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UPDATE
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OIG Releases Special Fraud Alert Regarding Physician-Owned Distributorships

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On March 26, 2013, the Office of the Inspector General (OIG) issued a Special Fraud Alert (the Alert) regarding physician-owned entities or distributorships (PODs) that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered and used by physician-owners in procedures they perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

The OIG views PODs as "inherently suspect" under the Anti-Kickback Statute (AKS). In the Alert, the OIG highlights a number of POD characteristics that will trigger heightened scrutiny of a POD by the OIG. While the Alert focuses on PODs, the OIG notes that the principles discussed in the Alert will apply to the OIG's evaluation of arrangements involving other types of physician-owned entities.

POTENTIAL FOR VIOLATION OF THE ANTI-KICKBACK STATUTE

Any business arrangement that creates an opportunity for a referring physician to profit from referrals for health care services or devices paid for by a federal health care program implicates the AKS.

In the Alert, the OIG states that a POD presents an opportunity for its physician-owners to realize increased income resulting from the use of devices sold by the POD, thereby incentivizing such physician-owners to perform procedures that may not be medically necessary and to use devices sold by the POD in lieu of other, more appropriate devices. Such conduct violates the AKS and may lead to exclusion from participation in federal health care programs and the imposition of civil money penalties. The OIG explains that the potential for such conduct is heightened in the context of implantable medical devices because physicians are often in a position to choose, or influence the choice of, both the brand and the type of device used in a hospital or an ASC.

SUSPECT CHARACTERISTICS OF PODS

The OIG lists a number of "suspect characteristics" of PODs, including, but not limited to, the following:

- The prices paid by physician-owners for ownership interests in a POD vary due to the volume or value of the physicians' use of devices sold by the POD.

- Distributions made by the POD to a physician-owner are disproportionate to each physician-owner's investment in the POD.
- Physician-owners condition referrals to a hospital or ASC based on such hospital or ASC using devices sold by the POD or engage in other similar coercive conduct.
- A POD requires or pressures a physician-owner to use or refer the devices sold by the POD to avoid consequences such as decreased distributions or the divestiture or repurchase of a physician-owner's ownership interest by the POD.

OTHER HIGHLIGHTS OF THE SPECIAL FRAUD ALERT

The OIG notes that a physician's disclosure of his or her financial interest in a POD does not address the OIG's concerns regarding fraudulent conduct under the AKS. In addition, the OIG cautions that hospitals and ASCs that enter into an arrangement with a POD are also at risk under the AKS if a hospital or ASC purchases devices from a POD to secure or maintain referrals from physician-owners of such POD.

In light of the Alert, hospitals and ASCs may want to review any existing or potential purchasing relationships with PODs owned by physicians who perform services at the hospital or ASC to ensure that the relationships do not involve characteristics that could be subject to scrutiny by the OIG. In addition, in view of the OIG's list of suspect characteristics of PODs, physician-owners of PODs may wish to review their agreements with such PODs regarding distributions of profits and divestments of interest.

Federal Agencies Propose to Extend EHR Donation Sunset Date

On April 10, 2013, the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services' Office of the Inspector General (OIG) (collectively, The Agencies) released complementary proposed rules (Proposed Rules) amending the electronic health records (EHR) exception under the Stark Law (EHR Exception) and the EHR Safe Harbor under the Anti-Kickback Statute (EHR Safe Harbor). Both the EHR Exception and EHR Safe Harbor are scheduled to sunset on December 31, 2013. The CMS proposed rule may be accessed here. The OIG proposed rule may be accessed here.

The Proposed Rules would extend the December 31, 2013, sunset date to December 31, 2016. These rules would remove the requirement that donated EHR contain an electronic prescribing capability. In addition, the Proposed Rules would revise interoperability requirements to require EHR systems to be deemed interoperable by an agency authorized by the Office of the National Coordinator for Health Information Technology (ONC) in accordance with the timeframes established by the ONC.

The Agencies are soliciting comments on the proposed changes, including whether the December 31, 2016, sunset date should be further extended. The Agencies are also soliciting comments on whether the types of providers and suppliers permitted to donate EHR should be limited (for example, by excluding laboratories, durable medical equipment suppliers, and/or independent home health agencies), whether any conditions to the EHR Exception and the EHR Safe Harbor should be added or modified to ensure that donors cannot lock-in referrals or interfere with the exchange of data, and whether the scope of technology covered by the EHR Exception and EHR Safe Harbor should be further clarified.

Comments on the Proposed Rules must be submitted to CMS or OIG by 5:00 p.m. on June 10, 2013.

If you have any questions regarding the OIG Special Fraud Alert or would like assistance in submitting comments to the Agencies in response to the Proposed Rules, please contact a member of Robinson & Cole's Health Law Group.

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