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Implications of OIG's Special Fraud Alert on current PODs and their customers and suppliers: No more free lunch

As noted in our recent [alert¹](#), OIG's recent [Special Fraud Alert on Physician-Owned Entities²](#) is the strongest statement to date that investing in or doing business with a physician-owned distributor, or POD, is a significant Antikickback law risk, not only for the POD and its physician-investors but for the hospitals and ASCs that purchase from PODs and the manufacturers that sell to them.

Some PODs and their promoters have reacted to the Fraud Alert by attempting to reassure investors, and the hospitals, ASCs, and manufacturers with which the PODs do business, that the Fraud Alert is just predictable "business as usual" from OIG and if a POD was "legal" before the Fraud Alert, it is still legal. Both of these assertions seriously understate the risks to POD participants, suppliers, and customers.

Simply put, by identifying as "inherently suspect" features that are present in all PODs, the Fraud Alert puts to rest any myth that the POD business model can be pursued safely or lawfully.

Not business as usual. First, the very issuance of a Special Fraud Alert is a remarkable event. Including the first [Special Fraud Alert on Join Venture Arrangements³](#) from 1989, OIG has issued only [14 such pronouncements⁴](#) in almost 25 years. This one is even more remarkable in that the OIG's Office of Evaluation and Inspections is currently engaged in a [congressionally-requested study⁵](#) of PODs. To issue this statement before the study of the same subject matter is even concluded is unprecedented. Moreover, every other Special Fraud Alert issued by OIG – beginning with the *Hanlester* case shortly after the issuance of the OIG's original Joint Venture Fraud Alert – has been accompanied by [significant enforcement efforts and penalties.](#)⁶

Second, there is nothing predictable or ordinary about the substance of the new Fraud Alert, which is more forceful and specific than any of OIG's past guidance on physicians benefiting from their passive referrals through "investments." Prior OIG advice identified certain "suspect features," but never before has OIG called a physician-owned business model "inherently suspect" under the AKL. This statement thus represents an escalation in tone that is considerably beyond anything OIG has ever had to say about physician ownership. In addition, no previous pronouncement on physician-ownership has identified specifically suspect features that are so fundamental that they cannot be avoided in operating the business. In particular, the Fraud Alert identifies as inherently suspect the following characteristics *that exist in every POD*:

- The POD offers investment interests only or primarily to physicians who are expected to order or recommend implants sold by the POD
- The POD exclusively or primarily serves its physician-owners' patient base
- POD owners shift to the POD's products on a primary or exclusive basis in connection with joining the POD



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- The physician-owners condition their referrals to hospitals/ASCs on their purchase of implants from the POD by coercion (stating or implying that otherwise they will take their business elsewhere) or promises (stating or implying that they might refer more if the hospital does buy from the POD)
- Investor-physicians are few enough in number that the volume or value of a physician's own referrals correlates closely to investment return

There is no POD that, for example, does not deal nearly exclusively with its physician-owners' patients, and there is no physician-owner who does not make purchasing primarily through the POD a condition of that physician's referrals for implant surgery to the hospital or ASC, either explicitly or by implication.

In sum, OIG's issuance of this Special Fraud Alert is significant, both procedurally and substantively. It is not something that industry can complacently pass off as "predictable" or as "business as usual."

If you thought it was legal before, you can't think that anymore. Because all PODs involve remuneration to the physician in connection with the ordering or recommending of implants, the "legality" of a POD (and its hospital/ASC/manufacture relationships) has always depended simply on whether there was a basis to infer that "one purpose" of the remuneration was to induce the physician to choose the POD's implants, or refer to the hospital/ASC that bought them. Now that OIG has made clear that the intent to induce is inherent in the basic features of a POD's business – for example, either serving the physician-owners' patient base nearly exclusively, or referring implant patients only or primarily to hospitals and ASCs that will buy from the POD, is a basis to infer unlawful intent – the inference of improper intent in every POD (and POD relationship) is inescapable. In other words, if a hospital used to rely on a legal opinion advising that buying from a POD was okay as long as the physician investment return was commensurate with the physician's invested capital (and perhaps some other features were present), that reliance would no longer protect the hospital if it knows that the POD serves only or primarily the physician-owners' patient base.

In the past, some legal advocacy supporting PODs has simply rejected OIG's interpretation of the AKL, and instead relied on an almost 20-year old judicial decision that addressed very different circumstances. (*Hanlester Laboratory Network v. Shalala*, 51 F.3d 1390 (1995)). This reliance has always been misplaced, in that the law requires courts to defer to OIG's interpretation, but never has that reliance been more misplaced than it would be now. To begin with, the *Hanlester* court applied the same legal standard toward physician ownership that OIG continues to apply: remuneration from investment in an entity to which the owner-physician refers federal healthcare program business will violate the AKL if it is intended to induce the physician to make those referrals. Some point to *Hanlester* as support for the proposition that physician-owned entities including PODs do not violate the AKL as long as return is proportional to invested capital rather than to individual referrals, but the case addressed circumstances that have little relevance to PODs. Among other things, *Hanlester* involved physician investment in a clinical laboratory – a regulated provider of healthcare services – and not a middleman supplier, and unlike with PODs there was no indication of overutilization or questions about medical necessity. Perhaps most important, the conduct challenged in *Hanlester* occurred before OIG had ever issued guidance on the application of the AKL to physician investment, and the *Hanlester* court recognized this fact in declining to hold the *Hanlester* defendants responsible for not following that guidance. In contrast, after 20 years of OIG interpretation, and especially after the recent Fraud Alert, industry is now clearly on notice of the factors that will make an AKL violation out of dealings with a POD. Thus, if it ever did, *Hanlester* will no longer provide any significant protection from the AKL for PODs or their customers or suppliers.

The Special Fraud Alert should be viewed as a game-changer for PODs. It is an extraordinary statement, pointing with specificity to the basic features of the POD business model and making clear that these are "inherently suspect" under the AKL, sufficient on their own to show that the arrangement is motivated by unlawful intent. In addition to common sense, explicit OIG guidance now provides open and notorious notice that merely investing in or dealing with a standard POD provides all the evidence that is necessary to find unlawful AKL intent. Whatever situation might have existed before, PODs, their hospital/ASC customers, and their manufacturer suppliers can no longer take comfort in the fact that prior OIG guidance may not have been sufficiently specific to identify their business as inherently suspect, or in legal advice that is inconsistent with OIG's now clearly-stated interpretation of the law.

1) <http://ehoganlovells.com/rv/ff000ed763db64bfee4de524744eb30604348813>.

2) https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.

3) <https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.

4) <https://oig.hhs.gov/compliance/alerts/index.asp>.

5) <http://www.finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c>.

6) <http://www.hoganlovells.com/files/Uploads/Documents/Special%20Fraud%20Alerts%20and%20Related%20Enforcement%20Actions.DOCX>.

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