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OIG determines that PODs are “inherently suspect” under the anti-kickback law

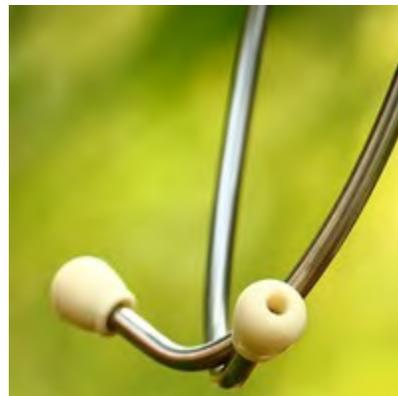
In its strongest statement so far on the subject, the HHS Office of Inspector General (OIG) today released a [Special Fraud Alert](#) which concludes that physician-owned entities that distribute the implantable medical devices ordered by the physician-owners for their own patients (PODs) are “inherently suspect under the [Federal Health Care Programs] anti-kickback statute” (AKS).¹

The document – [Special Fraud Alert: Physician-Owned Entities](#) – reiterates many of OIG’s often-stated concerns with PODs but goes further than any of its prior statements in cautioning that physicians, hospitals, and ASCs incur significant AKS risks when they choose to deal with PODs that exhibit the most basic and commonplace features of the POD business model.²

Of particular significance, the [Special Fraud Alert](#) effectively rebuts the claims of POD promoters that PODs are lawful if they are structured as investment interests where the physician’s return is proportional to the capital invested. OIG reiterates that the test for whether an investment interest violates the AKS is *not* whether it is a “plain vanilla” investment, but whether the intent underlying the arrangement is to induce or reward referrals, and that such intent may be inferred from the POD’s characteristics. OIG emphasizes this point by observing that because the test for an AKS violation is bad intent, “an arrangement may not exhibit any of the [listed] suspect characteristics and yet still be . . . unlawful.”

Inherently suspect characteristics. Although the presence of one or more of the enumerated suspect characteristics is not necessary in order for an AKS violation to exist, the [Special Fraud Alert](#) demonstrates that unlawful intent is present in virtually all PODs by identifying – as “specific attributes and practices of PODs that we believe produce substantial fraud and abuse risk and pose dangers to patient safety” – several inherently suspect characteristics that are common to all PODs:

- *The physician-owners are the POD’s primary customers.*
 - OIG repeats that “selecting investors because they are in a position to generate substantial business for the entity” has long been a “questionable feature.”
 - With regard to POD ownership in particular, OIG identifies the following “suspect characteristics:”
 - “[a] POD that exclusively serves its physician-owners’ patient base”
 - a POD in which “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 the hospital or an ASC does not purchase devices from the POD.”



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- “Investment return” is high or correlates to referrals.
 - “Because the investment risk associated with PODs is often minimal, a high rate of return increases both the likelihood that one purpose of the arrangement is to enable the physician-owners to profit from their ability to dictate the implantable devices to be purchased for their patients and the potential that the physician-owner’s medical judgment will be distorted by financial incentives.”
 - Physician-owners are few in number “such that the volume or value of a particular physician-owner’s recommendations or referrals closely correlates to that physician-owner’s return on investment.”
- POD owners change their practices and product allegiance. Physician-owners “alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs’ devices on an exclusive, or nearly exclusive basis).”
- Product superiority claims do not rebut bad intent. “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 physician-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs.”

The Special Fraud Alert also contains the usual cautions concerning truly egregious features of physician investment ventures, such as:

- size of investment varies with expected or actual volume or value of referrals;
- distributions are directly proportional to referrals instead of to “investment” interests;
- physicians who do not make use of the POD are required to divest and the POD retains the right to repurchase;
- the entity is a shell that does not conduct appropriate product evaluations, maintain or manage sufficient inventory, or have personnel necessary for operations;
- the POD does not maintain oversight of distribution functions;
- POD owners fail to make required disclosures.

However, these features appear to be listed primarily for completeness, and OIG notes that they “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.” Since PODs can easily structure their operations to avoid these egregious features, it is the OIG’s description of the other “inherently suspect” characteristics summarized above that constitutes the real “news” underlying this Special Fraud Alert.

Disclosure not a remedy. Finally, OIG’s observations on the merits of ownership disclosure rebut any contention that the recently-enacted Federal Sunshine law provides any degree of protection for PODs from AKS liability. Quoting its earlier observations on the difficulties with disclosure as a remedy for conflict of interest, OIG states:

. . . disclosure in and of itself does not provide sufficient assurance against fraud and abuse . . . [because] disclosure of financial interest is often part of a testimonial, i.e., a reason why the patient should patronize that facility. Thus, often patients are not put on guard against the potential conflict of interest, i.e., the possible effect of financial considerations on the physician’s medical judgment.

The Special Fraud Alert is the OIG’s most important statement to date of the AKS risks to physicians, hospitals, ASCs, and medical device manufacturers who are tempted to fall prey to the siren song that giving physicians access to easy money for their implant orders, and hospital/ASC referrals, can be done safely. Especially because PODs will have to begin preparing [reports of their financial relationships with physicians](#) starting later this year, the reasons for getting out of the POD business are now stronger than ever.

1) The Special Fraud Alert defines POD broadly to include “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.” *This definition captures physician-owned buy-and-resell or “stocking” distributors, manufacturers, and group purchasing organizations (GPOs).*

2) While the Special Fraud Alert does not refer specifically to the AKS risks to manufacturers that sell to PODs, there is no doubt that the decision to give a referring physician a profit-making opportunity by agreeing to sell through his/her POD implicates the AKS in the same way as the hospital’s or ASC’s decision to purchase through the POD.

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