health System.” The organization was opening the doors to its new multimillion-dollar joint-venture ambulatory surgical center (ASC). All of the executives who had played important roles in forming the joint venture were present—XYZ’s CEO, CFO, COO, and CMO, and the physician leaders of XYZ’s partner multispecialty physician group—and all were basking in the glory of their achievement. Soon after, however, an agent from the HHS Office of Inspector General (OIG) arrives unannounced to speak with XYZ’s CEO, stating that the ASC, as currently structured, is in violation of federal fraud and abuse law and will be the subject of an enforcement proceeding.

OK, this scenario is admittedly far-fetched. But if your organization were in the advanced stages of developing a similar joint venture with physicians, or already had commenced operating such a venture, and the OIG declared your arrangement illegal, it wouldn’t much matter how you received the news. It would still be a major setback.

The OIG’s Guidance
As part of their business strategies, hospitals nationwide are actively considering or pursuing joint ventures with physicians to develop ASCs. To ensure that these jointly owned ASCs comply with federal fraud and abuse law, hospital executives must structure the arrangements in accordance with the ASC safe harbor, adopted by the OIG in 1999, and additional guidance issued by the OIG since then.
The ASC safe harbor comprises 13 requirements (see the sidebar on the following page). Three recent OIG advisory opinions provide insight into how the OIG might rule on a joint-venture ASC’s compliance with these safe-harbor requirements. These pronouncements suggest that the agency will be flexible in determining whether a jointly owned ASC has met some of these requirements, while it will apply more strict standards for compliance with others.

In each opinion, the OIG analyzed a proposed arrangement that failed to satisfy all of the requirements. The OIG approved two of the proposed arrangements, demonstrating flexibility in applying certain requirements of the ASC safe harbor. In both opinions, the agency found that the risk for fraud and abuse in such arrangements was sufficiently mitigated by built-in safeguards. The OIG issued an unfavorable ruling in the third advisory opinion.

**November 2001 Opinion**

In its first advisory opinion applying the ASC safe harbor, issued in November 2001, the OIG analyzed a proposed hospital-physician ASC that raised a concern regarding compliance with the safe-harbor requirement that investment terms be unrelated to referrals (number 4). Under the proposed arrangement, the price per unit of interest in the ASC varied among the investors, and accordingly, each investor’s return would not necessarily be proportional to the amount of their investment.

Nevertheless, the OIG issued a favorable ruling, finding that the disparity in the purchase price paid by the investors for each unit of interest was the result of the timing of such purchases and appreciation in the value of the ASC and, therefore, was not related to actual or expected volume or value of referrals generated by investors.

**January 2003 Opinion**

In its second favorable advisory opinion, issued in January 2003, the OIG considered a proposed ASC that raised a concern with respect to compliance with the safe-harbor requirement regarding physician owners (number 3). The physicians retained their interest in the ASC through a holding company, rather than directly or through their group practice. The OIG indicated that it is generally concerned with intermediate investment entities potentially being used to redirect revenues to reward referrals, because such an arrangement could effectively circumvent the safe-harbor requirement that distributions to owners be proportional to their ownership interest and capital investment (number 8).

Nonetheless, the OIG approved the arrangement, concluding that the holding company was being operated merely as a pass-through entity, and that the physicians’ return on their investment would have been identical even if the physician ownership were held directly by physicians or their group practice.

In the January 2003 advisory opinion, the OIG also addressed the question of whether the proposed arrangement met the physician-income safe-harbor requirement (number 5). Eight of the 16 physician owners (all orthopedic surgeons) did not derive at least one-third of their medical practice income from the performance of Medicare-covered ASC procedures. The OIG, however, allowed the arrangement because the eight physicians did derive one-third of their practice income from performing procedures that can be conducted in either an ASC or a hospital operating room. The OIG reasoned that because the physicians routinely performed procedures that required at least an ASC level of support, they were more likely to be users of the ASC than passive referral sources to the ASC.

**Common Findings**

In both of these favorable opinions, the OIG also discussed the safe-harbor requirement regarding use of hospital space, equipment, or services (number 11). In both proposals, the ASCs had service agreements with the hospital that did not satisfy this requirement: rather than having a minimum term of one year, their fee terms could be renegotiated, and they could be terminated for cause at any time.

In approving the proposed arrangements despite this shortcoming, the OIG reasoned that the termination provisions were strictly limited to certain requirements.
13 SAFE-HARBOR REQUIREMENTS FOR HOSPITAL-PHYSICIAN JOINT-VENTURE ASCs

1 Medicare-certified; exclusive space. The ASC must be Medicare-certified, and its operating room and recovery room space must be dedicated exclusively to the ASC.

2 Notice to patients. Patients referred to the ASC by a physician-owner must be informed of the referring physician’s ownership interest in the ASC.

3 Physician owners. They must be (a) physicians in a position to refer patients directly to the ASC and perform procedures at the ASC on such referred patients; (b) group practices composed solely of such physicians; or (c) physicians who are not employed by the ASC or any of its owners, and who are not in a position to make or influence referrals to or provide services to the ASC or any of its owners.

4 Investment terms. Terms on which ownership interests in the ASC are offered to investors must not relate to the previous or expected volume of referrals, services provided, or business otherwise generated from the investor to the ASC.

5 Physician income. At least one-third of each physician-owner’s medical practice income from all sources for the previous fiscal year or 12-month period must have been derived from the physician’s performance of procedures that Medicare covers if performed in an ASC.

6 Proportion of procedures performed at ASC (for multispecialty ASCs only). If the physician-owners of the ASC are not all general surgeons, not all surgeons practicing the same surgical specialty, or not all engaged in the same medical practice specialty, then at least one-third of all Medicare-covered ASC procedures performed by each physician-owner during each fiscal year or 12-month period must be performed at the ASC.

7 Loans to purchase ownership interest. Neither the ASC nor any of its owners may loan funds to, nor guarantee a loan for, another owner if any part of the loan will be used for the purchase of an ownership interest in the ASC. This means that the ASC cannot accept installment payments over time from an owner, and cannot offset future distributions from the ASC against an owner’s buy-in amount.

8 Return on investment relative to capital investment. Payments by the ASC to its hospital and physician-owners in return for their investment in the ASC (dividends, distributions, etc.) must be directly proportional to the amount of capital investment to the ASC (including the fair market value of any preoperational services rendered) made by each owner.

9 Ancillary services. All ancillary services performed at the ASC for federal healthcare program beneficiaries must directly and integrally relate to primary procedures performed at the ASC and may not be separately billed to a federal healthcare program.

10 Nondiscriminatory treatment. The ASC and its hospital and physician-owners must treat patients covered by federal healthcare programs in a nondiscriminatory manner.

11 Use of hospital space, equipment, or services. The ASC may not use space in the hospital (such as operating and recovery rooms), hospital equipment, or hospital services without entering into leases and management services contracts that comply with other relevant safe harbors. These safe harbors generally require that (a) the arrangements be in writing and be for a term of at least one year, (b) the aggregate compensation over the term be set in advance and be consistent with fair market value in an arms-length transaction, and (c) the services or items provided be legitimate and delivered on commercially reasonable terms.

12 Hospital cost report. The hospital owner may not include on its cost report, or on any other claim for payment from a federal healthcare program, any costs associated with the ASC (unless otherwise required by rules governing federal healthcare programs).

13 Hospital referrals. The hospital may not be in a position to make or influence referrals, directly or indirectly, to the ASC or any of its physician-owners.

In both favorable opinions, the OIG also showed some latitude in determining whether the arrangements met the safe-harbor requirement regarding hospital referrals to the ASC (number 13). In each case, the hospital was in a position to influence referrals to the ASC and its physician-owners. Nonetheless, the OIG approved the arrangements.
because the following safeguards were in place:

- Physicians employed by the hospital would not make referrals directly to the ASC (but could refer to physicians who use the ASC).
- The hospital would not require or encourage any physicians on its medical staff to refer patients to the ASC or its physician-owners, and the hospital would not track such referrals.
- Compensation paid by the hospital to any physicians would not be directly or indirectly related to the volume or value of any referrals made to the ASC or its physician-owners.
- The hospital agreed to notify physicians on its medical staff of these safeguards against fraud and abuse annually.

February 2003 Opinion

In February 2003, the OIG evaluated a proposed ASC joint venture involving a hospital and a multispecialty group composed of surgeons and nonsurgeons. The OIG rejected the proposal, asserting that it violated the physician-owner safe-harbor requirement (number 3). The OIG reasoned that because nonsurgeons, such as family practitioners and pediatricians, constituted a majority of physician-investors in the ASC, there was a greater likelihood of cross-specialty referrals for services performed at the ASC.

Thus, the nonsurgeons could potentially profit “passively” from their referrals to the ASC, or to the surgeons in the group performing procedures at the ASC, through their receipt of dividends or other distributions as owners in the venture. The OIG noted that this kind of profit is precisely the type of “kickback” that federal fraud and abuse law prohibits. This ruling suggests that the OIG will not be flexible regarding the requirement that physician-owners of ASCs be surgeons who personally use the ASCs in connection with their medical practices.

The Key to Compliance

No hospital should ever enter a partnership with physicians to develop a jointly owned ASC without taking the necessary steps to comply with the ASC safe harbor. The OIG’s advisory opinions regarding such ASCs provide helpful guidance on how to proceed by indicating when the OIG will be strict and when it will allow some leeway in determining the arrangement’s compliance with the safe harbor.

Following this guidance, however, will only minimize, rather than eliminate, the risk that your joint-venture ASC may be noncompliant. The OIG’s application of the requirements may change, or the agency may disapprove of arrangements that present different circumstances from those discussed in the three advisory opinions issued to date. You should therefore remain alert to further OIG guidance and potential legislative and regulatory changes. By taking into account these and other considerations, you will ensure your organization has its best chance of achieving its financial and strategic objectives in the most compliant manner possible.

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