September 1, 2016

Via Overnight Mail

Erin Skinner, Esq.
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-1654-P - Mail Stop C4–26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1654-P: Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Reports of Payments or Other Transfers of Value to Covered Recipients

Dear Ms. Skinner:

On behalf of the members of the Advanced Medical Technology Association ("AdvaMed"), we write in response to the Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") request for comments on the Open Payments Program contained in the proposed 2017 Physician Fee Schedule rule ("Proposed Rule"). 1 AdvaMed appreciates the ongoing, open dialogue that we have shared with CMS regarding the impact of the agency’s Open Payments Program, created to implement the U.S. Physician Payments Sunshine Act ("Sunshine Act"). 2 We also appreciate CMS’s willingness to account for the practical impact and potential administrative burden of disclosure requirements on applicable manufacturers and group purchasing organizations ("GPOs") in considering enhancements to the Open Payments Program. AdvaMed supports the purpose and intent of the Sunshine Act and other transparency measures (i.e. to provide the public and patients with clear, meaningful information concerning industry relationships with health care providers) while acknowledging that such transparency measures should not discourage beneficial interactions critical to the development of safe and effective use of innovative medical technologies. AdvaMed understands that the agency does not intend to finalize any rulemaking as a result of the Proposed Rule, and we provide our comments below.

I. PAYMENT CATEGORIES

AdvaMed recommends that CMS should adopt four new payment categories in order to enhance the accuracy of data disclosed under the Open Payments Program and to provide greater clarity for the public and patients with respect to interactions between industry and covered recipients. These proposed categories would include: Equipment Evaluation/Loan; Debt Forgiveness; Acquisition Payments; and Other.

In the Proposed Rule, CMS requests whether "the nature of payment categories as listed at § 403.904(e)(2) are inclusive enough to facilitate reporting of all payments or transfers of value to covered recipient physicians and teaching hospitals" and seeks feedback on "further categorization of reported research payments."³ AdvaMed believes that additional categorization would benefit patients, the public, and other stakeholders by facilitating clearer, more meaningful reporting of payments or transfers of value to covered recipients. In particular, AdvaMed recommends the addition of the following categories:

- **Equipment Evaluation/Loan.** The Sunshine Act and CMS regulations require applicable manufacturers to report any capital equipment evaluations or loans that extend beyond 90 days;⁴ however, neither the statute nor the regulations provides a nature of payment category that squarely fits these arrangements. Disclosing a

---

3. 81 Fed. Reg. at 46,395. Section 403.904(e)(2) of 42 C.F.R. includes the following nature of payment categories for use by applicable manufacturers and GPOs in submitting annual reports on transfers of value and payments made to covered recipient physicians and teaching hospitals:

   (i) Consulting fee.
   (ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.
   (iii) Honoraria.
   (iv) Gift.
   (v) Entertainment.
   (vi) Food and beverage.
   (vii) Travel and lodging (including the specified destinations).
   (viii) Education.
   (ix) Research.
   (x) Charitable contribution.
   (xi) Royalty or license.
   (xii) Current or prospective ownership or investment interest.
   (xiii) Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.
   (xiv) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
   (xv) Grant.
   (xvi) Space rental or facility fees (teaching hospital only).

42 C.F.R. § 403.904(e)(2).

non-research-related evaluation or loan beyond 90 days under another category might not provide the most accurate description to the public and, in turn, might lead to a misunderstanding of the nature and scope of these legitimate, necessary arrangements. To provide the most clarity and accuracy, a category for “Equipment Evaluation/Loan” would permit manufacturers to disclose on the general, non-research report these circumstances in a way that provides the greatest transparency and does not create any misleading or inaccurate disclosures.

- **Debt Forgiveness.** As with any commercial operation, applicable manufacturers are occasionally required to forgive unpaid debts from customers that have defaulted on payments. According to CMS’s Frequently Asked Questions, debt forgiveness “for the remaining balance of a covered drug, biological, device or medical supply purchased by a covered recipient is considered a payment or transfer of value and reportable for purposes of Open Payments.”

Manufacturers, however, may need to disclose these payments under other categories and, in particular, the “Gift” category as there is no category that best describes debt write-off. Requiring manufacturers to disclose debt forgiveness as a “Gift” could present a misleading image to the public, would draw inappropriate and inaccurate inferences about the relationship between the manufacturer and the customer, and might impact other legal standing issues between the manufacturer and the customer (i.e. the creditor-debtor relationship), among other concerns. Accordingly, the addition of a category specifically designed to capture and account for these payments would provide greater clarity to these types of legitimate, standard commercial interactions between industry and covered recipients.

- **Acquisition Payments.** Medical device companies engage frequently in corporate transactions, as described in greater detail in Section IX of this letter, including the acquisition of other companies. In the course of these acquisitions, there may be situations in which a company makes a payment to a physician shareholder of the acquired company for a variety of purposes (e.g., purchase payments made in exchange for the physician’s equity in the acquired company, escrow release payments, executive compensation plan payments, and FDA milestone payments). These payments are legitimate and necessary as part of many corporate transactions. To the extent that these payments are reportable, there is no clear, relevant nature of payment category that applies. Certainly, disclosing

---


6. The payments anticipated for inclusion in this new payment category related to debt forgiveness are distinct from payments made to physician covered recipients in connection with legal settlements, which are exempt from reporting. 42 C.F.R. § 403.904(h)(2)(13). See also Centers for Medicare & Medicaid Services, Frequently Asked Question 9120, available at https://questions.cms.gov/faq.php?id=5005&faqId=9120.
such a payment as a “Gift” or as a “Royalty” to a physician would not provide the public with the most accurate depiction of these types of arrangements and could even be considered misleading, as the payment reflects the fair market value consideration provided in exchange for the physician’s ownership interests. Accordingly, we recommend the addition of a category specifically designed to capture and account for payments associated with acquisitions.

- **Other or Miscellaneous.** We believe that with the existing nature of payment categories and the addition of the three categories discussed above, most payments and transfers of value will be accurately and specifically categorized. However, there may be occasional instances in which none of the categories serves as an accurate description of the payment or transfer of value at issue, leaving companies to make a “best guess” or use the category that most closely approximates the transaction.\(^7\) The result is that data disclosed to the public might be complete but might also fail to provide patients and the public with the clearest picture of the transaction, preventing an accurate analysis. Accordingly, AdvaMed recommends the addition of an “Other” or “Miscellaneous” category that requires a brief, free-text description of each payment that a manufacturer discloses hereunder. This would represent a small proportion of payments each year; but it would also provide additional clarity to the Open Payments reporting system, would avoid circumstances in which companies are forced to depend upon the “Gift” category unnecessarily, and would help to ensure that the patients and the public have the best and most accurate information.

- **Research Categorization.** CMS also seeks feedback on further categorization of reported research payments. AdvaMed does not believe that additional categorization of research-related payments is necessary and that the current rubric for categorizing research related payments, as specifically detailed in the regulations and available guidance, is sufficient. Our members report that they have received few, if any, disputes related to the categorization of research payments.\(^8\) In addition, requiring manufacturers to further categorize research payments may be disruptive as any such change would require adjustments to established tracking and reporting systems.

---

7. Companies are required to “categorize each payment or other transfer of value . . . with one of [these] categories . . . using the designation that best describes the nature of the payment.” Further, to the extent that a payment might fall within one or more categories, a manufacturer is urged to “select one category that it deems to most accurately describe the nature of the payment or transfer of value.” 42 C.F.R. § 403.904(e)(2) (emphasis added).

8. Instead, research payment disputes have tended to relate to the identification of the principal investigators and/or appropriate payees.
II. RECORD RETENTION

_AdvaMed recommends that CMS establish a cap on reporting, limited to the two most recently published program years for Open Payments reporting purposes._

In the Proposed Rule, CMS seeks feedback on how many years an applicable manufacturer or GPO should continue to report on past program years for Open Payments reporting purposes, noting that the regulations are silent on this point.9 AdvaMed’s member companies have committed significant resources to developing Open Payments compliance programs intended to capture and disclose fully and accurately all payments and other transfers of value made to U.S. physicians and teaching hospitals. These compliance programs reflect the culmination of years of development and testing of their effectiveness and ability to capture and report this data.

AdvaMed would propose a cap on updating previous years’ data limited to the two most recently published program years (for example, as of the date of the drafting of this letter, this would include 2014 and 2015). Reporting on previous years’ transactions requires substantial resources, including technology to monitor such data, human resources intended to review and analyze past years’ data, and human resources to file updated reports on such data. Limiting the reporting requirement to the most recent two published years alleviates a significant resource burden for manufacturers while simultaneously benefiting the integrity of the data reviewed by the public. It is also within this same period of time that companies are more likely to uncover any technical oversights leading to the need to refresh Open Payments data. Further, by establishing a clear cap on companies’ obligations with respect to monitoring and refreshing previous years’ data, the agency would essentially create “final” data for the public’s review and assessment, which would ultimately enhance public and patient confidence in the data.

III. REFRESHED AND ARCHIVED DATA

_AdvaMed recommends that CMS publish and refresh data on the agency’s website for the same period of time that manufacturers are obligated to monitor and refresh data from past years._

_AdvaMed also recommends that CMS archive data on its website for a maximum period of five years from the date the payment or transfer of value is published on the Open Payments website._

CMS has requested feedback from stakeholders on (a) how many years of Open Payments data is relevant to continue to publish and refresh annually on the CMS website and (b) how many years of such data might be useful to Open Payments data users as archive files available for download on the CMS website.10

---

10  See id.
With respect to refreshing data contained on its own website, CMS depends upon updated and refreshed data from applicable manufacturers and GPOs. Accordingly, to the extent CMS obligates applicable manufacturers to monitor and report on past program years, CMS should limit its requirement to update data on the website to the same degree.

With respect to archiving data on CMS’s website, because applicable manufacturers and GPOs must maintain records on payments and transfers for a period of five years from the date the payment or transfer of value is published on the Open Payments website, the most appropriate and equitable approach would be to limit the archived data on CMS’s website to five years. To the extent that companies receive inquiries from the public, patients, physicians, or the press on past years’ data found on CMS’s website, companies should only be expected to respond to such inquiries if they relate to data from the previous five years. Accordingly, CMS should only continue to post previous years’ data to match this timeframe. To post more than five years’ worth of data on the CMS website would create a de facto recordkeeping obligation for manufacturers of longer than five years as well. It also helps to ensure that companies are able to respond to inquiries with the most accurate and best data available.

IV. REGISTRATION REQUIREMENT

*AdvaMed strongly discourages the agency from adopting any rule or standard that would obligate applicable manufacturers and GPOs to register with CMS even if there are no reportable payments in a calendar year or that would require applicable manufacturers and GPOs to disclose a reason indicating why the entity did not have reportable transactions for the year.*

*AdvaMed recommends that the agency clarify that any entity with reportable physician ownership interests — for example, a physician-owned distributor or POD — is obligated to register and file reports annually.*

In the Proposed Rule, CMS solicits feedback as to whether applicable manufacturers and GPOs should be obligated to register with CMS each year, regardless of whether the entity will be reporting payments or other transfers of value or ownership/investment interests. For those entities that do not have any payments to report, CMS seeks comment on requiring these manufacturers and GPOs to include the reason for not reporting any payments, transfers of value, or ownership or investment interests. In brief, mandating registration of non-reporting companies and mandating reporting of “non-disclosure” reasoning would not serve to increase the accuracy and completeness of the data that other companies disclose and would not benefit the patients or the public. Patients and the public will typically research their individual physician or hospital names and, accordingly, including companies that did not report would not assist these individuals in making an informed decision about the independence of the care that...

---

11. *See 42 C.F.R. § 403.912(e)(ii).*

they receive. Such a requirement would only add to the administrative burden and cost of compliance for all manufacturers and GPOs.

More specifically, registration with CMS under the Open Payments program should not be required if there are no payments to be disclosed. Currently, if an applicable manufacturer made no reportable payments or transfers of value or had no reportable ownership or investment interests under the Sunshine Act, the manufacturer is specifically not required to file a report with CMS or register with CMS. Put another way, there is no statutory or regulatory requirement for manufacturers to report on the absence of payments. Manufacturers are subject to significant other registration and licensure requirements. An additional registration with the U.S. government as an applicable manufacturer or GPO for purposes of Open Payments would not result in any efficiencies for the Medicare program or for Medicare beneficiaries, nor would it increase the transparency of payments and transfers of value made by other manufacturers.

Further, companies are already expected to comply with the Sunshine Act and CMS’s implementing regulations, which includes conducting their own internal legal analyses as to whether specific payments must be disclosed and/or whether a company must register with the agency. To the extent that a company’s legal analysis concludes that registration is not required as a result of having no disclosable transactions during the year, this decision would be documented internally for future reference, when appropriate. As such, the current regulations are sufficient on this point.

Similarly, companies should not be obligated to include a reason for not reporting any payments or transfers of value. As noted above, there is no requirement in the statute or regulations for manufacturers to report on the absence of payments. A company’s compliance with the Sunshine Act and Open Payments Program should be based upon the company’s own internal legal analysis as to whether there have been any reportable payments. If the company concludes that it does not have reportable payments, this is an internal decision based on the company’s internal analysis that would be documented, when appropriate. Similar to the registration question, requiring companies to disclose a reason for the absence of reportable payments – which could implicate privileged, confidential, and/or proprietary company information – creates a de facto reporting requirement outside of the statute. Registration requirements and any form of disclosure (whether disclosing the amounts of actual payments or disclosing the reason for not having made any payments) requires company resources and is a timely process.

There are some circumstances, however, where it would be beneficial for CMS to make more clear that entities are required to register and disclose data on an annual basis. For example, non-publicly held companies with physician ownership interests, whether such interests are held directly by physicians or indirectly through physician family members, must disclose such interest annually. Indeed, the Senate Finance Committee recently charged CMS with enhancing its enforcement of the Sunshine Act specifically with respect to physician-owned

---

13. See 42 C.F.R. § 403.908(b).

14. See id. § 403.906.
distributors or PODs. AdvaMed recommends in Section XI of this letter several additional enhancements that would benefit the agency in this effort; but one critical component to such enforcement would be to ensure that all PODs are registering and reporting on an annual basis. This could include clarifying in its regulations implementing the Sunshine Act that PODs are considered to be physician-owned entities that qualify as GPOs and/or applicable manufacturers and, accordingly, must disclose all physician ownership interests on an annual basis.

V. PRE-VETTING OF DATA WITH COVERED RECIPIENTS

AdvaMed recommends that CMS should facilitate but not require pre-vetting of Open Payments data with covered recipients.

CMS has requested comments on whether applicable manufacturers and GPOs should pre-vet payment information with covered recipients, physician owners, and investors prior to reporting the information to the Open Payments system. CMS notes that such pre-vetting could be based on threshold payment amounts or based on random samplings of covered recipients. While some companies do engage in pre-vetting of Open Payments data with covered recipients in advance of disclosure, AdvaMed strongly recommends that the agency should not adopt a pre-vetting requirement for several reasons:

- An effective and comprehensive pre-vetting program would require substantial resources from applicable manufacturers and GPOs. Pre-vetting, depending upon its scope, would obligate companies to prepare submissions to countless numbers of covered recipients, many of which have inaccurate or incomplete contact information in the relevant CMS databases. This would require company resources to draft, review, and quality check communications disclosing such information as well as company resources available to respond to questions from covered recipients.

- Given the sheer numbers of covered recipients with which many companies interact, there is a great potential of creating an unintended privacy risk to the extent that physicians and others are accidentally afforded access to others’ data.

- Adding a pre-vetting requirement would add a substantial burden to the already narrow timeframe that companies have to review, validate, process, and disclose information under the Open Payments Program. This will be especially impactful.


16. PODs, by their very nature as physician-owned companies, would always be subject to registration and physician ownership reporting requirements under the current regulations. See generally 42 C.F.R. § 403.906.

on companies with fewer resources available to address modifications to the Open Payments program. The current reporting window closes on March 31st of each year. Companies currently spend significant time and resources during the first quarter of the calendar year to review, prepare, finalize, and submit their Open Payments data. Adding a pre-vetting requirement would add another several weeks to the process, and the result would be rushed data and inaccuracies — not better, more accurate data.

- The substantial burden of conducting mandatory pre-vetting activities is likely to outweigh any benefits resulting from the same. This is particularly true given that mandatory pre-vetting activities would necessarily be focused on small dollar transactions (e.g., meals) since large value transactions, such as consulting arrangements, grants, and research payments, are already subject to contracts and written documentation, which provide covered recipients sufficient notice of reportable payments and transfers of value. Given the great variation in companies’ technological ability to pre-vet small dollar transactions, it is impractical and unfair to mandate pre-vetting activities.

- The pre-vetting process would duplicate the efforts that companies undertake in order to respond promptly, accurately, and completely to covered recipients in connection with the Open Payments dispute resolution process.

AdvaMed does support the agency in any efforts it would undertake to encourage and facilitate companies’ pre-vetting with covered recipients — to the extent that individual companies believe they have sufficient resources to handle such a process. This could include, for example, instituting measures such as providing key hospital contact information, communication tools, or an online forum that would assist those companies that opt to pre-vet their data voluntarily.

VI. DEFINITION OF COVERED RECIPIENT TEACHING HOSPITAL

AdvaMed recommends that the agency provide clear guidance on the use of the Open Payments List of Teaching Hospitals and a comprehensive list of teaching hospitals, identified by their tax identification numbers ("TINs"). CMS should also clarify that manufacturers must only disclose reportable payments or other transfers of value that are made to entities with the TINs on the List.

CMS notes in the Proposed Rule that the agency has received feedback that the current definition of a covered recipient teaching hospital makes reporting payments or transfers of value difficult in many instances. Given that the U.S. Physician Payments Sunshine Act does not contain a definition of this term, CMS has requested feedback on the challenges that the term
“teaching hospital” has posed and proposed alternative definitions. Manufacturers have experienced several challenges related to reporting payments and transfers of value to teaching hospital covered recipients. Our members have experienced the following issues:

- Teaching hospitals requesting that payments be made to alternative branches of the institution or foundations in order to prevent the payment or transfer of value from being reporting;
- Teaching hospitals that use D/B/A names so that correlation to the published list of teaching hospitals is difficult or impossible;
- Teaching hospitals may have multiple TINs; and
- Teaching hospitals with fluid corporate structures, making it difficult or impossible for manufacturers to identify the appropriate covered recipient to be reported.

Given these situations, manufacturers are frequently left to conduct their own research and investigation into the corporate structures and identities of hospitals, developing their own understanding of whether and how seemingly affiliated hospital entities relate to one another. The potential result is data and information that is inconsistent from manufacturer to manufacturer.

Rather, manufacturers need clear guidance from CMS on how to use the Open Payments List of Teaching Hospitals (“List”), and request a clear and comprehensive List. It must include all teaching hospital covered recipients and their component organizations for purposes of Open Payments reporting. Teaching hospital covered recipients should be identified on the List by their TINs and CMS should clarify that a manufacturer is only required to report those reportable payments or other transfers of value that are made to entities with the TINs identified on the List. Manufacturers should not be required to conduct endless independent research into the naming conventions and corporate structures of teaching hospitals (which may be ever-changing, as noted above). A single, comprehensive List based on a discreet piece of data actually available to manufacturers (i.e. TINs) ensures consistent and accurate Open Payments reporting and data.

VII. TEACHING HOSPITAL REPORTING INFORMATION

*AdvaMed supports the voluntary addition of nonpublic data elements that might assist Teaching Hospitals in the review and verification of data disclosed under their names.*

CMS has noted that some stakeholders report difficulty verifying receipt of payments or transfers of value to teaching hospitals, leading to payment disputes. CMS is seeking feedback

18. 81 Fed. Reg. at 46,395. CMS regulations currently define “Teaching Hospital” as “any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act [medical education-related payments under Medicare] during the last calendar year for which such information is available.” 42 C.F.R. 403.902.
on adding “a new nonpublic data element to assist in review and affirmation of payment records,” including hospital contact name, department, etc.\(^{19}\) including whether a free-text form would be preferable.

In brief, AdvaMed supports the opportunity to voluntarily provide data on teaching hospital transactions. Indeed, it has been the experience of many AdvaMed members that some teaching hospitals will dispute all data disclosed under their names in an effort to solicit additional details about the payments being disclosed. Accordingly, AdvaMed believes the voluntary addition of any information to the data disclosure field – for example, nonpublic data elements designed to assist in the review of such information – would be helpful for teaching hospitals, manufacturers, and ultimately the public. It could be especially beneficial, for example, for manufacturers to provide the name of the department to which it made the payment (if known) and the name of a contact person at the hospital associated with the payment (if known). This additional information should be sufficient to assist teaching hospitals in verifying these payments without initiating disputes of all data disclosed under their names. Further, this additional voluntary information should provide teaching hospitals with sufficient details in order to track the payments made to their institutions. Adding the option to provide such data in those cases where it is available could help to improve the accuracy of the data disclosed publicly under the Open Payments program.

**VIII. EARLY AND ONGOING REPORTING THROUGHOUT THE YEAR**

AdvaMed supports the agency’s efforts to facilitate but not to mandate early and ongoing reporting throughout the year.

CMS has requested whether permitting early or ongoing data disclosure throughout the year – for example, prior to the end of the calendar year for which data is collected – would be beneficial to applicable manufacturers and GPOs.\(^{20}\) AdvaMed supports any opportunity to allow – but not require – companies to submit data on a rolling or ongoing basis. Some companies review and verify data internally on a quarterly or semi-annual basis. Permitting companies to disclose early may allow for a more efficient use of resources. However, most companies review and validate their data annually, once all data has been received internally. As such, early or ongoing disclosure should not be mandated but rather voluntary, as companies’ systems for reviewing and verifying payment data vary depending upon the size and resources of the relevant company. Among the steps that CMS could take to facilitate such voluntary early or ongoing reporting:

- Update the Open Payments reporting system such that companies are not limited from entering, submitting, and validating data to a specified timeframe within the year;

- Modify the dispute resolution process such that covered recipients are notified on

---

\(^{19}\) 81 Fed. Reg. at 46,395-96.

\(^{20}\) Id.
a rolling basis of disclosures made under their names and providing them with a rolling dispute window of 45 days upon receiving such notice;

- Enhance the process by which CMS validates and uploads covered recipient contact information, which allows for a more streamlined dispute resolution process;

- Publish changes to data in a timely manner; and

- Adjust systems to make sure that revisions to the law or regulations or informal guidance are not applied retroactively to previously disclosed data.

IX. CORPORATE TRANSACTIONS

AdvaMed recommends that CMS adopt revisions within its Open Payments system that would permit companies to disclose and update data on payments and transfers of value made to physicians and teaching hospitals in a way that accounts for the practicalities of engaging in corporate transactions, such as mergers, acquisitions, and other arrangements.

CMS seeks feedback in the Proposed Rule on how CMS might change its reporting requirements to account for industry mergers, acquisitions, corporate reorganizations, and other transactions.\textsuperscript{21} The medical device industry is a highly dynamic industry characterized by rapid innovation across all specialties and sectors. Corporate transactions play a significant role in the lifecycle of medical technology innovation. Companies frequently engage in a variety of transactions, such as acquisitions, divestitures, and investments, to fuel growth and innovation. Many of these transactions involve purchasing, investing in, or selling smaller companies. Indeed, the majority of companies (approximately 86\%) in the medical device industry are companies with fewer than 100 employees – companies particularly prone to involvement in corporate transactions.\textsuperscript{22} Accordingly, understanding the impact of the Sunshine Act on corporate transactions is critical for the industry.

A common example of the type of transaction we are referencing would be a situation in which one company ("Purchaser") purchases the equity or assets of another company ("Target"). In some cases, the Target ceases to exist as a separate legal entity after the transaction has closed. In other cases, part of the Target is rolled into the Purchaser while other components of the Target continue to operate independently and not under any common ownership with the Purchaser. In yet other cases, a company might sell or spin-off portions of its business, but not the entire business. In each of these situations, the application of Open Payments in connection with these deals creates some areas of practical concern.

\textsuperscript{21} Id.

\textsuperscript{22} Approximately 70\% of AdvaMed's membership, in fact, is comprised of small, innovator companies.
A. Complete Acquisition

In a complete corporate acquisition, the purchaser acquires all of the stock or assets of the Target. Upon the close of the transaction, the Target ceases to exist as a separate legal entity. CMS, however, only permits the release of Target’s roles and responsibilities in the Open Payments system upon receipt of written permission from Target on legacy letterhead and requires Purchaser to recertify the Target. Upon the close of the transaction, however, the Target no longer exists as a distinct legal entity. Often, the individuals responsible for Sunshine Act compliance on behalf of the Target are no longer employed by the Purchaser after the transaction closes. It becomes difficult for the Purchaser to access the Target’s previously submitted data.

Accordingly, AdvaMed recommends that CMS permit the Purchaser to submit a notification to CMS that the corporate transaction has been completed and that the Purchaser is now responsible for the Target’s data. CMS should also (i) include an option that allows the Purchaser to indicate for previously submitted data that the Target is no longer active, which should be disclosed on the Open Payments website and (ii) permit the Purchaser to clarify on the Target’s previous disclosures that Target is now owned by Purchaser. Allowing this type of public disclosure about the transaction will also assist in dispute resolution by providing covered recipients with notice that the Purchaser is now the relevant entity to contact. It will also provide greater and better clarity with respect to the data being disclosed, thereby continuing to improve the meaningfulness of the Open Payments data.

B. Partial Acquisition

In those circumstances in which the Purchaser acquires only one of the Target’s business lines, upon the close of the transaction, Target continues to operate independently; however, part of Target’s previous business is now owned and operated by Purchaser. The acquired business may maintain its original TIN after the acquisition. In these cases, AdvaMed would request that CMS issue guidance clarifying that responsibility for disclosure and responsibility for payments previously disclosed must be determined independently by the parties to a corporate transaction and documented in the purchase or other transactional agreement(s). To the extent that these agreements are silent, we would recommend that (a) the Target business remains liable and responsible for all data disclosed prior to the date on which the transaction closed and (b) the Purchaser is obligated to file Sunshine Act reports on Target business’s payments and transfers of value made to U.S. physicians and teaching hospitals on or after the closing date. AdvaMed would also recommend that CMS issue guidance clarifying a process to follow in the CMS Open Payments reporting system in these circumstances.

Additionally, because the TIN of the acquired business was unchanged, the CMS portal does not allow for two separate instances of the same entity to be registered (i.e. one entity registered for the disclosable transfers of value made prior to the acquisition; one entity registered for the disclosable transfers of value made after the acquisition). Therefore, each manufacturer (the manufacturer that sold the business and the manufacturer that acquired the business) would need to use the same registered entity in the CMS system during the same reporting period to submit pre- and post-acquisition transfers of value. AdvaMed recommends
that CMS permit some flexibility in permitting companies to register pre- and post-acquisition businesses under different names, even if the TINs remain the same.

C. Delayed Disclosure

With respect to payments disclosed by the Target that are subject to delayed disclosure and that Purchasing company will be responsible for continuing to maintain and monitor after closing, it has come to AdvaMed’s attention that CMS is unable to transfer the delayed disclosure payments from the original entity to the new entity. AdvaMed recommends that CMS allow the Purchaser to flag data previously submitted by the Target and incorporate enhancements to the system that would automatically transfer these line items to the Purchaser’s name/TIN.

There may also be circumstances in which the Target does not have any delayed transactions; however, Purchaser is required to maintain the Target’s registration and profile. AdvaMed recommends that CMS require the Purchaser to maintain the Target’s registration and profile for only two years after the Target’s final reporting of pre-acquisition payments. (If the Target has delayed transactions, this period should increase to four years after the Target’s final reporting year of pre-acquisition payments.) The Purchaser should provide notice to CMS that it will no longer maintain the Target as a separate entity and after the Target’s registration and profile are no longer maintained, CMS should keep the data on the Open Payments website as “read-only.”

D. Dispute Resolution Window

AdvaMed has received some reports that physicians and other covered recipients may be able to initiate disputes about data after the end of the calendar year. This could have a significant impact on corporate transactions, as disputes may arise with respect to data that was not submitted by the Purchaser and for which the Purchaser has little information. Accordingly, AdvaMed recommends that CMS ensure that the dispute resolution function is closed for previously submitted data on December 31st of each year.
X. REQUIREMENTS FOR REPORTING OWNERSHIP AND INVESTMENT INTERESTS

Advamed recommends that CMS clarify that the value of a physician's ownership interest in a manufacturer or GPO — including PODs — should reflect (a) the fair market value in dollars of the ownership or investment interest at the end of the year for which the data is being gathered or (b) if such ownership or investment interest has been sold, transferred, or otherwise disposed of during the calendar year, the fair market value in dollars of the ownership or investment interest on the last day such interest was held by the physician.

Advamed also recommends that CMS clarify entities' obligations with respect to reporting the "terms" of ownership. In addition, "dollar amount invested" should reflect the actual amount that a physician invests in an entity at the time of the investment.

CMS has requested feedback on definitions regarding physician ownership and investment interests. In particular, CMS seeks feedback on operationally feasible definitions of the terms "value or interest" and "dollar amount invested," among other terms that stakeholders believe require additional clarification.23

Advamed appreciates the opportunity to provide feedback on certain definitions regarding physician ownership and investment interests. Clarifying the reporting requirements for physician ownership and investment interests will help to ensure consistent reporting obligations among applicable manufacturers, PODs, and GPOs.24 We believe the current definition of "ownership or investment interest" at section 403.902 of 42 C.F.R. sufficient and no further clarification is required with respect to this definition. However, additional clarification with respect to the "value" of each ownership or investment interest and "dollar amount invested" would be beneficial.25 First, to ensure accurate and consistent reporting, we believe "value" should be measured as (a) the fair market value in dollars of the ownership or investment interest at the end of the year for which the data is being gathered or (b) if such ownership or

---


24. Clear and consistent reporting is particularly important in light of the Senate Finance Committee's call for CMS to ensure PODs are complying with the Sunshine Act. See SFC Report, suprA note 15, at 25 ("CMS should undertake increased enforcement actions [against PODs] to ensure compliance with Sunshine Act reporting requirements."). We discuss PODs in more detail in Section XI.

25. Current CMS guidance in the form of an FAQ notes that reporting entities "have some flexibility to decide how to report the 'value'” of ownership interests and that they must simply document the method used to estimate such value. The same guidance also notes that manufacturers and GPOs, including PODs, would report "the total value a physician owner or investor or physician owner or investor's immediate family member holds in an applicable manufacturer or applicable group purchasing organization at the end of preceding calendar year." Centers for Medicare & Medicaid Services, Frequently Asked Question 8376, available at https://questions.cms.gov/faq.php?id=5005&faqId=8376.
investment interest has been sold, transferred, or otherwise disposed of during the calendar year, the fair market value in dollars of the ownership or investment interest on the last day such interest was held by the physician. (For example, on March 31, 2016, a POD would be obligated to disclose the value of each physician’s ownership interest as of December 31, 2015. If, however, a physician owner has sold his/her ownership interest on August 1, 2015, the POD would be obligated to disclose the value of the physician’s interest as of July 31, 2015.)

Equally imperative is the need for CMS to make clear in its guidance and in its Open Payments reporting system that the agency’s existing regulations require entities disclosing physician ownership interests to disclose not only the value of the interest but the “terms” of the interest. See 42 C.F.R. 403.906(b)(5). CMS’s current guidance on this topic simply requires identifying the type of ownership or investment interest (e.g., stock, stock options, etc.); however, AdvaMed believes that this information does not reflect the “terms” of the ownership interest but rather only describes the type of ownership interest. In order to provide greater information to the public and to patients, a more robust disclosure would include, among other things, the duration of ownership, the ability for a physician owner to earn any commissions or other sales-related payments, whether ownership is contingent upon the physician undertaking any sales or marketing role for the company, whether the physician can earn a commission on procedures that he/she performs (or his/her immediate family member performs or that result from his/her referrals), and any other material information that would allow a patient to identify whether the ownership interest creates a conflict such that it would impact the physician’s independent medical judgment.

Second, the “dollar amount invested” should reflect (a) the actual dollar amount a physician has invested in an entity, as measured at the time of investment and (b) any other terms or conditions that the physician has agreed to undertake as consideration for an ownership interest in the POD. See Centers for Medicare & Medicaid Services, Frequently Asked Question 8376, available at https://questions.cms.gov/faq.php?id=5005&faqId=8376. Clarification as proposed with respect to both value and dollar amount invested could be made either through regulatory definitions or through CMS guidance (e.g., FAQs). We believe that clarification of these data points (the amount originally invested as measured at the time of investment, the present-day value of the investment as of the end of the reporting year and/or at the time of disposition of the ownership interest, and the terms of the ownership interest) would be elaborative and serve to provide the public and patients with great clarity and insight into the scope and degree of an individual physician’s financial interests in entities like PODs, which the Senate Finance Committee recently indicated “present an inherent conflict of interest that can put the physician’s medical judgment at odds with the patient’s best interest.”

26. See 42 C.F.R. 403.906(b)(5).
28. In some cases, physicians may not make an actual dollar investment in exchange for ownership interests in a POD; rather, physicians might agree to sell or market POD products or agree to use POD products in their own surgeries.
XI. PHYSICIAN-OWNED DISTRIBUTORS ("PODs")

AdvaMed recommends that CMS adopt a clear definition of "physician-owned distributor," make clear that all PODs are obligated to submit reports under the Sunshine Act, and implement regulatory revisions to address recommendations contained in the Senate Finance Committee's recent report on PODs.

CMS has requested suggestions on how to define PODs for data reporting purposes, as well as what data elements PODs should be required to report. The issue of PODs has become a significant matter in recent months, especially in light of a new report from the Senate Finance Committee (May 2016) which included specific recommendations for CMS to address with respect to the treatment of PODs under the Sunshine Act.

A. Proposed Definition

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 by the Physician Owner to other physicians who perform procedures using products distributed by the POD; and

30. Id.

31. See SFC Report, supra note 15. Among the recommendations directed at CMS with respect to the Open Payments Program:

- CMS should require hospitals and ambulatory surgical centers to examine the Open Payments data collected under the Sunshine Act, and document that they have taken such data into account when making device purchasing decisions. See SFC Report at 24.

- CMS should undertake increased enforcement actions to ensure compliance with Sunshine Act reporting requirements. CMS and Congress should examine the benefit of increased penalties for intentional violations of the Sunshine Act. HHS OIG and law enforcement should investigate potential violations of the Stark Law and the Anti-Kickback Statute. See id. at 25.

- CMS should provide additional Sunshine Act guidance or rulemaking to make clear that the exception from reporting requirements for employment applies only to manufacturers (not GPOs), and only to bona fide employment, including standards that would preclude sham "employment" relationships from qualifying. See id.
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 POD’s sale or distribution of 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) from the POD. As a result, all spine surgeons at a local hospital may end up being pressured, to some degree, 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.32

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”).33

B. PODs’ Current Obligations to Report under the Sunshine Act

1. GPOs

For purposes of applying the Sunshine Act to PODs, CMS has been clear that the term “GPO” includes PODs.34 A GPO is defined under CMS’s regulations as “an 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.”35

32. 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.


34. See 78 Fed. Reg. 9,458, 9,493 (Feb. 8, 2013).

35. 42 C.F.R. § 403.902.
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 – the POD owners. PODs can also be argued to 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. Accordingly, all PODs – whether they sell to one or more entities – meet this definition.

37. Id.
38. “[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).
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. 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.

2. 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.

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.

39. 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-7(h)(e)(1) (emphasis added).
3. **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.

**C. 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.\(^{41}\)

- 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.\(^{42}\)

---

\(^{41}\) See 42 U.S.C. § 1320a-7(h)(1); see also 42 C.F.R. § 403.904.

\(^{42}\) See 42 U.S.C. § 1320a-7(h)(2); see also 42 C.F.R. § 403.906.
D. 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 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:

(a) The entity derives any proportion of its revenue from (i) 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 (ii) patient referrals by the Physician Owner to other physicians who perform procedures using products distributed by the POD; and

(b) 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 (i) 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 (ii) 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 – and for CMS to include in its public-facing data – whether they are applicable manufacturers, GPOs, distributors that take title to product, 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.

Fourth, as highlighted in Section IV of this letter, CMS should clarify that all entities with physician ownership interests – and in particular, PODs – are obligated to register and file reports annually. This clarification should assist the agency in meeting the Senate Finance Committee’s mandate to increase enforcement under the Sunshine Act.

Fifth, in addressing the recommendations from the Senate Finance Committee report, CMS should clarify that the exemption from reporting requirements for employment relationships only applies to applicable manufacturers and only to bona fide employment relationships.

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.\textsuperscript{43}

XII. OTHER OPPORTUNITIES FOR EFFICIENCIES

\textit{AdvaMed} recommends several additional revisions to the implementation of the \textit{Open Payments} Program and to its underlying regulations that could result in enhanced efficiencies and greater clarity and accuracy of data. These include modifying the preemption language to help ensure that the language addresses all state-level transparency obligations, clarify CMS's previous regulatory language regarding the reporting of continuing medical education-related payments, and enhancing the \textit{Open Payments} reporting system to account for technical concerns.

CMS has requested additional suggestions on opportunities to streamline and make the \textit{Open Payments} process more efficient, while continuing to ensure oversight, compliance, and enforcement.\textsuperscript{44} \textit{AdvaMed} recommends several additional recommendations, which we have outlined below:

A. Clarify Preemption Language

Based on the Sunshine Act's language, CMS has included a federal preemption provision in its current \textit{Open Payments} regulations.\textsuperscript{45} While the purpose of this language is to help ensure consistent reporting requirements and consistent data, some states have continued to issue industry transparency requirements and/or to modify their existing requirements to require continued reporting from manufacturers. For example, in Massachusetts, companies are required to report quarterly on meals with health care providers — including physicians — and to provide additional information beyond that required under \textit{Open Payments}.\textsuperscript{46} Given the significant resources that companies devote to compliance with transparency requirements, \textit{AdvaMed} recommends that CMS consider adopting stronger, clearer preemption language that would prohibit states from creating separate transparency reporting obligations or modifying existing ones.

\textsuperscript{43} See 42 U.S.C. § 1320a-7h(a)(2); see also 42 C.F.R. § 403.906.
\textsuperscript{44} 81 Fed. Reg. at 46396.
\textsuperscript{45} 42 C.F.R. § 403.914.
\textsuperscript{46} 105 MASS. CODE REGS. 970.006(4). Although the statute and related regulations remain in effect, Massachusetts has indicated, "A guidance document regarding the new quarterly meal reports is being worked on, and will be released in the near future. Until that time, manufacturers should not take any action regarding the quarterly meal reports. Once guidance is released, it will be available in this location." Press Release, Massachusetts Department of Public Health, Pharmaceutical and Medical Device Manufacturer Code of Conduct, (May 30, 2014) (\textit{available at} http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/healthcare-quality/pharm-code-of-conduct/medical-device-manufacturer-code-of-conduct.html). Massachusetts has not yet released this guidance.
More specifically, Advamed recommends the following revisions to the current preemption language found at section 403.904 of 42 C.F.R. (additions in **bold & italics**, deletions are struck-through):

In the case of *any* payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statutes or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, *any* the type of information regarding *any* the payment or other transfer of value *made to a covered recipient* required to be reported under this subpart.

We also believe that this language would prohibit states from requiring companies to add new disclosure systems designed specifically toward capturing data associated with only one state, especially when this data has already been considered and contemplated as reportable or not reportable by the federal government.

**B. Clarify Reporting Requirements for Continuing Education-Related Payments**

Advamed commends the agency's previous efforts to clarify when continuing education-related payments must be disclosed under the Sunshine Act. CMS included in its 2015 Physician Fee Schedule revised regulatory provisions that (1) removed the previous exemption from reporting for payments made in connection with continuing educational programs that were accredited by a limited list of accreditation organizations and (2) instructed manufacturers to report those continuing education-related payments that were determined to qualify as "indirect payments."47 The release of several FAQs and additional iterations of the same FAQs,48 however, has resulted in confusion among manufacturers and other entities — for example, medical specialty societies — with some parties asserting that no continuing education-related payments must be disclosed and others asserting that some such payments are disclosable.

Applicable manufacturers typically fund continuing education programs, which are organized by and implemented by third parties and not by manufacturers themselves, through unrestricted educational grants to the organizer.49 Educational grants provided to appropriate third-party conference organizers are not intended to benefit specific physicians or individuals. Manufacturers typically do not have visibility to how an organizer uses these funds. Indeed, the


49. These grants are largely considered "unrestricted" grants in the sense that manufacturers do not place limits on the topics or agenda items or require the use of funds to be directed at specific physicians or speakers. Manufacturers do, however, frequently "restrict" these grants by requiring third-party conference organizers to meet critical compliance obligations, by prohibiting organizers from using the funds to pay for meals or entertainment, or by mandating that third-party conference organizers' must return any unused funds.
AdvaMed Code of Ethics on Interactions with Health Care Professionals states:

Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be \textit{paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for bona fide educational activities}. Such grants also should be consistent with applicable standards established by the conference sponsor and any body accrediting the educational activity. \textit{The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.}\textsuperscript{50}

In other words, educational grant support for third-party medical education conferences in the medical device industry is intended to be used solely at the discretion of the third-party conference organizer and is not directed at any specific physician or individual recipient.

Because CMS’s explanation of the indirect payment analysis is contained in the preamble to the Final 2015 Physician Fee Schedule and in informal guidance (FAQs), the agency’s previous statements do not have the same degree of precedential value and impact as language found in a final regulation. Further, the FAQs have not clarified but rather confused interpretations. As a result, manufacturers have varied interpretations of the preamble language from the 2015 Final Physician Fee Schedule and the various iterations of the related FAQs. While some companies have concluded that all of their educational grants are exempt from disclosure, others have concluded that they must report educational grants. Put briefly, manufacturers do not have a clear rule in this area, and the data being disclosed to the public and by patients presents a distorted and inconsistent image of these transactions.\textsuperscript{51}

AdvaMed believes that the guidance previously offered by CMS should be enhanced to include a clear and simple statement clarifying that educational grants made to third-party


\textsuperscript{51} Current legislative efforts recognize a need for clarity in this area. Most notably, current Senate Bill 2978 works to address this point of confusion by proposing an exemption for “an indirect payment or transfer of value . . . that serves the sole purpose of providing the covered recipient with medical education, such as by providing the covered recipient with the tuition required to attend an educational event or with materials provided to physicians at an educational event.” S. 2978, 114th Cong. §2(a)(2) (2016).
educational conference organizers are not reportable under the Sunshine Act. More specifically, AdvaMed recommends that CMS rescind its previous FAQs and add the following language at section 904(h) of 42 C.F.R., specifically excluding these types of payments from reporting:

(h) Exclusions from reporting. The following are excluded from the reporting requirements specified in this section: . . . (15) In the case of continuing education provided to physicians and organized by third-party educational providers that are not affiliated with or established by an applicable manufacturer or GPO, amounts paid in the form of educational grants to such third-party educational providers to the extent that (i) the third-party educational provider independently controls and is responsible for the selection of program content, faculty, educational methods, and materials and (ii) the third-party educational provider is not a Covered Recipient.

By focusing on the degree of control that a manufacturer holds – or rather does not hold – with respect to a continuing education program, CMS will successfully exempt from reporting those payments that do not risk creating a conflict of interest for an individual physician (i.e., because he or she is unaware of the specific source of specific funds supporting a specific continuing education event). This will also serve to help ensure that patients and the public are reviewing the best, most appropriate data about industry-physician interactions.

C. Additional Context to Open Payments Website

The Sunshine Act requires CMS to establish a clear and understandable website that reports the required data and payment provisions, but also includes background information on industry-physician relationships. As AdvaMed has noted previously, including fulsome, accurate, and appropriate context information on the Open Payments website is critical. The Open Payments website currently does include some background information on industry-physician relationships; however, we believe additional context information is necessary to ensure that the legislative intent of Open Payments is met without discouraging beneficial interactions critical to the development and safe and effective use of innovative medical technologies.


53. See, e.g., AdvaMed’s letter dated July 12, 2011 to Dr. Berwick regarding implementation of Section 6002 of the ACA; AdvaMed’s letter dated February 17, 2012 commenting on the proposed rule implementing Section 6002 of the ACA; AdvaMed’s letter dated April 9, 2013 commenting on the final rule implementing Section 6002 of the ACA; AdvaMed’s letter dated May 8, 2014 to Shantanu Agrawal, M.D., Deputy Administrator and Director; and AdvaMed’s letter dated September 3, 2015 commenting on the proposed 2016 Physician Fee Schedule provisions involving Open Payments and the Physician Compare database.

As we noted in our previous comments, giving consumers understandable and robust context information on the Open Payments website regarding reported payments and other transfers of value ensures that reported data is meaningful and helpful in a patient’s decision-making and prevents consumers from forming mistaken impressions that all payments to physicians are suspect. To this end, AdvaMed recommends that the context information included on the Open Payments website should be revised to include additional and more specific information regarding the various common arrangements between industry and physicians and teaching hospitals.

For example, any conversation about the context of physician- and hospital-industry interactions must include the ways that such relationships not only drive technological innovation but also support good patient outcomes. There are numerous ways in which medical innovation companies engage with physicians, academics, and health care professionals, including for their time providing consulting services on complex areas needing medical and clinical expertise, and for their intellectual property in connection with the development of new medical technologies and the improvement of existing technologies. Medical device companies require health care professionals to provide training and education to other health care professionals on the safe and effective use of medical technology. This training can only be provided by someone with the medical expertise and teaching skills in order to instruct other physicians how to perform extremely complex procedures using highly nuanced products. All of these arrangements fuel advances in medical technology, and improve medical care and the quality of health care available to American patients and consumers.

In addition to the above information, it is important to include a discussion that industry-physician relationships are driven by manufacturers’ voluntary compliance with and adoption of codes of conduct, such as AdvaMed’s Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code” or “Code”). AdvaMed’s Code distinguishes interactions that result in bona fide contributions to the advancement of medical technology and has long guided companies on structuring many of the relationships pursuant to which reportable transfers of value are paid (e.g., consulting, royalties, etc.). Pursuant to the AdvaMed Code, medical technology companies, both AdvaMed members and non-members, may certify that they have agreed to abide by the Code, and further that they have implemented policies and procedures to implement the Code as part of an effective compliance program.

In addition to the Code, AdvaMed takes aggressive steps on an ongoing basis to educate the industry and health care professionals about the Code, ethical interactions, and compliance. The AdvaMed Board Committee on Ethics and Health Care Compliance has approved a series of Code of Ethics Best Practices guidance documents to assist companies in ensuring that their interactions with health care professionals, including physicians, are ethical and compliant. In developing website content related to the nature of relationships between physicians and teaching hospitals and the industry, including an explanation of beneficial interactions, we recommend that CMS incorporate existing industry codes of conduct and guidance, including the information

---

referenced above. Such codes and guidance are widely accepted within the industry and have
been developed with the intent to differentiate beneficial financial relationships from those that
may create improper conflicts of interest.

Further, we ask that CMS not limit the context information included on the Open
Payments website to industry-physician relationships, because teaching hospitals are also
covered recipients, and providing the context on transfers of value to teaching hospitals will be
equally important.

Given the importance of background and context information on industry-covered
recipient relationships, we encourage CMS to share with the industry proposed revisions to the
context text for review and comment in advance of final publication on the Open Payments
website.

D. Delayed Publication Provisions

With respect to the Open Payments provisions on delayed publication for certain
research-related expenditures, AdvaMed believes that delayed publication data should be
assessed and submitted based upon the technical rules and regulations application at the time the
payment occurred and at the time the payment was originally submitted for disclosure. This
means:

- Companies should not be required to resubmit to CMS all data previously marked
as subject to the delay. By requiring companies to resubmit yearly, companies
must review and revalidate all delayed publication data against CMS’s database, a
rather resource-intensive endeavor. A more efficient approach would be to
require companies to submit a listing of the record IDs previously disclosed as
being subject to delayed publication and to identify which of those record IDs
should continue under the delay and which record IDs are now ready for
publication. Under this approach, companies would save resources by focusing
on merely flagging delayed data that is ready for publication and has already been
reviewed by companies internally, submitted to CMS, and validated against CMS
databases. CMS would save resources by not needing to revalidate year-over-
year the delayed publication data.

- To the extent that companies continue to be required to resubmit all data
previously marked as subject to delayed publication, this previously submitted
delayed publication data should be analyzed based upon the technical
requirements and regulations at the time the original data was disclosed to CMS.
For delayed publication records, the Open Payments program currently requires
the user to resubmit the entire record and manage the matching validation issues
each year. However, the system re-validates all information and the recipient
against the current year’s technical algorithms, which are generated from
regulations that are effective currently and not based on the regulatory
requirements that were in place at the time the payment was originally disclosed.
The result is that data that was appropriately disclosed according to the regulations that were in effect at the time are now considered to be out of line with existing regulatory requirements. Put another way, requiring revalidation of delayed publication data against the current year’s regulatory requirements has the effect of retroactively applying regulatory changes.

• Several companies have noted that the Open Payments system prevents a company from resubmitting delayed publication data (that continues to be under delay) if the physician is no longer part of the CMS physician profile database. This could occur if, for example, the physician ceases practicing. The result is that data that should have been published but for the delayed publication will not ever be published because of a change in the physician database. Company data submitted to CMS for disclosure subject to delayed publication should all be disclosed, even if a physician was previously but is no longer considered a covered recipient.

In brief, AdvaMed believes that these few changes – not requiring the resubmission of all delayed publication data or in the alternative, analyzing past data based on the contemporaneous regulations, and disclosing all delayed publication data at the appropriate time, even if the relevant covered recipient is no longer considered to be a covered recipient – would significantly improve the delayed publication system.

E. Technical Updates to Open Payments Data Fields & Data Validation

AdvaMed member companies also have several recommendations with respect to technical updates to the Open Payments data submission program, which we believe would create a more efficient process for submitting, reviewing, and finalizing data:

• **CMS should allow for the use of all taxonomy codes in disclosing physician covered recipients and should ensure taxonomy code information is up-to-date.** We are aware of several circumstances in which a number of payments or transfers of value could not be submitted, because the physician covered recipient had a National Provider Identifier with an associated taxonomy code that is not permitted under Open Payments. Given the wide variety of physician types and specialties and the wide range of physician interactions with manufacturers, it would be critical to permit all taxonomy codes to be submitted under the Open Payments Program. Otherwise, the result is an increased delay in disclosing data and an increase in calls and contacts to the CMS Help Desk. In many instances the taxonomy information in CMS’s database has not been updated or continues to be inaccurate through no fault of the manufacturer, and this information is not something that the manufacturer can correct. For example, many practicing physicians are still listed under the student taxonomy code from their residencies; however, these physicians are active and should be considered covered recipients. We recommend that CMS encourage physicians to review and update their taxonomy information in NPPES as often as necessary, that CMS update the
validation database regularly to include accurate and current taxonomy information, and that CMS allow the use of all taxonomy codes. Given the significant level of due diligence that companies undertake, we also believe that there is minimal risk of over-reporting payments and transfers of value.

- **CMS should permit the submission of all dollar amounts disclosed.** We have also been made aware of several hyper-technical errors that prevented submission of Open Payments data (for example, not recognizing dollar amounts lacking the "0.00" at the end). In these cases, because many databases automatically remove the "0.00" from whole numbers, CMS should recognize whole numbers even without the .00 on the end in order to avoid requiring tedious, manual data corrections that consume great resources from manufacturers but that result in no additional meaningfulness for patients.

- **CMS should include a description of error codes when retrieving error reports.** When retrieving error reports, it would be helpful if the description of each error code was included in the report as well. We believe that by undertaking this small step, CMS will save companies a great deal of time and resources that otherwise goes into comparing the error code descriptors to the report.

- **CMS should expand the currently published "Validated Physicians List" to include all practitioners on whom manufacturers may report during the year (not just those with NPIs).** We would request that CMS provide a specific list of all practitioners (including related identifier information) on whom manufacturers might report during the year — not just those with NPI numbers. This benefits CMS in that it would allow manufacturers to report data that has already been validated against the lists that CMS employs to validate data. This creates much greater consistency and uniformity to the data and helps to ensure that the public and patients have confidence in the data available on interactions with manufacturers. Finally, this saves manufacturers resources by eliminating additional rounds of due diligence after CMS has validated the data that has been submitted.

- **CMS should limit the number of times that a single record can be disputed.** Our member companies have seen several circumstances in recent years in which the same record is disputed multiple times, the result of which is a great deal of resources spent by companies to address the same dispute multiple times. Such a situation is unnecessary since the current dispute resolution system sufficiently accounts for disagreements between covered recipients and manufacturers by permitting unresolved disputes to be published and demarcated as unresolved. To the extent that a dispute is initiated once, it cannot be closed until both parties agree that the data reported is accurate. This should be a sufficient safeguard against the reporting of information about which the covered recipient disagrees.
CMS should require the initiator of a dispute to include their contact information as a mandated field. CMS's efforts to enhance the dispute resolution process by including manufacturer contact information has been of great assistance in streamlining and making the process more efficient. AdvaMed believes that requiring those parties that submit disputes to provide contact information would even more significantly streamline the dispute resolution process. Commonly, companies that receive disputes will be required to conduct significant research to determine the appropriate contact at the disputing party, especially with respect to hospital-initiated disputes. In an effort to resolve disputes much more quickly and to allow manufacturers to devote resources to resolving the dispute (rather than spending countless hours researching a disputing party's contact information), AdvaMed recommends that CMS require parties submitting a dispute to include contact information in a mandated field. In addition to realigning manufacturer resources, we believe that more disputes will be resolved during the dispute resolution window, resulting in greater clarity, consistency, and accuracy in the data that is released to the public.

CMS should provide full data reports in connection with downloads from Open Payments. AdvaMed requests that data downloads under the Open Payments Program include additional fields (for example, Name of Associated Covered Device or Medical Supply and Nature of Payment or Transfer of Value) in order to help ensure better accuracy from manufacturers as they validate their data on an annual basis. During the validation process, it is imperative that companies have full access to their data file in order to better verify the accuracy and completeness of the data submitted. The result of better verification is better, more accurate data for the public and for patients.

CMS should notify manufacturers when a duplicate "Home Payment ID" is uploaded. Due to the functionality of the Open Payments system (especially downloading/deleting and re-uploading expenses for reporting), duplicate expenses can occasionally be reported in error. In order to fix this issue, the manufacturer should be alerted whenever a duplicate Home Payment ID (a unique number that each company assigns to an expense when a transaction is loaded into Open Payments) has been used. This will help to minimize data entry errors and the accidental over-reporting of payments.

AdvaMed requests a more significant notice period for changes to technical and other requirements. Any addition or revision to the Open Payments system (for example, requiring a new data field or revising how to use a data field) results in companies’ remapping and re-automating internal data collection and reporting processes. This takes a substantial amount of time to reconfigure systems and to test systems to help ensure that the data output of the systems remains accurate and complete. AdvaMed members would request a substantial notice period (three months, for example) prior to making any such changes effective.
F. Reporting Thresholds

AdvaMed recognizes that the reporting exclusion for payments and transfers of value less than $10 or $100 in the annual aggregate amount is statutorily prescribed\textsuperscript{56} such that CMS may be limited in its authority to revise the current reporting thresholds (other than to update the thresholds based on the consumer price index, per the statute). AdvaMed nonetheless believes that a revision to the reporting thresholds would mark an important step in greater efficiency and in generating a more meaningful and useful database for the public and requests that CMS support such a legislative change.

Currently, the vast majority of expenses reported under Open Payments are smaller expenses under $100 (for example, snacks or cups of coffee). By elevating the thresholds for reporting – perhaps to $50 minimum or $150 or $250 in the aggregate – consumers will have access to the most meaningful and useful data and information. Such a change would also permit companies to focus their limited resources on ensuring that those payments that are more likely to impact consumer considerations are reported accurately and completely.

G. Attestation Program

AdvaMed believes there may be room under the current Open Payments program for additional efficiencies with respect to the attestation process. Currently, each time a company submits data an attestation related to such data must also be submitted. While company officers complete such attestations to the best of their knowledge, information, and belief, there may be instances in which data must be corrected or updated based upon a company’s continued monitoring efforts or dispute resolution, which submissions also require new, separate attestations.

AdvaMed recognizes the importance of the attestation process, including the need to provide comfort to the agency regarding the data to be disclosed publicly. AdvaMed recommends, however, that CMS consider revising the attestation process to require a single, annual attestation focused on the scope, integrity, and accuracy of a company’s transparency compliance program more broadly (e.g., that the company maintains policies and processes to collect data and report data in a timely fashion, monitors data, and confirms data accuracy in advance of reporting). This program-wide attestation would replace multiple, data-focused attestations from companies each time new or refreshed data is submitted. Such an attestation as to a company’s transparency program could be incorporated into the Open Payments registration process, similar to how some state transparency programs operate.

Requiring a single, comprehensive annual attestation means one less technical step for manufacturers and CMS each time a piece of data is submitted, which will streamline the process and result in more efficient reporting under the Open Payments system. It will also ensure a meaningful focus on compliance with the Sunshine Act and Open Payment requirements, as opposed to a narrow focus on a single data point.

\textsuperscript{56} See 42 U.S.C. § 1320a-7h(e)(10).
XIII. CONCLUSION

We commend the Centers for Medicare and Medicaid Services for continuing to seek critical and insightful feedback to enhance and develop its regulations implementing the Sunshine Act. We believe that the comments and feedback offered in this letter provide solid groundwork from which the agency can continue to grow an effective transparency program. Please feel free to contact me by phone or by email to the extent that you wish to discuss these or any other recommendations in greater detail.

Sincerely,

Matthew E. Wetzel, Esq.
Vice President & Assistant General Counsel
Advanced Medical Technology Association