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Via Electronic Delivery

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Centers for Medicare & Medicaid Services
7500 Security Boulevard – AR-14-21
Baltimore, MD 21244

Re: Reporting Obligations of Physician-Owned Distributors (“PODs”) under the U.S. Physician Payment Sunshine Act (“Sunshine Act”)

Dear Ms. Bellios:

The Advanced Medical Technology Association (“AdvaMed”) thanks you for the opportunity to provide information regarding the application of the Sunshine Act to PODs. As you know, the Sunshine Act and regulations issued by the Centers for Medicare and Medicaid Services (“CMS”) implementing the Sunshine Act require that applicable manufacturers and group purchasing organizations (“GPOs”) must file annual reports to CMS detailing most payments and transfers of value made to U.S. physicians and teaching hospitals.¹ The Sunshine Act also requires applicable manufacturers and GPOs to disclose to CMS ownership interests held by U.S. physicians to the extent that the manufacturer or GPO is not a publicly traded company.²

I. BACKGROUND

A “Physician-Owned Distributor” or “POD” is any entity, or any affiliate of an entity, in the medical device supply chain that has physician ownership, including ownership by individual physicians, a physician’s immediate family members or agents, trusts, partnerships, limited liability companies, corporations, unincorporated associations, or any other entity established by or on behalf of physicians (“Physician Owner(s)”) and that meets each of the following:

¹ See 42 U.S.C. § 1320a-7h; see also 42 C.F.R. §§ 403.900 et al.
² See 42 U.S.C. § 1320a-7h(a)(2); see also 42 C.F.R. § 403.906.
The entity derives any proportion of its revenue from (a) selling or arranging for the sale of medical devices ordered by Physician Owners for use in procedures using products distributed by the POD and performed by a Physician Owner or any other physician affiliated with the POD or affiliated with the Physician Owner or (b) patient referrals to other physicians who perform procedures using products distributed by the POD; and

Physician Owners are compensated in the form of a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from (a) the sale or distribution of POD devices used in procedures performed by such Physician Owner or any other physician affiliated with the POD or affiliated with the Physician Owner or (b) the referral of patients by the Physician Owner to other physicians who perform procedures using products distributed by the POD.

A POD might typically form when a group of physicians (for example, spine surgeons) at a local hospital creates a privately held entity (the POD) that purchases and distributes medical implants. The POD depends upon the heavy influence of its physician owners who admit patients to the hospital to encourage or pressure the hospital where they practice to purchase certain products (spinal implants) only from the POD. As a result, all spine surgeons at a local hospital may end up being pressured to use the POD’s products in connection with the relevant spinal surgeries. The physician owners receive compensation for performing the spinal surgeries (i.e. via a third-party payor) as well as a commission or return on investment from the POD due to the sale of the product to the hospital.³

Indeed, the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) has long emphasized the inherent fraud and abuse risks associated with PODs. According to the OIG, PODs “pose dangers to patient safety,” “produce substantial risk of fraud and abuse,” and are “inherently suspect,” as noted in its 2013 Special Fraud Alert (“Special Fraud Alert”).⁴

II. PODS’ CURRENT OBLIGATIONS TO FILE REPORTS UNDER THE SUNSHINE ACT

A. GPOs

For purposes of applying the Sunshine Act to PODs, CMS has been clear that the term “GPO” includes PODs.⁵ A GPO is defined under CMS’s regulations as “an entity that

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³ For additional information about the potential patient harm, overutilization, and unnecessary procedures that can result from inappropriate PODs, see generally Press Release, U.S. Department of Justice, Detroit-Area Neurosurgeon Admits Causing Serious Bodily Injury to Patient in $11 Million Health Care Fraud Scheme (May 22, 2015), available at https://www.justice.gov/opa/pr/detroit-area-neurosurgeon-admits-causing-serious-bodily-injury-patients-11-million-health.


(1) Operates in the United States; and (2) Purchases, 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.”

CMS notes in its final Sunshine Act rulemaking from 2013 that the term “GPO” includes “entities that purchase covered drugs, devices, biologicals, and medical supplies for resale or distribution to groups of individuals or entities. These interpretations would include, for example, physician owned distributors . . . of covered drugs, devices, biologicals, and medical supplies.” During the rulemaking process, commenters requested that CMS remove the reference to “group” in the definition of GPO in order to capture PODs that sell only to one hospital entity. CMS declined to make such change, noting:

While we appreciate the need to include as many PODs as possible, we are concerned that removing the word “group” from the definition would be contrary to the statutory phrase “group purchasing organization” which clearly implies that in order to be a GPO, the entity must be purchasing for a group. Therefore, we are not going to remove the word “group” from the definition . . . We recognize that this definition may not include every POD model; however, we intend for it to capture as many PODs as possible, while still aligning with the statutory language.

Based strictly on the language of the regulations and the rulemaking notice, therefore, PODs that sell to multiple hospitals or other entities are obligated to file payment and ownership reports under the Sunshine Act as GPOs.

It is simply not the case, however, that PODs selling only to one entity are exempt from the Sunshine Act, as such PODs might argue. CMS’s definition of GPO specifies that the entity is purchasing “for” a group of individuals or entities. The definition does not indicate what it means to purchase, arrange for or negotiate the purchase “for” a group of individuals. A plain reading of the word “for” means that the entity is purchasing, arranging for, or negotiating the purchase on behalf of or at the direction of or for the benefit of a group of individuals or entities. PODs are set up to purchase, arrange for, or negotiate the purchase of products in such a way as to benefit financially the POD owners and to handle referrals made by the POD owners. In other words, it is the very nature of all PODs to purchase, arrange for, or negotiate the purchase of a covered product for – i.e. on behalf of, at the direction of, or for the benefit of –

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6 42 C.F.R. § 403.902.
7 78 Fed. Reg. at 9493 (emphasis added).
8 Id.
9 “[A]n entity that (1) Operates in the United States; and (2) Purchases, 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.” 42 C.F.R. § 403.902 (emphasis added).
the POD owners. Accordingly, all PODs — whether they sell to one or more entities — meet this definition.\textsuperscript{10}

CMS has clear authority to define the term GPO to include all PODs without deleting the term “group.” In fact, the statutory definition of GPO expressly authorizes CMS to define the term further, and the statute does not specify which “group” must benefit from the GPO’s operations.\textsuperscript{11} Accordingly, CMS can issue guidance or FAQs that more clearly define PODs as suggested above and that make clear that PODs purchase, arrange for the purchase or negotiate the purchase of product on behalf of the “group” of individual physician owners as explained below. The result would be capturing all PODs (as highlighted by the OIG in its Special Fraud Alert) under the Sunshine Act.

B. Applicable Manufacturers

A POD must also file reports as an applicable manufacturer to the extent that it takes title to a product — regardless of how many entities purchase product from a POD. CMS notes in the preamble to its Sunshine Act implementation rules:

We agree that distributors and wholesalers . . . that hold the title to a covered drug, device, biological or medical supply meet the definition of an applicable manufacturer for the purpose of this rule. We believe that distributors that hold the title to a covered product are similar to applicable manufacturers since both hold title to the product at some point in the production and distribution cycle. These entities will be subject to the same requirements as all other applicable manufacturers . . . . Wholesalers or distributors that do not hold the title of a covered product will not be subject to the reporting requirements, unless they are under common ownership with an applicable manufacturer and provide assistance or support with respect to a covered drug, device, biological, or medical supply. Finally, an applicable manufacturer that has product(s) with titles held by distributors does not need to report payments or other transfers of value made by the distributor or wholesaler to covered recipients, since these will be reported by the distributor or wholesaler.\textsuperscript{12}

Nothing in the statute or in CMS’s regulations indicates that PODs are only subject to the Sunshine Act as GPOs or otherwise distinguishes PODs from other distributors. Rather, like all distributors of covered products, PODs can also be subject to the Sunshine Act as applicable manufacturers to the extent that they take title to the product being sold.

\textsuperscript{10} Alternatively, it could be argued that PODs purchase, arrange for, or negotiate the purchase of products on behalf of, at the direction of, or for the benefit of another group of individuals — namely, hospital purchasing staff, implanting physicians, patients, and others at a hospital setting who benefit from the use of the POD’s product.

\textsuperscript{11} The Sunshine Act states that GPO means “a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered [product] which is operating in the United States . . . .” 42 U.S.C. § 1320a-7h(e)(1) (emphasis added).

\textsuperscript{12} 78 Fed. Reg. at 9461-62 (emphasis added).
C. Summary of PODs’ Current Obligations to File Reports under the Sunshine Act

In summary, under the current Sunshine Act statutory language and CMS’s regulations implementing the Sunshine Act:

- A POD must comply with the Sunshine Act as a GPO if it purchases, arranges for, or negotiates the purchase of a product for a group of individuals or entities, regardless of whether the POD takes title to the product being sold. This includes purchasing, arranging for, or negotiating the purchase of a product for – i.e. on behalf of, for the benefit of, or at the direction of – the POD owners.

- A POD must also comply with the Sunshine Act as a manufacturer if it takes title to the product being sold, regardless of whether the POD purchases, arranges for, or negotiates the purchase of a product for (1) a single individual or entity or (2) multiple individuals or entities.

III. CONTENTS OF PODS’ SUNSHINE ACT REPORTS

The Sunshine Act requires PODs to disclose (a) most payments and transfers of value made to U.S. physicians and teaching hospitals, with some exceptions, and (b) certain information on physician ownership. More specifically:

- PODs must disclose payments and transfers of value made to U.S. physicians and teaching hospitals. This includes information about the recipient, a description of the form of the payment or transfer of value (e.g., cash, in-kind items, stock, etc.), and a description of the nature of the payment (e.g., consulting fees, honoraria, gifts, entertainment, food, travel, charitable contributions, etc.). There are some exceptions that CMS outlines in its regulations – for example, discounts and rebates offered on products.\textsuperscript{13}

- PODs must also disclose information regarding ownership or investment interests held by a physician or an immediate family member of the physician during the preceding year. This includes (a) the dollar amount invested by each physician holding such an ownership or investment interest; (b) the value and terms of each such ownership or investment interest; and (c) any payment or other transfer of value provided to a physician holding such an ownership or investment interest; among other information.\textsuperscript{14}

IV. RECOMMENDATIONS

Understanding the scope and nature of the ownership interests held by physicians in PODs, including the value and terms of such ownership, is critical in order to enforce the Stark Law and the Anti-Kickback Statute as they relate to PODs. Despite the OIG’s concerns over PODs highlighted in its Special Fraud Alert, a lack of transparency raises issues about the OIG’s ability to ensure that these arrangements do not violate the Anti-Kickback Statute and the Stark

\textsuperscript{13} See 42 U.S.C. § 1320a-7h(a)(1); see also 42 C.F.R. § 403.904.

\textsuperscript{14} See 42 U.S.C. § 1320a-7h(a)(2); see also 42 C.F.R. § 403.906.
Law as well as protecting patient safety and quality of care. In keeping with the purpose of the Sunshine Act and the identified needs of the OIG, transparency of POD relationships with physicians would enable providers and patients to identify more clearly unlawful PODs and conflicts of interest of their treating physicians.

As such, AdvaMed would suggest the recommendations outlined below:

**First, CMS should issue guidance that adopts a standard definition of “PODs.”** This should serve to provide clarity to stakeholders as to the types of entities CMS is addressing. AdvaMed recommends the definition used at the outset of this letter:

A “Physician-Owned Distributor” or “POD” is any entity, or any affiliate of an entity, in the medical device supply chain that has physician ownership, including ownership by individual physicians, a physician’s immediate family members or agents, trusts, partnerships, limited liability companies, corporations, unincorporated associations, or any other entity established by or on behalf of physicians (“Physician Owner(s)”) and that meets each of the following:

- The entity derives any proportion of its revenue from (a) selling or arranging for the sale of medical devices ordered by Physician Owners for use in procedures using products distributed by the POD and performed by a Physician Owner or any other physician affiliated with the POD or affiliated with the Physician Owner or (b) patient referrals to other physicians who perform procedures using products distributed by the POD; and

- Physician Owners are compensated in the form of a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from (a) the sale or distribution of POD devices used in procedures performed by such Physician Owner or any other physician affiliated with the POD or affiliated with the Physician Owner or (b) the referral of patients by the Physician Owner to other physicians who perform procedures using products distributed by the POD.

**Second, CMS should issue guidance clarifying that all PODs must comply with the Sunshine Act.** Such guidance (an FAQ or other information guidance) could clarify the points described above. In brief:

- All PODs must report as GPOs, regardless of whether they sell to one or multiple entities. A POD must comply with the Sunshine Act as a GPO if it purchases, arranges for, or negotiates the purchase of a product for a group of individuals or entities. Because the statute and regulations do not specify which “group” a GPO must purchase for and because the statute gives CMS broad discretion to further
define GPO, this necessarily can include a POD’s purchasing, arranging for, or negotiating the purchase of a product for – i.e. on behalf of, for the benefit of, or at the direction of – the POD owners.

- All PODs that take title to product must report as applicable manufacturers. This requirement relies on the plain language of CMS’s previously issued Sunshine Act regulations. CMS should also require companies submitting reports to indicate affirmatively whether they are PODs that take title to the products being sold.

Third, in addition to clarifying that all PODs qualify as GPOs, CMS should require parties submitting data into its Open Payments website to indicate whether they are applicable manufacturers, GPOs, or PODs. Given hospitals’ and the OIG’s lack of visibility into which entities are PODs – and given the risks identified by the OIG in its Special Fraud Alert – it would significantly help move the issue forward if PODs were obligated to self-identify as such on the Open Payments website.

Finally, CMS should clarify in its guidance that PODs must disclose ownership interests, including how such interests are valued. More specifically, CMS should clarify that PODs must disclose ownership or investment interests held by a physician or a physician’s immediate family member during the preceding year, including (a) the dollar amount invested by each physician holding such an ownership or investment interest; (b) the value and terms of each such ownership or investment interest; and (c) any payment or other transfer of value provided to a physician holding such an ownership or investment interest; among other information.\footnote{See 42 U.S.C. § 1320a-7(b)(2); see also 42 C.F.R. § 403.906.}

V. CONCLUSION

AdvaMed appreciates the opportunity to provide information on the applicability of the Sunshine Act to PODs and the critical need for transparency in this area. We are happy to provide any additional details or input that CMS might require as you continue to examine this issue. If you have any questions, please feel free to contact me directly.

Sincerely,

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Advanced Medical Technology Association