

To: Fraud and Abuse; Hospitals and Health Systems; and
Physician Organizations Practice Group Members

From: Fraud and Abuse; Hospitals and Health Systems; and
Physician Organizations Practice Group Leaderships

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Summary of OIG Special Fraud Alert on Physician-Owned Entities

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On March 26, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued a [Special Fraud Alert](#) (Alert) entitled, "Physician-Owned Entities" (PODs). This Alert highlights what OIG considers substantial fraud and abuse concerns with such entities under the federal Anti-Kickback Statute (AKS). For purposes of the Alert, OIG defines a POD as "any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices," including "physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation." Significantly, the Alert focuses on arrangements where physician owners of the PODs order "*implantable medical devices*"¹ for services performed on their own patients at hospitals or ambulatory surgical centers (ASCs). However, OIG notes that "the same principles would apply when evaluating arrangements involving other types of physician-owned entities." OIG views PODs as inherently suspect under the AKS because 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 AKS.

In the implantable medical device context, devices are typically "physician preference items," allowing the physician to have a strong influence over the brand and type of device. Therefore, the financial incentives arising from physician investment in PODs may, according to OIG, induce the physicians to: (1) perform more, or more extensive, procedures than are medically necessary; and/or (2) use the device that the POD sells instead of another, potentially more clinically appropriate device. OIG also expressed concern that the financial incentives could lead to corrupted medical judgment, increased healthcare costs, and unfair competition.

The extent to which PODs comply with the AKS depends on the intent of the parties, which may be evidenced by characteristics such as legal structure and operational safeguards. In the Alert, OIG provides the following eight-point bulleted list of suspect POD characteristics that would trigger concern:

- 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 (e.g., by stating or implying that 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 or 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; and
- 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.

Furthermore, OIG's concerns are magnified in cases where physician-owners: (1) are few in number, such that the volume/value of a particular physician owner's recommendations/referrals closely correlates to that physician owner's return on investment; or (2) alter their medical practice shortly before investing in the POD (e.g., by performing more, or more extensive, surgeries, or by switching to using their POD's devices on an exclusive or nearly exclusive basis). Lastly, OIG says it does not believe that disclosure to a patient of the physician's financial interest in a POD is sufficient to address the concerns raised above and encourages the use of the OIG Advisory Opinion process to address such issues.

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³ Emphasis added.

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