HINSHAW
& CULBERTSON LLP

Health Law ALERT

OIG Fraud Alert on Physician-Owned Distributorships (PODs)

April 2, 2013

On March 26, 2013, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services issued its "Special Fraud Alert: Physician-Owned Entities" (Alert). The Alert addresses physician-owned distributorships (PODs) that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs). The Alert focuses on the specific attributes and practices of PODs that the OIG believes "produce substantial fraud and abuse risk and pose dangers to patient safety."

Application of the Anti-Kickback Law to PODs

The opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the Anti-Kickback Statute. The Anti-Kickback Statute is violated if even one purpose of the remuneration is to induce such referrals. In the Alert, the OIG notes the following "specific attributes and practices of PODs that . . . produce substantial fraud and abuse risk and pose dangers to patient safety:"

- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
- Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.

- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.

- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.

- The POD does not maintain continuous oversight of all distribution functions.

- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

PODs that exhibit any of these questionable features potentially raise four major concerns typically associated with kickbacks: (1) corruption of medical judgment; (2) overutilization; (3) increased costs to the federal health care programs and beneficiaries; and (4) unfair competition. The OIG stated that

> "the financial incentives PODs offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices."

The OIG is particularly concerned about the presence of such financial incentives in the implantable medical device context because "both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed."

Legal Liability Risk for Hospitals, Ambulatory Surgery Centers, and Other Entities That Do Business With PODs

The OIG recognized that both the provider of a service (a hospital or ASC), and the referral source (the physician investor in the POD), could have liability exposure under the Anti-Kickback Statute. The OIG, when evaluating such arrangements, assesses whether the maintenance or the securing of a referral source is one underlying purpose of the hospital's or the ASC's decisions to purchase devices from the POD. To best protect the interests of those doing business with PODs, competent counsel should assess any current arrangements in light of the OIG guidance.

What Actions Should Be Taken to Ensure Compliance With the OIG Fraud Alert?

Publication of a Fraud Alert generally is a warning that increased investigative and enforcement activity is likely to follow. In the Alert, the OIG acknowledges that

> "the lawfulness of any particular POD under the Anti-Kickback Statue depends on the intent of the parties . . . which may be evidenced by the PODs's characteristics, including the details of its legal structure, its operational safeguards; and the actual

conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations."

Notwithstanding the above, the Alert highlights the OIG's significant fraud and abuse concerns with the POD business model. It documents the OIG's position that such arrangements are highly suspect for fraud and abuse violations and dismisses some common justifications for the business model. According to the OIG, PODs cannot avoid scrutiny by simply structuring themselves around the OIG's guidance because a POD arrangement "may not exhibit any of the above suspect characteristics and yet still be found to be unlawful." Moreover, the OIG indicates that ownership disclosure does not provide sufficient assurance against violation of the Anti-Kickback Statute because patients do not understand "the potential conflict of interest, i.e., the possible effect of financial considerations on the physician's medical judgment." A hospital or ambulatory surgery center should have a rational business purpose for purchasing the medical devices from the POD rather than through alternative means.

There are several steps that should be taken with respect to the Alert and ensuring POD compliance. Physicians who are considering investing in a POD should ask specific questions of the POD owners and get assurances that the POD structure complies with the Alert before investing in the POD. Physician investors who are already part of a POD should consult with competent health care law counsel to reassess their investment interest and to ensure that the POD has been structured in a way that does not include any of the OIG-identified suspect characteristics. Hospitals and ASCs that have relationships with PODs that include referring physicians to their facility should have their legal counsel reassess existing arrangements to make sure the arrangement complies with the federal Anti-Kickback Statute.

For further information, please contact Michael A. Dowell or your regular Hinshaw attorney.
