

PUBLICATION

OIG Calls PODs "Inherently Suspect" [Ober|Kaler]

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Making its most strongly worded statement to date, the Department of Health and Human Services Office of Inspector General (OIG) issued a Special Fraud Alert on Physician-Owned Entities on March 26, 2013, calling physician-owned distributors (PODs) “inherently suspect” under the federal Antikickback Statute. The OIG describes a number of suspect attributes of PODs and identifies additional factors that may magnify its concerns about them. The OIG also states that the Special Fraud Alert is “not intended to serve as a blueprint for how to structure a lawful POD, as an arrangement may not exhibit any of the ... suspect characteristics and yet still be found to be unlawful.” Significantly, the OIG warns hospitals and ambulatory surgery centers (ASCs) that they may be at risk for purchasing from physician-owned entities in an attempt to maintain or secure referrals from physician-owners of PODs.

The direct and negative tone of the Special Fraud Alert is a departure from the OIG's prior statements on PODs that were both more general and less critical. The OIG cites its 1989 Special Fraud Alert on Joint Venture Arrangements as establishing a long-standing concern about physician investment in entities to which they refer. The OIG also cites its October 6, 2006, letter as recommending close scrutiny of physician investments in medical device manufacturers and distributors.

Although it is well known that the Senate Finance Committee is conducting [an ongoing investigation](#) into the proliferation of various physician-owned entities, it is less clear whether that effort may have pressured the OIG to provide more detailed guidance. Letters were exchanged between the Senate Finance Committee, the OIG, and the Centers for Medicare & Medicaid Services (CMS) in 2011. In letters to CMS and the OIG, the Senate Finance Committee raised concerns about the adequacy of existing guidance on PODs. [The OIG responded](#) that it was studying the issue, but expressed uncertainty about its ability to issue further guidance given the variability of physician-owned entities. As part of its study of PODs, the OIG has requested information from various hospitals regarding their relationships with PODs. This Special Fraud Alert appears to have been issued before the OIG finalized its review of the responses.

The Special Fraud Alert defines PODs as any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices and includes physician-owned entities that “purport” to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation. The OIG notes that the guidance applies regardless of whether the entity is called a POD, a physician-owned company, or something else. The OIG also notes that while the Special Fraud Alert focuses on arrangements involving implantable medical devices because they are typically physician preference items, the same principles apply to other types of physician-owned entities.

The OIG begins its analysis by reiterating its long-standing guidance that the opportunity for a referring physician to earn a profit could constitute illegal remuneration under the Antikickback Statute. The OIG cites three questionable features of physician-investment arrangements: (1) selecting investors because they are in

a position to generate substantial business, (2) requiring investors who cease practicing in the service area to divest their investment, and (3) distributing extraordinary returns compared to the risk.

In a variety of contexts, the OIG cites to seven concerns that the Antikickback Statute is designed to address – namely, additional costs, overutilization, quality of care, access to care, patient's freedom of choice, competition, and professional judgment. In the Special Fraud Alert, the OIG warns that PODs raise four of these concerns – corruption of medical judgment, overutilization, increased costs to federal healthcare programs, and unfair competition.

Citing a prior discussion of the limitations of patient disclosure in the context of the ASC safe harbor, the OIG warns that disclosure to patients of a physician's financial interest in a POD is not sufficient to protect those patients from the dangers of conflicts of interest. In fact, the OIG raises the concern that patient disclosures are often viewed more as a “testimonial,” rather than as a legitimate effort to raise the potential conflict of interest issue.

In stopping short of declaring all PODs unlawful, the OIG acknowledges that the ultimate decision of whether a POD violates the Antikickback Statute depends on the intent of the parties. However, the OIG identifies eight suspect characteristics it associates with PODs:

1. The size of investment offered to physicians varies with expected or actual volume or value of referrals.
2. Distributions are not in proportion to ownership interests or physicians pay different prices for their ownership interests due to the volume or value of devices used by the physician.
3. Physician-owners condition referrals to hospitals or ASCs on the purchase and use of devices from their POD. The OIG recognizes that such pressure may be explicit or implicit and could include exclusive purchase arrangements.
4. Physician-owners are required, pressured, or actively encouraged to refer or are punished for failing to use their POD's devices.
5. The POD retains the right to repurchase the interest of a physician-owner if the physician is unable to refer due to relocation, retirement, or otherwise.
6. The POD is a shell and does not conduct appropriate product evaluations, maintain sufficient inventory, or employ (or contract with) necessary personnel.
7. The POD does not maintain continuous oversight of all distribution functions.
8. Physician-owners fail to disclose or conceal their ownership interest in a POD from hospitals and ASCs that require conflict-of-interest disclosures.

According to the OIG, the presence of any of these suspect characteristics is concerning. As noted above, the OIG also warns that the suspect characteristics are not meant as a blueprint for structuring lawful PODs and that PODs that do not exhibit any of these suspect characteristics may still be unlawful.

The OIG identifies two situations in which its concerns about PODs may be magnified: (1) where the physician-owners are few in number so the volume or value of a physician-owner's referrals tracks the physician-owner's return on investment and (2) where the physician-owners change their behavior either shortly before or after investing in a POD.

Recognizing that some PODs “purport” to design or manufacture devices, the OIG warns that claims of superiority of devices by physician-owners do not necessarily avoid unlawful intent. The OIG is especially concerned about unsubstantiated claims about devices. The OIG cautions that the risk is particularly high for PODs whose devices are used solely by their physician-owners.

In an effort to address both sides of POD arrangements and perhaps to create more pressure for change, the OIG warns hospitals and ASCs that they also may be at risk for purchasing from physician-owned entities, if doing so constitutes an attempt to maintain or secure referrals from the physician-owners of the physician-owned entities.

Comments

In light of the negative views expressed by the OIG in the Special Fraud Alert on Physician-Owned Entities, arrangements involving PODs should be carefully considered. This review should be conducted by the physician-owners of existing PODs, as well as by hospitals and ASCs that currently purchase items, particularly implantable medical devices, from PODs.

As physicians, hospitals, and others re-evaluate existing arrangements, many tough questions will be presented. Should physician-owners sell their interest in PODs? Who will buy their interests and how will they be valued in light of the OIG's position? Should (must?) hospitals immediately terminate arrangements with PODs? What additional due diligence should hospitals conduct on their existing arrangements with PODs? In light of the OIG's statement that the same analysis may apply to other physician-owned entities, should hospitals and ASCs also review their current arrangements with such entities?

Over the years, the OIG has issued numerous Special Fraud Alerts, Special Advisory Bulletins, and other industry guidance. This Special Fraud Alert, however, seems to be different in its scope and tone. Specifically, it appears to be considerably more negative and evidences, at least in our view, a clear signal from the OIG that the structure and operation of PODs, as well as arrangements to purchase from PODs, may be subject to significant, and focused, scrutiny going forward.