OIG Special Fraud Alert

HEALTH CARE CLIENT ALERT
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On March 26, 2013, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") issued a Special Fraud Alert (the "Alert") concerning physician-owned entities 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, like the recently issued final regulations on the Physician Payments Sunshine Act, provides evidence of the increasing scrutiny of physician financial arrangements with medical device companies due to the possibility that such financial arrangements may improperly influence physician ordering practices for devices. (The Sunshine Act final regulations were discussed in another Client Alert which can be accessed here.)

The Alert states that the OIG believes that these entities (commonly referred to as physician-owned distributorships or "PODs") are "inherently suspect." While the term "POD" refers to distributorships, the OIG made clear that it intended the Alert to also address entities that purport to design or manufacture their own devices. The Alert states: "OIG does not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent. The risk of fraud and abuse is particularly high in circumstances when such physicians-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs."

The Alert notes the following "suspect characteristics" of PODs which give the OIG particular concern:

- 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, but are based on 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; for example, by stating or implying their choice of where they will perform surgeries or refer patients is dependent upon purchases from the POD.
- Physician-owners are required, pressured, or actively encouraged by the POD 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 has 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 (e.g., it 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.
- 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, even if the hospital or ASC requires disclosure of such ownership.

The OIG goes on to note that "[t]hese criteria are not intended to serve as a blueprint for how to structure a lawful POD, as an arrangement may not exhibit any of the above suspect characteristics and yet still be found to be unlawful. Other characteristics not listed above may increase the risk of fraud and abuse."

The OIG concludes the Alert by noting that hospitals and ASCs that enter into arrangements with PODs may also be at risk, and that the OIG Advisory Opinion process is always available should parties have concerns about a particular POD arrangement.

For complete copy of the Alert, please click here.