

OIG Issues Special Fraud Alert on Physician-Owned Distributorships (PODs)

On March 26, 2013, the Office of the Inspector General (“OIG”) of the Department of Health and Human Services issued its first [Special Fraud Alert](#) in three years. The new Alert focuses on physician-owned distributorships (“PODs”), adding significantly to the agency’s limited-scope 2006 [Open Letter](#)—and responding to a [public call](#) from the Senate Finance Committee in 2011 that OIG issue more specific guidance in this area.

Apart from PODs themselves, the Special Fraud Alert is of most direct importance to medical device companies and distributors that have sometimes found themselves at loggerheads with PODs, and to hospitals and ambulatory surgical centers with active or prospective PODs. While focused on PODs, the Special Fraud Alert has passages that will be of interest more broadly throughout the industry.

Physician-Owned Distributorships

The Special Fraud Alert focuses broadly on any physician-owned business that “derives revenue from selling, or arranging for the sale of, implantable medical devices,” including both distributor-model PODs and “physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation.”

OIG’s Analysis

OIG’s analysis is sharp, describing PODs as “inherently suspect under the anti-kickback statute,” and as presenting “four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition.”

Strongly echoing its 1989 Special Fraud Alert (republished in 1994) and 2003 Special Advisory Bulletin on joint ventures, OIG listed “suspect characteristics,” including whether—

- higher volume physicians are offered larger investment opportunities;
- physician owners receive higher returns than non-physician owners;
- physician owners are pressured to use or refer the devices sold by the POD;
- a non-practicing physician must tender his or her shares for repurchase;
- the POD does not maintain continuous oversight of all distribution functions;
- the POD predominantly serves the area in which its physician owners practice;
- physician owners conceal their ownership interest in the POD from others;
- there are relatively few physician owners;
- physicians’ practice patterns change shortly after becoming owners; or
- the primary users of a POD’s products are its owners.

Taking aim at PODs’ market potential, OIG warns that, “because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible ‘kickback’ transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute.” Putting a further point on the issue, OIG explicitly notes the risk that “one purpose” behind a hospital’s or ASC’s “decision to purchase devices from a POD [may be] to maintain or secure referrals from the POD’s physician-owners.”

Applicability beyond PODs and their Customers

While focusing on PODs, the Special Fraud Alert makes some statements that have broader implications in the industry. These statements do not break entirely new ground, but serve as reminders of significant OIG positions. Some of the most prominent are noted below.

First, although nominally focused on PODs, the criteria that OIG listed, together with OIG's other existing guidance in the area, should be part of the regulatory analyses of joint ventures with referral sources generally.

Second, and perhaps most conspicuously, OIG began its analysis by reaffirming that "[l]ongstanding OIG guidance makes clear that the opportunity for a referring physician to earn a profit . . . could constitute illegal remuneration under the anti-kickback statute." The opportunity-as-remuneration analysis continues to find expression in OIG analyses and in enforcement actions, and is an important consideration when assessing relationships with referral sources.

Finally, referring back to 1999 commentary, OIG implied that sunshine, even if a strong disinfectant, has its limitations. Specifically, OIG noted that a physician's disclosure of his or her interest in a POD is insufficient to ameliorate the risks that OIG believes PODs present. Coming on the heels of CMS's final rule implementing the Federal Sunshine Law, this carries the flavor of a warning that disclosure of financial relationships does not suffice to eliminate risks that they otherwise present, and certainly will not foreclose further inquiry.

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If you have questions about this Special Fraud Alert or other issues surrounding relationships among referral sources, please contact the Ropes & Gray attorney who normally advises you.