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Finance Committee Report Place Medical Device Arrangements under Increasing Scrutiny

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Hospitals and providers participating in physician-owned distributorships, or "PODs" may be at increased risk for government investigation or enforcement. A Senate Finance Committee (SFC) Report issued this month highlights the SFC's concerns that certain POD structures may violate fraud and abuse statutes, including the Anti-Kickback Statute, Stark Law, as well as the Sunshine Act.

According to the SFC Report, PODs are "physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients in hospitals or ambulatory surgery centers (ASCs)."

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The Committee's Report takes the position that the POD structure creates an "inherent conflict of interest" between the physician's incentive to promote certain medical devices (for the purchase of which he or she will be compensated) and the patient's best interest. The Report specifically focuses on spinal surgery as a practice area the SFC believes is particularly susceptible to fraud and abuse for two reasons: (1) spinal patients rely on their physician's medical device recommendations and (2) hospitals usually purchase spinal devices that their physicians prefer—so called "physician preference items." Thus, according to the Report, the physician is at the epicenter of the medical device decision-making and the physician's arrangement with the POD creates a perverse incentive for the physician to choose medical devices supplied by the POD over non-POD suppliers.

The Report gives a litany of reasons in support of the SFC's argument that participation in PODs influences physician behavior and creates those above-described perverse incentives. The Report noted that data compiled by CBS News indicates that spinal surgeons who participate in PODs saw more patients, performed almost twice as many spinal fusion surgeries, and performed surgeries at a higher rate than non-POD surgeons. Hospitals, as well as physicians, are being influenced by PODs according to the Report. The rate of spinal surgeries at hospitals purchasing from PODs is growing at a rate faster than that of non-POD purchasing hospitals.

Citing a Department of Health and Human Services, Office of Inspector General (OIG) study, the Report states that POD-supplied spinal devices are not cheaper than non-POD spinal devices. SFC is also concerned about overutilization and increased long-term Federal health care program costs, noting that "PODs supplied the devices to 1 in 5 spinal fusion surgeries billed to Medicare in 2011." Competition is also a concern of the SFC. The Report states that where PODs are present, a potential anti-competitive threat can crop up between POD and non-POD physicians. According to the Report, because POD physicians are able to supplement their income from medical device sales, theoretically, POD physicians may agree to lower reimbursement rates from insurance companies and price the non-POD physicians out of the market creating an anti-competitive environment. The Report admits that this assertion is based on anecdotal evidence.

The Report gives the following recommendations:

1. Federal law should require physicians to disclose ownership in private device companies to the hospital where they practice and to the patients they treat.

2. CMS should require hospitals and ASCs to review Sunshine Act Open Payments data and document that they have taken the data into account when making purchasing decisions.
3. CMS and the OIG should consider supplementing their guidance about PODs.
4. The Government Accountability Office should do a cost-benefit analysis of requiring CMS to conduct enhanced quality assurance and utilization reviews of hospitals that purchase from PODs.
5. Law enforcement should continue to prosecute PODs, hospitals, and physicians that violate the law.
6. Hospitals should review the OIG Special Fraud Alert (SFA), issued March 26, 2013 and any other guidance to inform and implement policies regarding their relationships with PODs. CMS should set a date by which hospitals must implement POD policies and non-compliant hospitals should not be reimbursed until they implement and enforce POD-specific policies.
7. CMS should undertake increased enforcement actions to ensure compliance with Sunshine Act reporting requirements.
8. HHS OIG should study the impact of the SFA and recent litigation and update its 2013 report and SFA as needed.

Hospitals that purchase from PODs and physician-owners considering joining or structuring a POD should consult with legal counsel to determine whether the particular POD's structure (structure can vary greatly) and compensation arrangement presents a significant risk under the fraud and abuse laws or the Sunshine Act. For further reference, the HHS OIG SFA outlines"suspect characteristics" of PODs that should be reviewed prior to establishing or joining a POD.