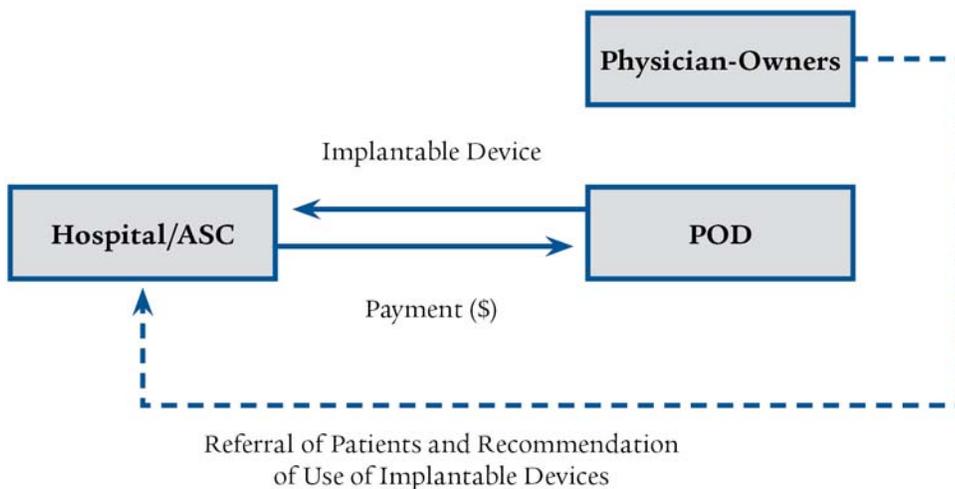


HEALTHCARE LEGAL UPDATE

OIG Issues Special Fraud Alert on Physician-Owned Distributors

On March 26, 2013, the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services issued a Special Fraud Alert on physician-owned entities. The Special Fraud Alert specifically addresses physician-owned distributorships (PODs) that profit from selling implantable medical devices for use on the patients of such physician-owners at hospitals or ambulatory surgical centers (ASCs). OIG previously had issued guidance on this topic on Oct. 6, 2006. In this Special Fraud Alert, OIG stated that it is “particularly concerned” about financial incentives in the implantable medical device context because these types of devices are “physician preference items,” meaning that the physician has the ability to strongly influence the choice of brand and type of device used, rather than having the hospital or ASC make those decisions. OIG specifically notes that disclosure to a patient of the physician’s financial interest in the POD is not sufficient to address fraud and abuse concerns. In fact, OIG in the Special Fraud Alert calls PODs “inherently suspect” under the Anti-Kickback Statute.

Diagram of a Typical POD Structure



The Special Fraud Alert lists a number of suspect characteristics that are warning signs for problematic PODs:

- 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 continual 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.

However, OIG is careful to point out that even if an arrangement does not display any of the above characteristics it still may be found unlawful. Because the investment risk associated with a POD often is minimal, the high rate of return increases the likelihood that one of the purposes of the arrangement is to enable physician-owners of the POD to profit from their ability to control which medical devices are used in their procedures. The OIG expressed heightened concerns in two situations: (1) where the physician-owners of the POD are few in number and (2) where physician-owners alter their practice or referral patterns shortly before or after investing in the POD.

Finally, OIG specifically noted both sides of these arrangements should be wary of potential criminal liability. This includes hospitals and ASCs, as well as the PODs and their physician-owners.

The Special Fraud Alert reiterates much of OIG's past guidance as well as specifically highlights the types of risks that it perceives with these types of arrangements.

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