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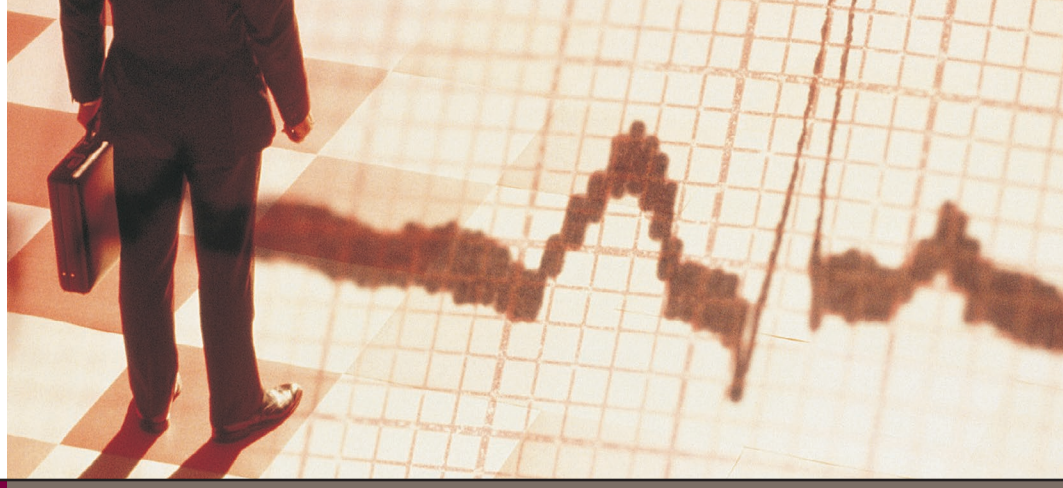

Health Care Bulletin

OIG PUBLISHES SPECIAL FRAUD ALERT REGARDING PHYSICIAN-OWNED DISTRIBUTORS ("PODS")—DESCRIBES PODS AS "INHERENTLY SUSPECT"

By: Frank Carsonie and Dan O'Brien

Introduction

Over the last several years, there has been a noted proliferation in the growth of physician-owned distributors ("PODs"). Along with this growth has come increased scrutiny and speculation as to the legality of PODs, with highly vocal critics and proponents on both sides of the debate. In fact, the Office of the Inspector General's ("OIG") 2013 Work Plan noted that the OIG planned to examine PODs in connection with reports of high utilization of spinal implants by hospitals associated with PODs.

Accordingly, on March 26, 2013, the OIG released a Special Fraud Alert (the "Fraud Alert") which provides long-awaited guidance concerning the legality of PODs. Although the Fraud Alert identifies a number of specific attributes and practices of PODs that the OIG believes produces substantial fraud and abuse risk, the Fraud Alert does not provide any bright-line tests that can be applied to determine the legality of a particular POD. Instead, the Fraud Alert merely states that "the lawfulness of any particular POD under the anti-kickback statute depends on the intent[1] of the parties." Despite the lack of any bright-line test, the Fraud Alert is nevertheless useful as it provides relevant insight with respect to the OIG's concerns with PODs.

The OIG's Primary Concerns

The Fraud Alert identifies four (4) primary concerns associated with PODs: (1) corruption of medical judgment; (2) overutilization; (3) increased costs to Federal health care programs and beneficiaries; and (4) unfair competition. At the most basic level, the Fraud Alert notes that these concerns arise because the financial incentives that PODs offer to their physician-owners may induce the physician to perform more procedures than are medically necessary and to use the devices sold by the POD when other devices may be more appropriate. Further, the Fraud Alert notes that it is particularly concerned with the financial incentives created by PODs that sell implantable medical devices, because such devices are typically "physician preference items," which allows for greater control and decision-making to be made by the physician.

Suspect Characteristics

As noted above, the Fraud Alert makes clear that the lawfulness of any particular POD depends upon the intent of the parties. The Fraud Alert further provides that intent is not solely subjective, and may be evidenced by the manner in which the POD is structured, its operational safeguards, and the actual conduct of the POD and its owners.

Despite the lack of a clear standard for compliance, the OIG's wariness with respect to the legality of PODs is made clear in the Fraud Alert when the OIG states that PODs are "inherently suspect" under the Anti-Kickback Statute. The Fraud Alert goes on to provide a list of "suspect characteristics" that cause particular concern for the OIG.

In reviewing the below list, however, please note that the Fraud Alert specifically states that *the list of "suspect characteristics" is not meant to serve as a blueprint for how to structure a lawful POD*, and that a POD that does not exhibit any of the "suspect characteristics" may nevertheless be found to be in violation of the Anti-Kickback Statute. The following are specifically identified in the Fraud Alert as "suspect characteristics":

A. The size of the investment offered to each physician-owner varies with the expected or actual volume or value of devices used by the physician-owner.

B. 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 physician-owners.

C. Physician-owners condition their referrals to hospitals or ASCs on

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their purchase of the POD's devices through coercion or promises, for example, by: (1) stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD; (2) by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD; or (3) by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.

D. 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.

E. 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.

F. 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.

G. The POD does not maintain continuous oversight of all distribution functions.

H. 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.

Additional Characteristics that Enhance Risk and/or provide Evidence of "Unlawful Intent"

In addition to the "suspect characteristics", the Fraud Alert notes that there are a number of additional characteristics that may also serve to increase the risk of fraud and abuse violations or otherwise provide evidence of "unlawful intent". These additional characteristics include the following:

A. PODs that exclusively serve their physician-owners' patient base;

B. PODs that generate disproportionately high rates of return for physician-owners;

C. PODs where the physician-owners are the sole (or nearly sole) users of the devices sold by the POD;

D. PODs that feature a limited number of physicians such that the volume of a particular physician-owner's recommendations closely correlates with such physician-owner's return on investment; and

E. PODs in which a physician-owner's practice is altered shortly before or after becoming involved with a POD, namely by performing more surgeries, more extensive surgeries, or by switching to the devices sold by the POD on an exclusive (or nearly exclusive) basis.

Conclusion

In light of the Fraud Alert, we believe that regulatory authorities are likely to increase their scrutiny of PODs and expect enforcement actions to follow. Accordingly, individuals or entities that are currently operating PODs should evaluate their structure and operations to determine whether their POD possesses any of the "suspect characteristics" or other features that the OIG outlined in the Fraud Alert as suggesting an "unlawful intent". To the extent that any of these features are present, the POD should take immediate action to modify, restructure or terminate the arrangement as necessary in order to mitigate health care regulatory risk. In addition, individuals or entities that are considering setting up a POD should strive to make certain that their POD is structured and operated in a manner that minimizes health care regulatory risk.

Further, hospitals, ASCs, and other entities that do business with PODs should note that the Anti-Kickback Statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Accordingly, these entities should conduct appropriate diligence when dealing with a POD to ensure that the POD is structured and operated appropriately and in a manner that does not expose the ASC or hospital to unnecessary risk.

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[1]The Anti-Kickback Statute is an intent-based statute, and a person can be found to violate the Anti-Kickback Statute if one purpose of an arrangement is to induce referrals for services. This is known as the "one-purpose test," and applies even if the arrangement also has a separate, legitimate purpose.

Additional Information

For additional information on the Fraud Alert, please contact **Frank Carsonie, Dan O'Brien**, or any member of Benesch's Health Care Department.

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