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HEALTH LAW NEWS

OCTOBER 28, 2013

OIG REAFFIRMS CONCERNS ON PREVALENCE AND USE OF SPINAL DEVICES SUPPLIED TO HOSPITALS BY PHYSICIAN-OWNED DISTRIBUTORS

EXECUTIVE SUMMARY

On October 24, 2013, the Office of the Inspector General ("OIG") released the results of a study beginning in the fall of 2012 on implantable spinal devices supplied to hospitals by physician-owned distributors ("PODs"). The OIG report entitled "Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use OEI-01-11-00660" ("Report") can be found here. This Report is in response to a letter the OIG received from the U.S. Senate Finance Committee, in which the Committee expressed concern about the proliferation of PODs and their "potential adverse effect...on Medicare beneficiaries and federal health care programs."

The study defines a POD as any entity in which a physician, including the surgeon who may implant the spinal device, has an ownership stake in the spinal device company. This ownership relationship offers physician-investors the potential opportunity to profit from using devices their POD sells. The OIG study was designed to explore the extent and nature of spinal implant device purchasing by hospitals from physician-owned distributors or entities and is based on a review of a data collection sample of 971 spinal fusion claims from 596 hospitals nationwide.

As part of the study, the OIG administered a questionnaire in the fall of 2012 to Medicare enrolled hospitals across the U.S. that billed for one or more spinal surgeries involving a spinal fusion procedure during FY 2011. Many of Hall Render's hospital clients participated in this OIG survey process. In the questionnaire, the OIG asked each hospital about its awareness of physician ownership (not including stock in a publicly traded company) among its suppliers of spinal devices. The participating hospitals were also required to complete a worksheet for each identified spinal surgery, providing details on the types of devices used and the entities that supplied them to the hospital. The OIG also requested invoices and purchase orders from the participating hospitals to substantiate the worksheet data. It is interesting to note that the OIG stated in the Report that it would refer the five hospitals that refused to supply their invoice information to the Centers for Medicare and Medicaid.

FINDINGS

In the Report, the OIG found:

1. For FY 2011, PODs supplied the devices used in almost one in five spinal fusion surgeries billed to Medicare;
2. Spinal fusion surgeries that used POD devices used fewer devices but did not, contrary to POD representations, have lower device costs;
3. Approximately one-third of the hospitals in the study sample purchased spinal devices from PODs;
4. When hospitals in the study sample began buying devices from PODs, their rates of spinal surgery grew faster than the rate for hospitals overall;
5. In FY 2012, hospitals in the study sample that purchased devices from PODs performed more spinal surgeries than those that did not purchase from PODs;
6. Hospitals identified surgeon preference as the strongest influence on their decisions to purchase spinal devices from PODs. "Surgeon preference" was a slightly stronger factor in the decision-making process than quality and effectiveness of the devices or the PODs' provision of additional services related to the spinal devices (e.g., technical support in the operating room or inventory);
7. Two-thirds of hospitals reported that they purchased spinal devices from PODs owned by physicians practicing in their hospitals; and
8. More than half of the participating hospitals had policies requiring physicians to disclose ownership stakes in device companies to the hospitals. On the other hand, very few (i.e., 8%) of the participating hospitals required physician disclosure of ownership to patients.

THE OIG'S CONCERNS

The OIG expressed the following concerns as a result of the Report:

Increased Costs to the Federal Health Care Programs. The OIG concluded that "PODs have a substantial presence in the spinal device market" and that, over time, Medicare expenditures on spinal surgery will increase, since surgeons performed more spinal surgeries in hospitals that purchased devices from PODs. Those same hospitals showed increased rates of growth in the number of spinal surgeries performed compared to hospitals that did not purchase devices from PODs. Additionally, the OIG did not find that PODs lowered the cost of the spinal implants used in these surgical procedures.

Conflicts of Interest-Overutilization and Objective Clinical Decision-Making. The OIG also is concerned with conflicts of interest that may exist because surgeons own the companies that supply the devices they are implanting. Accordingly, ownership could "encourage surgeons to perform unnecessary and inappropriate spinal surgeries to drive up sales for their companies." This conflict of interest concern is more acute to the extent many hospitals do not require their physicians to disclose ownership interests in PODs to the hospital or to hospital patients.

Fraud and Abuse Concerns. The OIG reiterated its position set forth in its Special Fraud Alert on physician-owned entities that PODs raise compliance concerns under the federal Anti-Kickback Statute ("AKS"). Surgical implants, including spinal devices, are "physician preference items" and the surgeons may strongly influence the hospital decision to purchase certain items as demonstrated in the Report. To the extent that the devices ultimately purchased by the hospital are manufactured or distributed by PODs, this POD patronage could potentially be viewed as remuneration to the surgeon owners to induce them to perform surgeries at the hospital. If this "payment for referrals" is intentional (knowing and willful), it may violate the AKS. The OIG has previously indicated that arrangements such as these should be "closely scrutinized."

CONCLUSION

In issuing the Report, the OIG articulated its findings and conclusions but did not make any particular recommendations. Although the stated purpose of the OIG's data collection request was for information gathering, the collected data could result in additional OIG inquiries to hospitals that participated in the study or other hospitals with POD relationships. These additional inquiries could focus on disclosed spinal device purchasing arrangements that appear to be based on reasons unrelated to patient safety, quality, clinical effectiveness, cost control, organizational efficiency or other commercially reasonable factors.

PRACTICAL TAKEAWAYS

Hospitals, including those that participated in the OIG survey process last year, should consider doing the following:

1. Confirm whether your hospital currently does business with any PODs and if the physician owners of these PODs are on your medical staff. If so, perform an internal review in conjunction with your compliance department and legal counsel to determine whether any changes should be made in these relationships based on the concerns expressed in the Report or for other regulatory reasons;
2. Examine your conflicts of interest, physician contracting, supply chain and vendor relationship and patient rights policies and procedures to see if they address physician ownership in PODs; if they do not, consider preparing appropriate policies and procedures and/or revisions to existing policies and procedures to properly address the hospital-POD relationships;
3. Verify that you have adequate control systems in place to make sure any claims submitted for payment to a Federal health care program involving a POD purchased implant satisfy applicable criteria for medical necessity and for quality of care purposes; and
4. Educate and prepare key staff at hospitals with existing POD relationships in the event subsequent government inquiries are made to your organizations.

If you have any questions or would like additional information about this topic, please contact:

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