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The Current Legal Landscape of Physician-Owned Distributorships

By Reesa Handelsman, Esq.
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In general, physician-owned distributorships (PODs) are companies with physician owners or investors that sell implantable medical devices to hospitals and healthcare facilities. The revenue generated by PODs typically derives from orders by the PODs' physician owners, who also use the implantable medical devices for procedures on their own patients at hospitals or healthcare facilities.

Although there are a variety of ways in which POD arrangements are structured, they generally offer physician investors the ability to gain a profit in the form of a return on investment, based on the volume or value of devices sold.

POD proponents assert that this model reduces costs to hospitals because PODs decrease the manufacturer's need for sales representatives and other expenses associated with marketing its products, and therefore the devices can be sold at lower prices. Proponents further argue that the POD model encourages innovation in the industry.

Meanwhile, critics of PODs claim that the arrangements create a conflict of interest with the potential to affect physicians' clinical decision-making by providing physicians financial incentives to use a specific device sold by the physician-investor's POD – thereby risking that the physician may make a profit-driven decision to use a device of inferior quality over another device that may be more medically appropriate under the circumstances. In addition, critics argue that PODs increase healthcare costs through increased utilization of implantable devices and associated surgical procedures. A recent study conducted last year by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) pertaining to PODs in the spinal device context lends support to the argument that PODs may result in increased utilization, and ultimately, increased costs to Medicare.

Recent Activity Surrounding Physician-Owned Distributorships

In a Special Fraud Alert issued by the OIG on March 26, 2013, the OIG reiterated its longstanding position that the opportunity for a referring physician to earn a profit, even through an investment for which the physician generates business, could constitute illegal remuneration under the federal Anti-Kickback Statute. Although the OIG stipulated that lawfulness of any particular POD depends

on the intent of the parties, it indicated that it believes that PODs are “inherently suspect” under the statute, and providing the following “suspect characteristics” of PODs that may evidence unlawful intent:

- The size of the investment offered to physicians varies based on the expected or actual volume of devices they used or will use;
- Distributions are not made in proportion to ownership interest, or physician owners pay different prices for their ownership interests on account of the expected or actual volume or value of devices they used or will use;
- The physician owners condition their referrals to hospitals or healthcare facilities on the purchase of the POD’s devices through coercion or promises;
- Physician owners are required, pressured, or encouraged to refer, recommend, or arrange for the purchase of the POD’s devices, (with threats of) negative repercussions for failing to use the POD’s devices on their patients;
- The POD retains the right to repurchase the physician’s ownership interest for the physician’s failure or inability to refer, recommend, or arrange for the purchase of its devices;
- The POD is a shell entity that does not conduct appropriate evaluations, maintain or manage sufficient inventory, or engage personnel necessary for operations;
- The POD does not maintain continuous oversight of its distribution functions; and
- Physicians actively conceal, or fail to disclose, their ownership interest in the POD when required to disclose conflicts of interest by a hospital or healthcare facility.

Furthermore, the alert notes that the OIG’s concerns are magnified when

- POD physician owners are few in number such that the volume or value of referrals correlates closely to the physician’s return on investment; and
- POD physician owners’ behaviors change after becoming an investor (e.g., increases in the volume or extensiveness of surgeries, or exclusive or near-exclusive use of the POD’s devices).

More recently, in September 2014, the U.S. Department of Justice (DOJ) filed two complaints under the False Claims Act against Reliance Medical Systems, Reliance’s owners, two Reliance PODs, and a neurosurgeon owner in one of the Reliance PODs. The complaints alleged that Reliance, its owners, and the neurosurgeon violated the Anti-Kickback Statute because Reliance’s PODs made payments to physicians to induce their use of the PODs’ implantable devices at the hospitals where the physicians performed their surgeries.

As part of the factual allegations within the complaint, the government alleges that the defendant neurosurgeon used Reliance implants in approximately 90 percent of the spinal fusion surgeries he performed during an eight-month period in 2010, from which he received approximately $265,000 as a return on his initial $5,000 investment. The government further alleged that the surgeon never used Reliance products prior to becoming a physician owner in a Reliance POD. While the complaint does not name the hospitals that purchased the devices as defendants, there still remains a possibility that this may happen as these cases move forward or in other future DOJ complaints relating to PODs.

What Does this Mean for You or Your Entity?

As demonstrated above, investigative and enforcement activity surrounding PODs has been on the rise. As such, entering into a business arrangement with PODs can prove to be a risky venture. First and foremost, the Anti-Kickback Statute assigns criminal liability to parties on both sides of a transaction that violates the statute. Therefore, hospitals and healthcare facilities that enter into arrangements with PODs are more susceptible to risk and may be subject to government investigations and actions.

If a hospital or healthcare facility is deemed to have violated the statute, the entity may be charged under the False Claims Act for submitting false claims to Medicare on behalf of procedures performed by physician owners in PODs, which may result in treble damages up to three times the value of the denied or disallowed claims. In addition, the entity may face claim denials and disallowances, which would result in overpayments that the entity must return to Medicare. Finally, the entity may face a higher risk of patient lawsuits alleging unnecessary or inappropriate procedures were performed by its surgeons.

Mitigating Risks

Hospitals and healthcare facilities are not without strategies for mitigating the risks associated with purchasing devices from PODs. First, hospitals and healthcare facilities can establish more stringent conflict-of-interest policies that identify and address financial relationships between physicians and PODs. With the establishment of the Physician Payment Sunshine Act, physician owners' arrangements with PODs are now more transparent. Effective last month, under the Physician Payment Sunshine Act, device manufacturers and group purchasing organizations are now required to report all physician ownership and investment interests to the Centers for Medicare & Medicaid Services on an annual basis. This information is made readily available to the public. Hospitals and healthcare facilities may also establish more transparent purchasing environments by standardizing product purchases to reduce purchasing preference by physicians. Such standardization will help ensure that purchasing choices are made based on appropriate factors. Lastly, some hospitals and healthcare facilities have even gone so far as to implement policies that prevent contracting with PODs or to implement strict contracting parameters regarding PODs, such as restricting contracting with PODs unless they comply with the "small entity safe harbor" of the Anti-Kickback Statute.

Conclusion

Again, PODs have been the subject an increasing amount of scrutiny in recent years. If current enforcement actions against PODs prove to be fruitful for the federal government, investigations and enforcement against PODs can only be expected to increase as the OIG views these models as creating opportunities for improper inducement between physicians and PODs. If the Anti-Kickback Statute is found to have been violated, the hospital or healthcare facility purchasing from the POD may be subject to liability under the False Claims Act for submitting false claims to Medicare, and might open itself up to additional claim denials and actions to recoup overpayments. In this environment, hospitals and healthcare facilities should take care to mitigate the risks associated with purchasing products from PODs.

About the Author

Reesa Handelsman is a partner at Wachler & Associates, P.C. Ms. Handelsman practices in all areas of healthcare law and devotes a substantial portion of her practice to transactional and regulatory matters. She counsels and represents various health providers nationwide on a variety of healthcare-related issues, including physician in-office ancillary arrangements; physician employment relationships; hospital and physician transactions and contracting.

Ms. Handelsman graduated Cum Laude from the Boston University School of Law.

Contact the Author

rhandelsman@wachler.com

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editor@racmonitor.com