

Background

Physician Owned Distributors (PODs) are supply chain entities that purchase medical devices from third-party manufacturers and are not the same as traditional medical device manufacturers that AdvaMed represents. Instead, PODs are distributors owned by physicians that derive revenue by selling devices to health care facilities where those physicians perform procedures, often using the same devices sold to the facility by the POD. The structure of these businesses raises serious ethical concerns among health care stakeholders, including the U.S. government and AdvaMed member companies.

AdvaMed first raised concerns regarding PODs and sought clarity from the Department of Health and Human Services' Office of Inspector General (OIG) in 2006. It is AdvaMed's position that these physician-owned entities create conflicts-of-interest between physicians' responsibility to act in the best interests of patients and physicians' equity interests, and can lead to the corruption of medical judgment and overutilization, since the physician owners are major revenue generators for their companies.

Similar concerns have also been expressed in recent years by OIG, the Centers for Medicare and Medicaid Services (CMS), and on Capitol Hill. In March 2013, OIG issued a Special Fraud Alert labeling PODs as "inherently suspect," and warning that PODs "produce substantial fraud and abuse risk and pose dangers to patient safety."

OIG subsequently issued a report in October 2013 on spinal devices supplied by PODs. The report highlighted the increased potential for conflicts-of-interest posed by PODs due to the lack of consistency in hospitals' policies requiring physicians to report their involvement in a POD. The report also found that POD-supplied devices do not lower costs, contrary to the claims of PODs supporters; that PODs drive increased utilization of certain spinal procedures; and that PODs may increase the cost of spinal surgery to Medicare over time.

AdvaMed has advocated for transparent, ethical business arrangements and ownership models for medical technology manufacturers and distributors under federal laws, and continues to take the lead in raising awareness and pro-active advocacy to address PODs-related concerns.

Recent Developments

In response to OIG's 2013 fraud alert on PODs, some hospital systems began taking an overly broad and conservative approach to implementing policies to avoid purchasing from PODs. The effect of the most stringent of these policies has been unfair discrimination against small, physician-owned medical technology innovators and manufacturers, precluding them from conducting business with hospitals.

Small, innovative medtech manufacturers are the lifeblood of the industry, and often may have at least some element of physician ownership. To appropriately distinguish between PODs and medtech manufacturers, and address the inherent conflicts-of-interest posed by PODs, AdvaMed has sought refinements to the law regarding physician self-referrals (the "Stark Law"), and issuance of government guidance to ensure appropriate clarity and transparency on PODs for providers, patients and other stakeholders.

AdvaMed applauds the Senate Finance Committee for its work in addressing the medtech industry's POD-related concerns, and its 2016 report on this important issue.

Key Resources

- **Senate Finance Committee Report:** *May 2016* – Senate Finance Committee issues a report, “[Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern](#),” and related [summary](#).
- **AdvaMed Letter to CMS:** *March 11, 2016* – AdvaMed’s letter to CMS on the need for guidance to ensure clarity and transparency on PODs for stakeholders is [here](#).
- **AdvaMed Letter To Congress:** *Feb. 5, 2016* – AdvaMed’s letter to the Senate Finance Committee and House Ways and Means Committee on potential approaches for improving the physician self-referral law (“Stark Law”) is [here](#).
- **Senate Finance Committee Hearing:** *November 17, 2015* – U.S. Senate Finance Committee holds [hearing on PODs](#). See AdvaMed’s written statement [here](#).
- **OIG Study:** *October 23, 2013* – OIG publishes a report, “[Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use](#).” See AdvaMed’s press release [here](#).
- **OIG Special Fraud Alert:** *March 26, 2013* – The U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a [Special Fraud Alert concerning physician-owned entities](#). See AdvaMed’s press release [here](#).
- **Inspector General Levinson Response to Senate:** *Sept. 13, 2011* document is [here](#).
- **CMS Administrator Response to Senate:** *August 10, 2011* document is [here](#).
- **Senate Letter to CMS Administrator Donald Berwick:** *June 9, 2011* document is [here](#).
- **Senate Letter to Inspector General Dan Levinson:** *June 9, 2011* document is [here](#).
- **Senate Finance Committee Report:** *June 2011* – Senate Finance Committee issues a report, “[Physician Owned Distributors \(PODs\): An Overview of Key Issues and Potential Areas for Congressional Oversight](#),” and issues requests to OIG and CMS to review POD arrangements.
- **OIG Response to AdvaMed:** *Oct. 6, 2006* – Office of Inspector General response letter is [here](#).
- **AdvaMed Letter to OIG:** *Sept. 6, 2006* – AdvaMed’s letter to the Department of Health and Human Services’ Office of Inspector General/Industry Guidance Branch, requesting guidance concerning certain physician-device firm arrangements, is [here](#).
- **For additional resources**, see AdvaMed’s website page on PODs [here](#).