# CMS and OIG Respond to Senate Inquiry on Physician-Owned Distributorships

By Thomas William Mayo | September 21, 2011

The Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) for the U.S. Department of Health & Human Services (HHS) have responded to the U.S. Senate's request for information on physician-owned distributorships (PODs). Earlier this summer, a bi-partisan U.S. Senate committee asked CMS and the OIG to study the proliferation of PODs, citing a lack of regulatory guidance on how these arrangements square with existing federal law. Daniel Levinson, HHS Inspector General, responded by refusing to outlaw PODs, stating that he will instead initiate a national review of the entities. Dr. Donald Berwick, CMS Administrator, responded that CMS will consider the impact of PODs as it drafts regulations implementing the Patient Protection and Affordable Care Act (PPACA).

Physician-owned distributorships are arrangements in which physicians purchase shares in entities that distribute products used in surgeries. They can save hospitals millions of dollars in supply costs and allow physicians to share in the savings. Critics of PODs, however, claim they cause an increase in utilization, especially in spinal fusion surgeries. Due to this criticism, in June 2011 a bi-partisan committee of Senators requested that CMS and the OIG examine PODs.

In response, the OIG refused to issue a blanket prohibition against PODs, citing the wide variety of POD models and organizational structures being used. The OIG acknowledged that varying levels of concern can arise depending on the specific facts of a case, stating, "[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." The OIG referred to its longstanding guidance on physician joint ventures in addressing how it will view PODs. In evaluating the legality of such ventures, the OIG will consider, among other factors, 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 OIG response contained a commitment to initiate a national review of PODs. The OIG will seek to determine the extent to which PODs provide spinal implants purchased by hospitals. The study will establish how widespread PODs are, what services they offer to hospitals and whether they save hospitals money. The OIG study will also analyze Medicare claims data to determine whether PODs are associated with the high use of spinal implants.

Dr. Berwick submitted the CMS response in which he stated that CMS will consider the impact of PODs as it develops regulations implementing PPACA. For example, CMS will consider whether the reporting requirement contained in Section 6602 of PPACA, which requires manufacturers of certain drugs, devices, biological or medical supplies to report payments or other transfers of value to physicians and teaching hospitals, should extend to PODs. CMS will also examine whether to treat PODs as group purchasing organizations, which are required to report ownership or investment interests held by physicians. Dr. Berwick further stated that CMS will examine whether it

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will grant waivers to PODs from the physician self-referral law (“Stark” law) and the Anti-Kickback law under the Medicare Shared Savings Program of PPACA.

The inquiry by the bi-partisan Senate Committee into PODs has definitely been heard by the regulators at CMS and OIG, and PODs will be under the microscope in the coming months. Physicians who are contemplating investing in such entities should take into account the factors the OIG lists in its Senate response to ensure they do not become a potential investigation target.

**More Information**

For more information please contact one of the following Haynes Boone lawyers.

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