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HEALTH LAW NEWS

AUGUST 27, 2015

OIG ISSUES REPORT ADDRESSING OWNERSHIP OVERLAP BETWEEN PHYSICIAN-OWNED HOSPITALS AND PHYSICIAN-OWNED DISTRIBUTORS

BACKGROUND

On August 13, 2015, the Department of Health and Human Services Office of Inspector General ("OIG") issued a Memorandum Report (the "Report") that examined the overlap between physician-owned hospitals ("POHs") and physician-owned distributors ("PODs") of spinal devices. PODs are medical device distributors whose owners are often physicians that use the devices sold by the POD. The Report was released as a follow up to the 2013 Special Fraud Alert issued by OIG ("Special Fraud Alert") that found PODs supplied 20 percent of the spinal fusion devices billed to Medicare. As a result of the Special Fraud Alert, the Centers for Medicare & Medicaid Services ("CMS") requested that OIG examine the overlap of common POH and POD physician owners. OIG analyzed the ownership of the potentially overlapping entities by looking at several public sources and concluded that there is a lack of transparency related to ownership information for PODs. The Report reaffirms what OIG and CMS have stated about PODs and POHs separately, suggesting that this lack of transparency could lead to potential abuse of the Medicare program.

METHODOLOGY AND OWNERSHIP OVERLAP

To determine the extent of physician ownership overlap between POHs and PODs, OIG used various sources of public information including POH websites, POD websites and state business registration websites. OIG also utilized CMS's Provider Enrollment, Chain and Ownership System ("PECOS"). Using these sources, OIG looked for named physician owners of these physician-owned entities to determine if a physician had an ownership interest in both the POH and POD in cases where the POD provided spinal devices to the POH.

The data revealed that 119 hospitals self-reported purchasing a spinal device from a POD. Of these 119 hospitals, 12 POHs reported purchasing spinal devices from 12 different PODs. Through its public sources, OIG was able to identify the physician owners of 5 of the PODs. Of the physician owners of the 5 PODs, OIG identified 1 physician who had an ownership interest in a POD that supplied spinal devices to a POH in which the physician also had an ownership interest. While this sample may seem small, the findings of the Report reflect OIG's continued concerns about physician-owned entities.

FINDINGS: FOCUS ON TRANSPARENCY

OIG expressed apprehension over the limited information that is available to identify physicians who are owners in both POHs and PODs. This lack of transparency raises potential Stark Law and Anti-Kickback Statute concerns for Medicare providers and the vendors that supply such Medicare providers with implantable devices. OIG also emphasized that the relationship a physician has with a POH and/or a POD may have implications for patient safety and quality of care. Ownership in a POD may affect a physician's clinical decision making and lead to unnecessary surgeries or a poor device choice based on the physician's financial interest.

Finally, OIG noted that surgical implants are often left to physician discretion, as opposed to the discretion of the hospital where the procedure is performed such that the unilateral physician discretion could result in the potential for improper inducements among physician investors and device vendors.

The Report noted that transparency may improve with the Physician Payments Sunshine Act ("Sunshine Act"), which requires manufacturers and group purchasing organizations ("GPOs") to report to CMS any ownership and investment interests held by physicians. While most PODs are already mandated to report ownership interests under the Sunshine Act, the Report indicated that it is likely many PODs may be underreporting.

OIG committed to monitoring the Sunshine Act database to help determine how it will impact transparency within the Medicare Program but made no recommendations in the Report.

PRACTICAL TAKEAWAYS

While the data gathered for the Report was limited, the Report underscores OIG's concerns related to the lack of POD ownership transparency and the potential for related fraud and abuse implications engendered by physician ownership in both POHs and PODs. As the

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health care market shifts to a value-based focus, the need for transparency will only continue to increase. If physician-owned entities are not proactive in shifting the focus to value and quality of the products and services offered, they will likely continue to find themselves as the subjects of government scrutiny. In order to limit this scrutiny and better prepare for the shift to value-based care, PODs and POHs should consider the following:

- Ensuring compliance with all reporting requirements required by the Sunshine Act;
- Requesting information about the legal structure of the physician-owned entity during business dealings and negotiations in order to determine if any physician investors are part of the pertinent hospital's medical staff;
- Assessing whether any physician owners condition their referrals to certain hospitals or providers;
- Confirming whether the physician investor has disclosed a conflict of interest due to his or her ownership interest in a POD or POH, if applicable;
- Reviewing internal policies and procedures related to business dealings with entities in which a physician investor may have ancillary financial relationships;
- Educating physician investors about appropriate business practices and requisite fiduciary duties to the organization;
- Performing supply chain analyses of the cost and quality of the product in the same manner any non-physician-owned vendor would be analyzed;
- Performing independent fair market value assessments in order to ensure that pricing of the products sold through a POD are consistent with other comparable products on the market;
- Requiring annual disclosure of conflicts of interest; and
- Evaluating current conflict of interest policies and disclosures and revising conflict of interest disclosure requirements if necessary.

If you have any questions regarding this topic, please contact:

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Special thanks to Maryn Wilcoxson, law clerk, for her assistance with the preparation of this Health Law News article.

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