LASHLY & BAER, P.C.
ATTORNEYS AT LAW

MISSOURI
714 Locust Street
St. Louis, MO 63101-1699
TEL: 314 621.2939
FAX: 314 621.6844
www.lashlybaer.com

ILLINOIS
20 East Main Street
Belleville, IL 62220-1602
TEL: 618 233.5587
By Appointment Only

Physician-Owned Distributorships-

Tread Carefully

By Stuart J. Vogelsmeier, J.D.

The Office of Inspector General (the OIG") issued a Special Fraud Alert on March 26, 2013, addressing physician-owned entities that derive their 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. These entities are frequently called physician-owned distributorships ("PODs"). The Special Fraud Alert includes PODs that design or manufacture their own medical devices or instrumentation. The fact that the OIG issued a Special Fraud Alert on this topic should cause hospitals and physicians to take note. The OIG has only issued six Special Fraud Alerts since 2000.

The OIG has long expressed concerns about the problems that could arise when a referring physician can earn a "profit" related to a referral. The OIG states that questionable features of PODs could include: (1) selecting investors because they are in a position to generate substantial business for the entity, (2) requiring investors who cease practicing in the service area to divest their ownership interest, and (3) distributing extraordinary returns on investment compared to the level of risk involved. PODs that exhibit these questionable features raise four major concerns typically associated with kickbacks: (1) corruption of medical judgment, (2) overutilization, (3) increased costs to Federal health care programs and patients, and (4) unfair competition. The OIG is concerned that the financial incentives that PODs offer to physician-owners may induce the physicians to both perform more procedures (or more extensive procedures) than are medically necessary, and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices. Given that implantable medical devices are considered "physician preference items" (i.e., the brand and type of device used may be made or strongly influenced by the physician, rather than being controlled by the hospital or ambulatory surgery center where the procedures is performed), the OIG believes that the review of PODs is critical.

The OIG's statements are not ambiguous. The OIG stated that "we believe that PODs are inherently suspect under the anti-kickback statute." The OIG is particularly concerned about PODs that exhibit **any** of these characteristics:

- The size of investment offered to each physician varies with the expected volume of devices used by the physician.
- Distributions from the POD are not made in proportion to ownership interest; rather by the expected or actual volume of devices used by physicians.
- The purchase price for the ownership interest in the POD varies by the expected or actual volume of devices used by physicians.
- Physician-owners condition the performance of surgical cases at a hospital or ASC on use of the devices purchased from the POD

- Physician owners are pressured or required to use the device sold by the POD for their patients, and are threatened with financial repercussions for failure to use the POD's devices.
- The POD retains the right to re-purchase the physician-owner's interest because of the physician-owner's failure or inability to refer.
- The POD is a shell entity that does not evaluate products, maintain or manage its own inventory, or maintain personnel to conduct operations.
- The POD does not maintain continuous oversight of all distribution functions.
- Failure of the physician-owners to disclose their ownership interests in the POD.
- Physician owners are few in number, such that the volume or value of a particular physician-owner's referrals closely correlates to the physician-owner's return on investment.
- Physician-owners who alter their medical practice shortly before or after investing in the POD (e.g., performing more surgeries, performing more extensive surgeries, switching to their POD's device on an exclusive or near-exclusive basis).
- The physician-owners of the POD are the sole (or near sole) users of the devices sold by the PODs.

What are the "takeaways" after reading the Special Fraud Alert?

- Hospitals should require disclosure of physicians' financial relationships with device manufacturers or distributors.
- Physicians who have the ability to influence the choice of the implantable device should proceed with extreme caution if approached about investing in a device manufacturer or distributor.

++

Stuart Vogelsmeier is a partner with the St. Louis law firm of Lashly & Baer, P.C. Mr. Vogelsmeier regularly counsels health care providers on issues such as Stark Law and Anti-Kickback Law compliance, corporate structure, employment agreements, joint ventures, adding ancillary services to practices, and asset protection. He can be contacted at (314) 436-8349 or at sjvogels@lashlybaer.com. The firm's website is www.lashlybaer.com.