

PUBLICATION

OIG Report Concludes that Physician-owned Distributors Increase Utilization [Ober|Kaler]

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In response to the U.S. Senate Committee on Finance's continued questioning of physician-owned distributorships (PODs), the U.S. Department Health and Human Services Office of the Inspector General issued its long-awaited report, [Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use](#), on October 24, 2013. Senator Orrin Hatch (R-Utah) of the Senate Finance Committee issued a statement that the report, which comes on the heels of the OIG's Special Fraud Alert declaring PODs "inherently suspect" under the federal antikickback statute, confirms his skepticism about PODs' claims that devices purchased from PODs cost less than those purchased from other suppliers. Moreover, the report concludes that the rate of growth in the number of spinal surgeries was three times higher for hospitals purchasing from PODs than that for all hospitals.

To conduct its study, the OIG reviewed a sample of 971 Medicare claims for spinal fusion procedures at 596 hospitals. The OIG relied on data that was self-reported from the hospitals, including responses to a questionnaire, and worksheets evaluating invoice data for each spinal surgery included in the sample. Hospitals were required to report whether they were aware of physician ownership among their suppliers, including physicians on their medical staff. In addition, the invoice worksheets compiled detailed data regarding the spinal devices used for the surgery and the entities that supplied the devices to the hospital. Notably, the OIG stated that five hospitals in the sample refused to provide invoice information regarding spinal devices implanted, noting without further explanation that those hospitals would be referred to CMS.

The OIG concluded the data did not support claims that POD devices cost less than those of other suppliers. While the OIG found spinal fusion surgeries that used POD devices used fewer devices than surgeries that did not implant POD devices, there was no statistical difference between the price hospitals paid PODs and other distributors for devices used in spinal surgeries.

In addition, the OIG concluded that the presence of PODs may encourage surgeons to perform more surgeries, or more complex surgeries, to increase device sales. The OIG determined that before hospitals started purchasing from PODs, they performed 95 spinal surgeries per 1,000 surgical discharges. That rate increased 16 percent after hospitals began purchasing from PODs, while the hospital overall rate grew only 5 percent during the same time period.

Somewhat surprisingly, the OIG found that only 34 percent of the hospitals in the sample reported purchasing spinal devices from PODs, including 119 that self-identified as purchasing from PODs and 84 that were determined to be purchasing from PODs based on data provided on invoices. Although federal law does not require physicians to disclose ownership interests in device companies to hospitals where they practice, 65 percent of hospitals reported having policies requiring such disclosure. In response to the OIG questionnaire, hospitals reported that surgeon preference ranked as the number one reason influencing the decision to purchase spinal devices from PODs, over quality and effectiveness.

Following the issuance of the OIG Report, the Senate Finance Committee issued a [press release](#) stating that the OIG report demonstrates a direct correlation between physician ownership in spinal device companies and an increase in spinal surgeries, including potentially unnecessary surgeries. Senator Max Baucus warns that

PODs require closer monitoring in light of the OIG findings and the OIG Special Fraud Alert issued earlier this year.

Ober|Kaler's Comments

The OIG Report will undoubtedly be relied upon as further evidence by the OIG and Congress that PODs raise serious concerns regarding conflicts of interest and potential overutilization. As emphasized in Ober|Kaler's article discussing the OIG Special Fraud Alert, arrangements involving PODs should be carefully considered and evaluated by physician-owners of existing PODs, and by hospitals and ASCs that currently purchase items, particularly implantable medical devices, from PODs. Such arrangements are considered "inherently suspect" by the OIG and, as such, are ripe for potential investigation.