

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**OFFICE OF INSPECTOR GENERAL** 

WASHINGTON, DC 20201

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TO: Andrew M. Slavitt Acting Administrator Centers for Medicare & Medicaid Services

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FROM: Suzanne Marrin Deputy Inspector General for Evaluation and Inspections

**SUBJECT:** Memorandum Report: Overlap Between Physician-Owned Hospitals and Physician-Owned Distributors, OEI-01-14-00270

This memorandum provides the results of OIG's examination of overlap between physician-owned hospitals and physician-owned distributors (PODs) of spinal devices. This work follows up on our October 2013 report *Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use* (OEI-01-11-00660), which found that PODs supplied the devices used in nearly one in five spinal fusion surgeries that were billed to Medicare.

#### METHODOLOGY

When we met with the Centers for Medicare & Medicaid Services (CMS) in September 2013 to discuss a draft of the report, CMS staff expressed interest in the overlap between owners of physician-owned hospitals and PODs of spinal devices. We agreed to analyze the extent to which such overlap exists. We used publicly available information (such as the Web sites for hospitals and PODs, as well as State business registration websites) and information from CMS's Provider Enrollment, Chain and Ownership System (PECOS) to attempt to determine whether a physician had an ownership interest in both a hospital and a POD that sold spinal devices to the hospital.

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

### RESULTS

#### Using available information, we identified one physician with an ownership interest in both a hospital and a POD

During data collection for the original report, 119 hospitals self-identified as having purchased spinal devices from PODs. Of these 119 hospitals, 12 self-identified as physician-owned and reported that they purchased spinal devices from 12 PODs.<sup>1</sup> All of these hospitals self-identified as physician-owned on their Web sites, and five of them identified physician-owners by name.

We also researched the ownership of the 12 PODs from which the 12 physician-owned hospitals reported having bought spinal devices. Two of these PODs identified physician-owners by name on their Web sites. We identified the physician-owners of an additional three PODs from our review of State business registration websites.

Using the physician ownership information we gathered on hospitals and PODs, we identified one physician who had an ownership interest in both a hospital and a POD that supplied spinal devices to that hospital.<sup>2</sup> However, it is possible that additional physicians had such ownership interests that we could not detect using the available information.

#### Available information about ownership interests is limited and raises concerns about lack of transparency

The limited information that is available to identify physicians who have concurrent ownership interests in PODs and hospitals raises concern about transparency among Medicare providers and the vendors that sell them implantable devices. Transparency of ownership is important for the Department of Health and Human Services to ensure that providers do not violate the referral and billing prohibitions of the Stark Law (also known as the Physician Self-Referral Law) and that they comply with OIG exclusions and the Anti-Kickback Statute. Additionally, the transparency of ownership information may have implications for patient safety and quality of care. One of the primary criticisms of PODs is that ownership may affect physicians' clinical decisionmaking, such as influencing them to perform unnecessary surgeries or to choose a device in which they have a financial interest rather than another device that may be more appropriate for the patient.

In 2013, OIG released a Special Fraud Alert on Physician Owned Entities that described a number of characteristics of concern.<sup>3</sup> OIG is particularly concerned about PODs because—as the Special Fraud Alert stated—surgical implants "typically are 'physician

<sup>&</sup>lt;sup>1</sup> Two PODs sold spinal devices to multiple hospitals included in this analysis.

<sup>&</sup>lt;sup>2</sup> This physician was listed as a physician-owner of a hospital both on the hospital's Web site and in CMS PECOS data.

<sup>&</sup>lt;sup>3</sup> OIG, *Special Fraud Alert: Physician Owned Entities* (March 2013). Accessed at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD Special Fraud Alert.pdf on August 4, 2015.

preference items,' meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than the hospital where the procedure is performed."<sup>4</sup> The alert echoes OIG guidance from 2006 that specifically addressed physician investments in manufacturers and distributors of medical devices. In that guidance, OIG acknowledged the "strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" and stated that such arrangements should be "closely scrutinized under fraud and abuse laws."<sup>5</sup>

## CONCLUSION

This work demonstrates that there is limited transparency with regard to ownership information for PODs and, to a lesser extent, of hospitals. CMS's implementation of the Physician Payments Sunshine Act (Sunshine Act) may improve the information available to identify the physician-owners of PODs.<sup>6</sup> The Sunshine Act requires manufacturers and group purchasing organizations to report to CMS any ownership and investment interests that are held by physicians.<sup>7</sup> OIG will monitor CMS's Sunshine Act database and determine how best to assess its impact on transparency within Medicare.

This report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-01-14-00270 in all correspondence.

<sup>&</sup>lt;sup>4</sup> OIG, Special Fraud Alert: Physician Owned Entities (March 2013). Accessed at

http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD\_Special\_Fraud\_Alert.pdf on August 4, 2015. <sup>5</sup> Ibid.

<sup>&</sup>lt;sup>6</sup> Entities that are required by the Sunshine Act to report ownership interests are listed at <u>http://www.cms.gov/</u>

OpenPayments/Program-Participants/Program-Participants.html. Accessed on July 7, 2015. 742 CFR §§ 403.900–403.914.