

*OIG Reaffirms:  
Physician-Owned Device Companies Can Be Properly  
Structured and Operated Under the Anti-Kickback Statute.*

The Office of Inspector General (OIG) of the Department of Health and Human Services provided an interim response on September 13, 2011 to the Senate Finance Committee's request for additional guidance regarding physician-owned device distributorships (PODs). On June 9, 2011, the Senate Finance Committee had requested that the Inspector General conduct a further review of PODs and provide additional guidance regarding the interplay between PODs and the Federal Anti-Kickback Statute.

The OIG's interim response reaffirmed that properly structured and operated PODs would not violate the Federal Anti-Kickback Statute. Although the OIG intends to conduct further investigation into the various POD models<sup>[1]</sup>, the OIG noted that "[t]he legality of any individual physician-owned entity under the Federal Anti-Kickback Statute is highly dependent on each entity's particular characteristics, including the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations."

The OIG maintains that current guidance outlines the key factors that OIG considers when evaluating potential investigation targets, such as "the terms under which a physician may invest in the entity and, conversely, the terms under which a physician-owner may be required to divest his or her ownership interest; the actual return or projected return on the physician's investment; and the amount of revenues generated for the entity by its physician-investors." The wide variety of POD models that are being utilized mean that "OIG's ability to issue guidance about the application of the [Anti-Kickback Statute] to these business structures is limited."

The OIG's response to the Senate Finance Committee reaffirms that a properly structured POD, operating with safeguards designed to prevent any illegal inducement, should not be found to violate the Anti-Kickback Statute or the Stark Law, but instead is an effective business model that can provide cost-savings to

hospitals and other health care providers.

The Senate Finance Committee also asked the Centers for Medicare and Medicaid Services (CMS) to consider preventing "less reputable POD models" from falling under waivers of the Anti-Kickback Law and Stark Law envisioned for Accountable Care Organizations (ACOs). CMS, in a response dated August 10, 2011, informed the Senate Finance Committee that the regulations governing ACOs are still being developed, and that CMS would consider the Committee's concerns during the development process.

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[1] The OIG has indicated that its investigation will include a nationally representative study of hospitals that bill Medicare for spinal surgeries, and will look at how widespread PODs are, what services PODs offer to hospitals, and whether PODs save money in the acquisition of implants. The investigation will also study whether PODs are associated with high use of spinal implants.

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