National Fraud and Abuse Compliance Update

Experts see increased enforcement and more whistle-blowers **BY SAHELY MUKERJI**

Although the laws have not changed recently, changes within the ASC industry are now raising more concerns related to fraud and abuse in federal health care programs than before. "Enforcement has been stepped up and there are more whistle-blowers," says Gary Herschman, chair of Health Care Practice Group at Sills Cummis & Gross in Newark, New Jersey. "It is becoming more and more important to be aware and play by the rules."

One operational area raising increased fraud and abuse concerns for ASCs is increasing consolidation in the health care delivery system, says Emily R. Studebaker, attorney at Garvey Schubert Barer in Seattle, Washington. "A case in point is the changing ownership landscape of ASCs, e.g., ASCs increasingly seeking financial partners and other types of financial relationships with physicians. Under these new arrangements, fraud and abuse laws, such as the federal Anti-Kickback Statute, need to be considered carefully."

Another primary area of concern is anesthesia, Studebaker says. "On May 25, 2012, the Office of the Inspector General (OIG) issued the Advisory Opinion, 12-06, that addressed the potential regulatory implications of certain business arrangements between ASCs and anesthesiology providers under the federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b). Before an ASC pursues a business arrangement that allows it to capture a portion of the proceeds from anesthesiology services provided at an ASC, it should carefully consider the legal implications."

Changing Ownership

Physician ownership in an ASC will comply with the federal anti-kickback safe harbor only when the terms on which the investment interest is offered are not related to referrals or other business generated by the physician owner, says Michael F. Schaff, chair of Corporate & Health Care Departments at Wilentz, Goldman & Spitzer in Woodbridge, New Jersey. "Currently, with increased competition, there is pressure to offer ownership to surgeons at an attractive buy-in price. In order to avoid risk of an Anti-Kickback Statute violation, the purchase and sale of ownership in an ASC should be priced at fair market value. Offering ownership interests at a reduced price may be construed as offering the interest based on the volume or value of the physician's referrals."

It is important for the owners of the ASC to document the value of their center when offering shares for sale to new investors and when redeeming the interest of existing owners, Schaff emphasizes. "Obtaining a third-party valuation provides evidence of the fair market value of the center. In the long

run, it is worth the effort and expense to document the value with as much detail as possible to avoid scrutiny under the anti-kickback statute."

The anti-kickback safe harbors for ownership of an ASC include the infamous "1/3 tests," explains Schaff, which require a physician investor to (1) derive at least 1/3 of his or her medical practice income from all sources for the previous 12-month period from the performance of ASC procedures; and (2) in the case of multi-specialty ASCs, perform at least 1/3 of his or her ASC procedures for the previous 12-month period at that ASC.

Often, an ASC will want to redeem the ownership of a physician who is not meeting the safe harbor, he says. "There are a number of considerations in determining whether such redemption is

appropriate, including whether the '1/3 tests' have been consistently applied, if a physician's specialty is unable to meet the '1/3 tests,' and the ASC's true intent in enforcing the safe harbor. Clearly, termination of a physician's ownership for failure to meet the '1/3 tests' should be to ensure compliance with the safe harbor and not to penalize a physician for lack of referrals."

ASCs should also be wary of business arrangements with physician owned distributorships (PODS), he advises. "A relationship between an ASC and a POD owned by an ASC investor is subject to heightened scrutiny by the OIG under the federal Anti-Kickback Statute. The OIG has provided significant guidance on the substantial risk of fraud and abuse arising from physician ownership of entities to which they refer, including a 1989 Special Fraud Alert on Joint Venture Arrangements."

More recently, in March, 2013, the OIG issued a Special Fraud Alert on PODs. The 2013 Fraud Alert warns that PODs are inherently suspect and

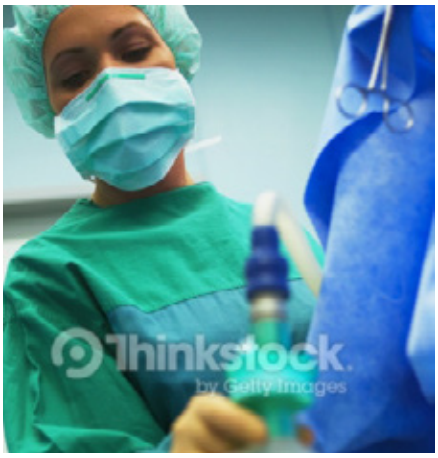
discusses the specific attributes and practices that it considers potentially unlawful. "In a typical suspect POD arrangement, physician investors in a medical device company are in a position to control the choice of medical devices to be used for their patients," Schaff says. "An example of a suspect characteristic, according to OIG, would be that the POD owners are the sole, or nearly the sole, users of the products. Business arrangements with PODs create a strong potential for a fraud and abuse investigation under the Anti-Kickback Statute and should therefore be reviewed carefully with legal counsel."

Anesthesia

The Anti-Kickback Statute 42 U.S.C. §1320a-7b(b) prohibits knowingly and willfully offering, paying, soliciting or receiving any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program, Studebaker says. "The 'knowingly and willfully' element may be satisfied if one purpose of the remuneration is to induce referrals. 'Remuneration' includes the transfer of anything of value in cash or kind directly or indirectly, overtly or covertly, such as bribes or rebates."

An anesthesiologist services group that was providing anesthesia services on an exclusive basis to several physician-owned, Medicare certified ASCs requested the Advisory Opinion 12-06. In that opinion, the OIG indicated that the two proposed business arrangements between the group and the centers would violate the Anti-Kickback Statute.

Under the first arrangement, the group would continue to serve as the centers' exclusive anesthesia provider, but would pay a new per-patient management services fee to the centers for all patients other than federal health care beneficiaries, Studebaker explains. Under the second arrangement, the centers' physician-owners would establish



separate companies, or subsidiaries, that would provide and bill for all anesthesia services performed at the centers. The subsidiaries would hire the group as an independent contractor to provide its management and professional anesthesiology services at a negotiated rate. Any of the subsidiaries' profits would be distributed to the physician-owners of the centers.

"Because both proposed arrangements involve prohibited remuneration, the OIG found that they would violate the Anti-Kickback Statute and the OIG could impose administrative sanctions," Studebaker says. "Violations of the statute include $25,000 fines, 5 years imprisonment, and exclusion from federal health care programs. The government could also seek civil monetary penalties and penalties under the False Claims Act."

An Advisory Opinion is issued only to the requestor of the opinion, and it is limited in scope to the specific arrangement described in the opinion, Studebaker says. "While an Advisory Opinion cannot be relied upon by any individual or entity other than the requestor, it offers some guidance regarding the OIG's approach to comparable arrangements."

The OIG is continuing to scrutinize joint venture relationships between anesthesiology providers and ASCs. "The costs of violating the Anti-Kickback Statute are high, and legal counsel should be sought prior to pursuing new ventures to capture part of the market for anesthesiology services provided in ASCs," Studebaker summarizes.

Other Enforcement Areas

In its 2014 work plan, Herschman says, the OIG also outlined another area that raises enforcement concerns: physician place-of-service coding errors. According to the work plan, the OIG will review physicians' coding on Medicare Part B claims for services performed in ASCs to determine whether they properly coded the places of service. The rationale behind this increased scrutiny is that prior OIG reviews determined that physicians did not always correctly code non-facility places of service on Part B claims submitted to and paid by Medicare contractors.

Herschman also recommends that ASCs conduct regular compliance reviews to ensure that all arrangements with physicians are fair market value and otherwise comply with the law, such as leases of space or staff, medical directorships and other administrative positions, and the provision of free or discounted services. For example, an Arizona surgery center recently utilized the OIG self-disclosure protocol when it discovered a potentially problematic lease arrangement in place with a physician who served as an anesthesiologist and medical director at the center. Under the lease arrangement, the physician rented office space at a rate below fair market value, and also was inappropriately provided two employees to staff such office space. After self-disclosing the arrangement, the surgery center agreed to pay $510,179 for allegedly violating Medicare laws prohibiting physician self-referrals and kickbacks. «