

Scrutiny Of Physician-Owned Distributors Is Far From Over

By **Tom Bulleit, Lillian Maguire and Gideon Palte** (April 26, 2019)

On March 19, 2019, Sens. Chuck Grassley, R-Iowa, and Ron Wyden, D-Ore., of the Senate Finance Committee wrote a letter to the U.S. Department of Health and Human Services Office of Inspector General and the administrator of the Centers for Medicare and Medicaid Services calling for increased scrutiny of the compliance by physician-owned distributors of implantable medical devices with the reporting requirements of the Physician Payments Sunshine Act.[1]

PODs have been less in the news since the SFC's last report on PODs in 2016. However, the POD letter, together with recent report from the Medicare Payment Advisory Commission, demonstrates that federal government scrutiny of the "inherently suspect" conflict of interest that inheres in the POD business model is far from over.

The POD letter also suggests that the Sunshine Act's existing ownership and investment reporting obligations may be far broader than many PODs currently believe.

Background on Fraud and Abuse Concerns Regarding PODs

As detailed over more than a decade of federal government attention, PODs purchase, or arrange for the purchase of, implantable medical devices ordered by their physician-owners for use in their own patient procedures.

Regulators and members of Congress from both parties have long recognized the potential for patient and program harm that may result from giving physicians a financial interest in whether to perform an implant surgery, and which device to choose:

- 2006: Assistant Inspector General (now OIG Chief Counsel) Gregory Demske testifies before Congress that "[PODs] raise substantial concerns that a physician's return on investment ... may influence the physician's choice of device" and that "these ventures should be closely scrutinized." [2]
- 2011: SFC staff issues the first of two reports echoing these concerns, and members pen letters to the OIG and CMS calling for an OIG investigation and requesting that CMS not inadvertently provide protection for PODs when drafting ownership disclosure requirements under the Sunshine Act. [3]



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- 2013: The OIG issues a special fraud alert [on] physician-owned entities warning that PODs “produce substantial fraud and abuse risk and pose dangers to patient safety” and that PODs are “inherently suspect” under the Anti-Kickback Statute.[4]
- 2013: Later that year the OIG issues the first of two reports, concluding that PODs lead to an increase in spinal surgeries and do not reduce, and in some cases increase, costs of the procedures in which implants are used.[5]
- 2015: The OIG issues the second report concluding that there is “limited transparency with regard to ownership information for PODs,” but that CMS’ implementation of the Sunshine Act may improve the information available. The OIG also states that it will monitor CMS’s Sunshine Act database and determine how best to assess its impact on transparency.[6]
- 2015: The SFC holds a hearing on whether PODs are harmful to patients and payers of health care services.[7]
- 2016: SFC staff issues its second report. Relying on evidence from its hearing and the 2013 OIG report, this one is highly critical, and concludes that PODs are likely to lead to overutilization, increased costs and harm to patients.[8] Especially pertinent to the POD letter, the report also highlights that PODs operate with a lack of transparency and have taken steps to conceal their financial relationships, and encourages CMS to undertake increased enforcement of Sunshine Act requirements.
- 2017: A Detroit-area neurosurgeon is sentenced to almost 20 years in prison after pleading guilty to criminal health care fraud involving PODs and the spinal implant company Reliance Medical Systems LLC. As part of his guilty plea, he admits that the financial incentives of PODs induced him to perform medically unnecessary procedures and that he purposefully concealed his ownership interest in the POD from hospital purchasers in his efforts to convince them to buy from the POD.[9]
- 2018: MedPAC issues its annual report to Congress and suggests ways in which policymakers can constrain risks posed by PODs. One suggestion is to require all PODs to report under the Open Payments program established by CMS (authorized by the Sunshine Act) by clarifying the definition of POD to prevent PODs with superficial variations in ownership and payment structures from being characterized as such.[10]

Apart from the Reliance cases, some of which are still pending, there has been little publicity about AKS enforcement against PODs. However, as the SFC's 2016 report noted, many large hospital systems have been adopting policies that constrain, and in some cases prohibit, purchasing from PODs.[11]

Enter the Sunshine Act

Citing the substantive concerns with PODs noted above, the senators turn to the Sunshine Act as a method of curbing the negative impact of PODs. In addition to its provisions requiring that drug and medical device manufacturers report annually on payments and other transfers of value to physician and teaching hospitals, the Sunshine Act also requires applicable group purchasing organizations to report on their ownership and investment relationships with physicians and immediate family members.

Recalling OIG's 2015 undertaking to monitor POD transparency under the Sunshine Act, the senators ask the OIG and CMS to report by April 15 what actions they have taken. As of this writing, the agencies do not appear to have responded.

Scope of Sunshine Act AGPO Investment Disclosure Obligations

Importantly, the POD letter suggests that the scope of the AGPO disclosure obligation under the Sunshine Act may be broader than many PODs currently assume. The POD letter states that PODs "are a subset" of AGPOs, suggesting that all PODs are obligated to report their physician investors, regardless of how many customers they have.

There is support for this conclusion, which was advanced by commenters to the Sunshine Act regulations, in the statute and regulations.[12] As the commenters pointed out, the Sunshine Act's definition of AGPO differs fundamentally from the definition of "group purchasing organization" set forth in the AKS safe harbor regulations, which define a GPO as a "purchasing agent for a group of individuals or entities"[13]

In contrast, the Sunshine Act defines an AGPO as "a group purchasing organization (as defined by the Secretary) that "purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply"[14] Thus, the Sunshine Act definition expands the scope of activities that define an AGPO beyond purchasing agent to include entities that arrange for or negotiate a purchase.

CMS's regulations mostly incorporate the statutory definition of AGPO, just adding a clarification to exclude purchases by end users.[15] CMS largely agreed with the commenters, stating that it intended to include PODs in its definition of AGPO because it interpreted the term AGPO in the statute "to encompass not only more traditional GPOs that negotiate contracts for their members, but also entities [such as PODs] that purchase covered drugs, devices, biologicals, and medical supplies for resale or distribution to groups of individuals or entities." [16]

While CMS declined to incorporate commenter suggestions to broaden the AGPO definition to encompass PODs that did not act on behalf of a group, it concluded that its definition "capture[d] as many PODs as possible, while still aligning with the statutory language." [17]

Notably, CMS did not clarify in the rule when a "group" exists. Neither does CMS's guidance on this point provide much helpful clarification, with its FAQs stating only that "a 'group' consists of two or more individuals and/or entities." [18]

Consistent with the regulatory language and guidance, the senators' letter supports the interpretation that, as long as the POD is acting to "arrange for or negotiate" a purchase on behalf of more than one individual, the entity is acting on behalf of a "group" and is therefore an AGPO. Because a POD acts not only on behalf of the purchasing hospital or ASC, but also on behalf of the physician-owners who order the POD's products, virtually all PODs that are not themselves manufacturers would meet this definition.

Thus, without any change in current regulations, CMS could begin to address the senators' concerns by clarifying that a "group" for the purpose of an AGPO may consist of a single owner and a single purchaser or multiple physician owners of a POD. Similarly, CMS and OIG could use the audit and civil monetary penalty powers granted in the regulations to pursue this broader range of PODs.

Conclusion

The POD letter is the latest development in a decade-long trend of increasingly intense and negative federal government scrutiny of the role of PODs in the implantable medical device supply chain. The POD letter's call for more action by CMS and the OIG, coupled with its broad statement that all PODs should be reporting under the Sunshine Act, should be viewed at a minimum as raising the stakes for PODs and the doctors and hospitals that deal with them.

In the short term, we should anticipate responses from CMS and the OIG that likely will attempt to make use of existing Sunshine Act data in a way that highlights whether it is or is not capturing POD activity. If the information is sparse, those responses may contain suggestions for legislative change that would more clearly require POD reporting. Responses could also take the senators' hint, and provide new guidance that would increase POD reporting even in the absence of new legislation. At this point, however, all we can do is wait and see whether this represents a blip, or portends a significant change in Sunshine Act reporting or enforcement, or other adverse attention to PODs in the future.

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[1] 42 U.S.C. §§ 1320a-7h et seq.

[2] Testimony of Gregory Demske, Assistant Inspector General for Legal Affairs, before the U.S. Senate Special Committee on Aging Examining the Relationship Between the Medical Device Industry and Physicians (February 27, 2008).

[3] Letter from Senator Grassley et al. to OIG (June 9, 2011); Letter from Senator Grassley et al. to CMS (June 9, 2011).

[4] Special Fraud Alert: Physician-Owned Entities, OIG (March 26, 2013).

[5] Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use, OIG (Oct. 2013).

[6] Overlap Between Physician-Owned Hospitals and Physician-Owned Distributorships, OIG (Aug. 13, 2015).

[7] Physician Owned Distributors: Are They Harmful to Patients and Payers, Full Committee Hearing, Senate Finance Committee, November 17, 2015.

[8] Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern, Senate Finance Committee (May 10, 2016) (the "2016 Report").

[9] Press Release, "Detroit-Area Neurosurgeon Sentenced to 235 Months in Prison for Role in \$2.8 Million Health Care Fraud Scheme." Department of Justice (January 9, 2017).

[10] Report to The Congress: Medicare and The Health Care Delivery System, MedPAC (June 15, 2018) at 158.

[11] See 2016 Report at 20, stating that "[h]ospitals have implemented varied and unique strategies to protect themselves from PODs" and highlighting examples of hospital anti-POD policies.

[12] See 78 Fed. Reg. 9458, 9493 (Feb. 8, 2013).

[13] 42 C.F.R. § 1001.952(j) (emphasis added).

[14] See 42 U.S.C. 1320a-7h(e) (emphasis added).

[15] 42 C.F.R. § 403.902 (defining an AGPO as an entity that "[p]urchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.>").

[16] 78 Fed. Reg. at 9493.

[17] 78 Fed. Reg. at 9493.

[18] See FAQ #8368 of the Open Payments Frequently Asked Questions (FAQs) (last updated Jan. 18, 2019).