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Physicians

Physician-Owned Distributorships Present High Risk of Fraud, OIG Alert Says

Physician-owned distributorships (PODs) pose a high risk of fraud and abuse and may lead to delivery of inappropriate and potentially harmful services, according to a Special Fraud Alert from the Department of Health and Human Services Office of Inspector General released March 26.

The alert, the first OIG has released since 2010, said ''financial incentives PODs offer to their physician-owners may induce the physicians both to 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.''

OIG said that physician disclosures to patients of their involvement in a POD would not alleviate OIG concerns over the arrangements.

Revenue generated under a POD could be considered illegal remuneration under the anti-kickback statute, the alert said, especially if the POD chooses physician investors based on their ability to provide business to the POD or if the POD mandates that physicians who stop practicing give up their ownership stakes.

As a result, ''we believe that PODs are inherently suspect under the anti-kickback statute,'' OIG said.

For the purposes of the alert, OIG defined PODs as physician-owned entities that produce revenue from selling, or arranging the sale of, implantable medical devices ordered by the physician-owners that are then used in procedures performed by the physician-owners in hospitals or ambulatory surgical centers (ASCs).

POD Warning Signs. The alert identified several characteristics that, if present in a POD, could result in a higher risk of fraud and abuse, including:

- the size of ownership stakes offered to physicians correspond to the expected or actual volume of the implantable medical devices used by the physicians;
- physician-owners are penalized for not using the POD's implantable medical devices on patients;
- the POD does not conduct consistent oversight over its distribution; and
- the POD has the right to buy out a physician's investment stake if the physician fails to refer or recommend the purchase of the POD's devices.

The alert also said PODs with a high return on investment rate have an increased risk of fraud and abuse.

''Because the investment risk associated with PODs is often minimal, a high rate of return increases both the likelihood that one purpose of the arrangement is to enable the physician-owners to profit from their ability to dictate the implantable devices to be purchased for their patients and the potential that the physician-owner's medical judgment will be distorted by financial incentives,'' the alert said.

Hospitals and ASCs that do business with PODs should also be aware that they may be at risk of violating the anti-kickback statute, as the statute ''ascribes criminal liability to parties on both sides of an impermissible 'kickback' transaction,'' OIG said.

OIG said the advisory opinion process is available to any POD or individual physician-owner with questions about their particular arrangement.

OIG Enforcement. Kathleen McDermott, an attorney with Morgan, Lewis & Bockius LLP, Washington, told BNA that the alert signals a clear enforcement position by OIG.

The alert ''sets forth clear criteria on suspect characteristics related to the formation and operation of PODs and takes the position that if these factors exist the arrangement is unlawful,'' McDermott said. ''Most POD arrangements, and probably all if one is realistic, have one or more of these suspect factors.''

McDermott said the alert distinguishes PODs from other physician-owned entities, such as ASCs, and debunks some compliance safeguards, such as patient disclosure. She said the alert compels hospitals with POD arrangements to conduct an immediate legal analysis of its POD contract.

Kirk Ogrosky, an attorney with Arnold & Porter, Washington, and former head of criminal health care enforcement at the Department of Justice, told BNA the alert represents the first direct guidance from OIG on PODs. He also said it will help level the playing field.

''It is clear that physicians who want to organize PODs, facilities that intend to purchase product from PODs, and the manufacturers who want to deal with PODs, must proceed carefully,'' Ogrosky said.

Ogrosky said significant concerns have been raised about the potential anti-kickback risk PODs present, as well as disagreement over whether PODs have had any impact—positive or negative—on patient care.

Congressional Reaction. Sen. Orrin G. Hatch (R-Utah) said in a March 26 statement that the OIG alert shows that ''anytime a few bad actors determine the treatment and care of patients, as this warning makes clear, patient safety is put at risk and millions of dollars are lost to fraud. This is simply unacceptable.''

Hatch, ranking member of the Senate Finance Committee, said he will continue ''to scrutinize these high-risk structures and demand answers from HHS.''

Senate Finance Committee Chairman Max Baucus (D-Mont.) said in a March 26 statement that ''patients have a right to know they're getting treatment that's tailored to them—not someone else's bottom line—but physician-owned distributorships may put that guarantee in doubt.''

In June 2011, Hatch released a report on PODs that showed an increase in the utilization of medical procedures by physician-owners.

At the same time, Hatch, along with then-Sen. Herb Kohl (D-Wis.) and Sens. Baucus, Bob Corker (R-Tenn.), and Chuck Grassley (R-Iowa), sent letters to HHS OIG and the Centers for Medicare & Medicaid Services, urging investigations into PODs.

In September 2011, HHS OIG Inspector General Daniel R. Levinson responded to the Senate letter, defending OIG legal guidance on PODs.

The OIG special fraud alert is at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf. The Hatch report on PODs is at http://op.bna.com/hl.nsf/r?Open=jswn-966ll8.