Health Law Alert: OIG Issues Special Fraud Alert on Physician-Owned Distributorships

April 12, 2013

On March 26, 2013, the Department of Health & Human Services Office of Inspector General (OIG) issued its latest in a line of "Special Fraud Alerts" that address the application of the Federal anti-kickback statute to specific arrangements. This recent alert focuses on "physician-owned entities" that derive revenue from the sale of implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs). Such entities are commonly referred to as physician-owned distributorships, or "PODs."

OIG makes clear in the Alert that it views PODs as "inherently suspect under the anti-kickback statute" because financial incentives offered by PODs to their physician-owners, may induce the physicians "both to perform more procedures than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices." According to the Alert, disclosure to a patient of the physician's financial interest in a POD is not sufficient to address these concerns.

It is important to note that OIG views PODs in the implantable medical device context as particularly suspect because the devices are "physician preference items," meaning individual physicians tend to have a strong influence over what devices are used in procedures. The OIG has always been concerned with arrangements where physicians obtain an investment interest and then generate profits for the entity in which they hold that investment through referrals. Nevertheless, the agency has offered some types of physician-owned entities more favorable treatment. OIG's decisions in this regard are generally due to some perceived benefit associated with the physician-owned entity. For instance, the agency created safe harbors for certain types of ASCs on the theory that legitimate ASCs are an extension of the investor physician's surgical practices, and a lower cost alternative to more expensive sites of services. PODs, however, do not enjoy this same level of confidence.

The Alert reiterates that any arrangement, however, including PODs, that exhibit certain questionable features raise major concerns associated with kickbacks - corruption of medical judgment, overutilization, increased costs to Medicare and other federal health care programs and beneficiaries, and unfair competition. These features 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 interests, and (3) distributing extraordinary returns on investment compared to the level of risk involved. More specifically, the OIG believes that medical device PODs that exhibit any of the following characteristics are highly suspect:

- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
- 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 a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POD does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

OIG reminds us in the Alert that a violation of the anti-kickback statute exposes both sides of an impermissible "kickback" to criminal liability punishable by a maximum fine of $25,000, imprisonment up to five years, or both. The OIG issues these "Special Fraud Alerts" every few years or so. The guidance in these alerts tends to reflect the OIG's view of various trends in the health care industry, and are often a precursor of enforcement actions in the area at issue. While the application of the anti-kickback statute to any particular arrangement, including a physician-owned POD, is a very fact-specific analysis, physicians and others involved in these types of relationships should pay close attention to the guidance set forth by the OIG. The OIG's alert can be found here: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.

If you have any questions about OIG's Special Fraud Alert or compliance with state or federal anti-kickback law, please contact Jesse Berg at jesse.berg@lathropgpm.com / 612.632.3374 or Jeremy Johnson at jeremy.johnson@lathropgpm.com / 612.632.3035.

This article is provided for general informational purposes only and should not be construed as legal advice or legal opinion on any specific facts or circumstances. You are urged to consult a lawyer concerning any specific legal questions you may have.