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February 17, 2012

Delivered by FedEx and electronically

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-5060-P: AdvaMed Comments on Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interest

Dear Acting Administrator Tavenner:

The Advanced Medical Technology Association (“AdvaMed”) is pleased to comment on the Department of Health and Human Services, Centers for Medicare & Medicaid Services (“CMS”) proposed rule (“Proposed Rule”) implementing Section 6002 of the Affordable Care Act (the “Sunshine Provisions”);¹ and we look forward to continuing our open dialogue with CMS regarding the realities and challenges of implementing the Sunshine Provisions in a manner that serves the legislative intent to provide patients with clear, meaningful information concerning industry relationships, without discouraging beneficial interactions critical to the development and safe and effective use of innovative medical technologies.

Below we first provide in Section I background information regarding AdvaMed, our membership, and the importance of industry–health care professional interactions. Next, in Section II, we comment on specific proposals included in the Proposed Rule. Our comments and recommendations in response to the proposals addressed in Section II are driven by guidance and examples provided by our members. Finally, in Section III, we discuss certain recommendations AdvaMed previously shared with CMS in a letter to Dr. Donald Berwick, dated July 12, 2011 (the “July 12, 2011 Letter”; attached hereto as Exhibit A), not addressed in the Proposed Rule. The issues identified in Section III continue to represent important considerations for AdvaMed members and are key to the successful implementation of the Sunshine Provisions consistent with the legislative intent. We therefore ask that CMS consider these recommendations as it works to finalize the Proposed Rule.

¹ 76 Federal Register 78,742 (Dec. 19, 2011).

I. Background

AdvaMed is the world's largest trade association of medical device manufacturers, which produce the medical technologies that are transforming health care through earlier disease detections, less invasive procedures, and more effective treatments. AdvaMed represents manufacturers of medical devices, diagnostics, and health information systems, ranging from the largest to the smallest medical technology innovators and companies.

AdvaMed supports and has proactively embraced appropriate disclosure of relationships between medical technology companies and physicians. We and our member companies recognize that strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals to produce the world's most advanced medical technologies. AdvaMed and our member companies take very seriously our responsibility to ensure ethical interactions with our physician partners, recognizing that adherence to ethical standards is essential to the industry's ability to continue its collaboration with health care professionals. These are among the reasons that, in 2003, AdvaMed developed a Code of Ethics on Interactions with Health Care Professionals (the "AdvaMed Code" or "Code")² to distinguish interactions that result in bona fide contributions to the advancement of medical technology, from interactions that may inappropriately influence medical decision-making. AdvaMed strengthened the Code in 2009, and takes aggressive steps on an ongoing basis to educate the industry and health care professionals about the Code, ethical interactions, and compliance. Arrangements among medical manufacturers and health care professionals are structured in accordance with and reliant on definitions set out in the AdvaMed Code.

The medical technology industry is fueled by intense competition, a commitment to scientific research and the innovative energy of our member companies—firms that drive very rapid innovation cycles among products, in some cases leading to new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients effectively and efficiently.

Physicians and teaching hospitals are partners in many aspects of innovation. They are often the inventors of new devices, and it is critical that our industry work closely with them to move their innovative ideas from concept to reality. Physicians make valuable recommendations on how to improve the safety and functioning of existing devices, and they provide ongoing consulting to furnish expert technical assistance and feedback to companies in the development and refinement of those improvements. In short, physician expertise, feedback, and experience are critical to ongoing advances and innovations in medical technology, and the Sunshine Provisions must be implemented in a manner that does not discourage physicians and teaching hospitals from participating in bona fide collaborations that fuel medical device innovation that improve patient care and treatment.

² Available at: <http://www.advamed.org/MemberPortal/About/code/>.

In addition, device companies forge important training arrangements with physicians and teaching hospitals, essential for the safe and effective use of medical devices. How well a medical device works often depends, in large part, on the skill and training of the physician utilizing the technology. In fact, the Food & Drug Administration (“FDA”) often requires device manufacturers to provide product-specific education and training to physicians as *a condition of* FDA clearance. The technique-specific nature of devices also makes physician involvement crucial to the training and education required after market approval, as specific techniques often need to be taught, and physician operators are best suited to provide this training to their fellow physicians. Some training on medical technologies requires travel to facilities that can accommodate large medical technologies or to specialized training facilities, such as simulated operating rooms.

Physician and teaching hospital innovation and collaboration with the device industry have led to groundbreaking advances in patient care that benefit millions of American patients. These innovations have helped fuel a robust, competitive U.S. medical technology industry that is the global leader. Not only is the industry a source of life-enhancing and life-sustaining treatments and cures, it is an important manufacturing industry and a driver of current and future U.S. economic growth. America is the acknowledged world leader in medical technology, as it is in the other life sciences industries.

This leadership is being challenged. We applaud President Obama’s focus on innovation as the key to our nation’s economic future, and our industry stands ready to play a key role. The Sunshine Provisions should be implemented in a manner that serves the legislative intent to provide patients with clear, meaningful information concerning industry relationships, but implementation must not discourage beneficial interactions critical to the development and safe and effective use of innovative medical technologies, and should not compromise our nation’s technology leadership through unintended competitive advantages afforded overseas or non health care manufacturers not subject to the Sunshine Provisions. For this reason, in our comments below, we offer recommendations in certain areas to provide clear rules and definitions to facilitate a common approach by manufacturers and to ensure the data is meaningful and consistent with the legislative intent and policy objectives.

II. Comments to CMS Proposals in the Proposed Rule

1. Definition of Applicable Manufacturer

CMS Proposal:	CMS proposes to define “applicable manufacturer” as an entity that is: (1) Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or (2) Under common ownership with an entity in paragraph (1), which provides assistance or support to such entity with respect
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	<p>to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.</p> <p>CMS also clarifies that any manufacturer that meets the definition of applicable manufacturer by selling or distributing in the United States at least one covered product is considered an applicable manufacturer, even though it may also manufacturer products that do not fall within that category. CMS proposes that all payments or transfers of value made by an applicable manufacturer to a covered recipient must be reported regardless of whether the particular payment or other transfer of value is associated with a covered product.</p> <p>CMS proposes to define “common ownership” as when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities. CMS is considering an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities.</p> <p>If two entities are under common ownership with one another, and both individually meet the definition of an applicable manufacturer under paragraph (1) of the definition, CMS proposes that the entities should report separately. However, if only one company under common ownership meets the definition of applicable manufacturer under paragraph (1), and the other company is required to report under paragraph (2) of the definition, CMS proposes that the affected entities can choose whether to report together.</p>
<p>AdvaMed Response:</p>	<p>First, AdvaMed submits that the proposed definition of applicable manufacturer extends beyond the statutory language of the Sunshine Provisions because (1) entities not operating in the United States are excluded from the definition of “applicable manufacturer” under Sunshine Provisions; and (2) under the express statutory language, the Sunshine Provisions do not anticipate applicable manufacturers reporting with respect to non-covered products.</p> <p>However, AdvaMed appreciates that CMS may be concerned about entities improperly seeking to avoid reporting payments or other transfers of value by making payments through foreign affiliates. We do not believe such activity would be consistent with the intent of the Sunshine Provisions, and therefore recommend that payments or other transfers of value made by foreign affiliates at the direction or request</p>

	<p>of an applicable manufacturer be reported by the applicable manufacturer.</p> <p>AdvaMed further recommends that CMS further consider the potential unintended consequences and inequities that may arise as a result of the proposed definition of applicable manufacturer. We discuss some of these inequalities below.</p> <p>Second, AdvaMed recommends that CMS clarify that applicable manufacturers are not required to report payments by distributors who have taken title of covered products.</p> <p>Third, AdvaMed recommends that the definition of “common ownership” be limited to circumstances where the same individual, individuals, entity, or entities own at least 50% of total ownership in two or more entities.</p> <p>Finally, AdvaMed recommends that manufacturers have flexibility to report either at the holding company level or by division.</p>
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Support for AdvaMed’s Response:

- a) *The proposed definition of applicable manufacturer extends beyond the statutory language of the Sunshine Provisions and there may be unintended and inequitable consequences as a result of the proposed definition of applicable manufacturer.*

AdvaMed supports appropriate disclosure of relationships between medical technology companies and covered recipients and therefore appreciates CMS’ attempts to define applicable manufacturer in such a way as to capture all manufacturers which may make reportable payments or transfers of value to physicians or teaching hospitals.

However, AdvaMed submits that the proposed definition of applicable manufacturer extends beyond the statutory language of the Sunshine Provisions. Section 1128G(e)(2) of the Sunshine Provisions limits the term “applicable manufacturer” to

“a manufacturer of a covered drug, device, biological or medical supply *which is operating in the United States*, or in a territory, possession, or commonwealth of the United States.”

CMS has proposed expanding the definition of applicable manufacturer to include all those manufacturers, and certain divisions or entities within a single manufacturer, whose products are sold or distributed in the United States, regardless of where the covered product is actually produced, or where the entity is actually located or incorporated. Accordingly, CMS’ proposed

definition extends beyond the express language of the statute. CMS does not have the authority to extend the definition of applicable manufacturer beyond the statutory definition.

The issue of defining applicable manufacturer is highly complicated, in large part due to the great variation among manufacturers in terms of corporate structure and organization. For example, many manufacturers operate under complex corporate structures, which may include multiple divisions, all of which are separate legal entities. Some applicable manufacturers may also have operating divisions that do not completely align with their legal entity structure.

It is for this reason that we recommend that CMS further consider the potential consequences and inequities that may arise as a result of the proposed definition of applicable manufacturer. As a reference, we provide below a few examples of potential unintentional consequences that may occur under the proposed definition. Before finalizing this or any definition of applicable manufacturer, CMS should consult with stakeholders regarding the practical effect of the definition, either through another open door forum, or through additional comment periods. CMS should take a balanced approach in ensuring that the definition it finalizes does not have the unintended consequence of unfairly disadvantaging those applicable manufacturers who are complying with the Sunshine Provisions in good faith.

i) Foreign Affiliates

CMS' expanded definition of applicable manufacturer now implicates multiple foreign affiliates that applicable manufacturers were not expecting to be included within the definition of applicable manufacturer. As a result, if CMS' proposed definition is finalized, extensive training and systems changes will be required, increasing the time, resources, and costs associated with implementation of the Sunshine Provisions. In addition, foreign affiliates are subject to a variety of local authorities and laws, including, for example, privacy laws, which may conflict with the requirements of the Sunshine Provisions. We recommend that CMS give further thought to the applicability of these local authorities and laws and consider how they may affect reporting by foreign affiliates which qualify as applicable manufacturers under the proposed definition.

We also submit that the proposed definition could produce anomalous results vis a vis U.S. manufacturers as opposed to non-U.S. manufacturers. For example, please consider the following scenario:

- A non-U.S. company manufactures a covered product and has an exclusive distributor relationship with a U.S. company that has no physician ownership or interest. The U.S. distributor engages in activities with covered recipients related to the covered products (*e.g.*, it provides grants, enters consulting agreements, and the like), all of which would otherwise have to be reported by applicable manufacturers. However, neither the non-U.S. manufacturer nor the U.S. distributor would be required to report such activities. The U.S. distributor, which is making otherwise reportable payments to covered recipients, would not qualify as an applicable manufacturer under CMS' definition because it is not engaged in the production, preparation, propagation, compounding, or conversion of a covered product, nor is it under common ownership with the non-U.S. manufacturer that is performing these activities. And the non-U.S. manufacturer would not be the entity providing reportable

payments or transfers of value to covered recipients. Accordingly, an arrangement between the U.S. distributor and a covered recipient will not be reportable, even though a competitor company that qualifies as an applicable manufacturer would be required to report payments related to the same type of arrangement with the same covered recipient.

Similarly, a foreign affiliate qualifying as an “applicable manufacturer” under CMS’ expanded definition may compete outside of the U.S. with certain foreign manufacturers who do not qualify as applicable manufacturers. These foreign manufacturers will not be subject to the Sunshine Provisions, but will have access to information regarding the activities of the applicable manufacturer foreign affiliate, including the covered recipients the affiliate has engaged and sensitive information regarding its research and development activities. The same information for the foreign manufacturer will not be available to the applicable manufacturer foreign affiliate. Such a result places foreign affiliates of U.S. manufacturers at a competitive disadvantage with respect to foreign manufacturers. CMS’ expanded definition of applicable manufacturer may also have the practical effect of discouraging foreign affiliates of U.S. manufacturers from using U.S. health care providers for research and development projects.

We ask that CMS consider these inequities and define applicable manufacturer in a manner that attains the transparency envisioned by the Sunshine Provisions, while also not placing foreign affiliates of U.S. manufacturers at a significant disadvantage with respect to their competitors.

Although entities not operating in the United States are excluded from the definition of “applicable manufacturer” under the express language Sunshine Provisions, AdvaMed appreciates that CMS may be concerned about entities improperly seeking to avoid reporting payments or other transfers of value by funneling them through foreign affiliates, inconsistent with the intent of the Sunshine Provisions. AdvaMed recognizes that such payments should be reportable and recommends that payments or transfers of value made by a foreign affiliate at the direction or request of an applicable manufacturer be reported by the applicable manufacturer.

We also recommend that to the extent reporting is required with respect to foreign affiliates CMS allow manufacturers the flexibility to report on behalf of foreign affiliates at the holding company level, as discussed in more below.

ii) Reporting Non-Covered Products

AdvaMed also recommends that CMS consider the consequences of requiring an applicable manufacturer of at least one covered product in the U.S. to report payments related to non-covered products.

Under the express statutory language, the Sunshine Provisions do not anticipate applicable manufacturers reporting with respect to non-covered products. CMS’ proposal to require applicable manufacturers manufacturing both covered and non-covered products to report with respect to non-covered products significantly expands the scope of reporting beyond that which is anticipated under the statute, and applicable manufacturers could not have anticipated and have not prepared for such an expansion.

As noted, many medical technology manufacturers are organized by separate divisions, and in some cases, these divisions may be organized by health care products. Under the proposed definition, an entire division could be dedicated to a non-covered product, and yet be required to report payments and transfers of value. Although our members support appropriate disclosures in the interest of transparency, the proposed definition would again produce anomalous results. For example, please consider the following scenarios:

- Two competing manufacturers have similar arrangements with physicians related to a Class 1 device, a non-covered product, both of which are appropriate and necessary. The first manufacturer qualifies as an applicable manufacturer by virtue of the fact that another, separate division within its company manufactures covered products. The second manufacturer does not qualify as an applicable manufacturer since none of its divisions manufactures covered products. Under this example, only the first manufacturer would be required to report payments and transfers of value related to such arrangements.
- Two life science research companies that both sell life science research products not used for clinical purposes have similar arrangements with physicians related to these non-clinical products. The first life science research company qualifies as an applicable manufacturer by virtue of the fact that it has common ownership with another, separate business unit that manufactures covered products. The second life sciences research company does not qualify as an applicable manufacturer as it has no common ownership with any entities that qualify as applicable manufacturers. Under this example, only the first life sciences research company would be required to report payments and transfers of value related to such arrangements.

The inequities noted above would have the effect not only of misrepresenting the nature and extent of physician-industry relationships, but also could create competitive disadvantages for the applicable manufacturer. Further, this result could impact covered recipients' decisions about the specific manufacturers with which to engage. Stated differently, physicians may find it preferable to engage in collaborative relationships and accept payments only from entities that will not be required to report such payments. We do not believe that CMS intended to disrupt the competitive marketplace in this way.

iii) Diversified Manufacturers

Finally, AdvaMed recommends that CMS consider how the proposed definition of applicable manufacturer will impact diversified companies. Consistent with the complex corporate nature of manufacturers, some manufacturers have very diversified business lines, within and outside the health care space. For example, some of our medical device manufacturer members operate under a corporate structure in which they share a common owner with a sister entity or entities that do not reside within the health care space. Such sister entities may manufacture non-health care items, or provide services entirely unrelated to health care. For example, a company working to develop a product completely outside of the health care space may contract with a university hospital and/or physician to perform research, such as a toxicology assessment of various potential raw materials. Under the broad definition of applicable manufacturer,

payments by such non-health care business divisions for such services may be reportable just by virtue of the fact that such non-health care division shares a common owner with a health care division. It is our position that reporting payments or transfers of value related to these non-health care items or services does not further the legislative intent of the Sunshine Provisions and also creates the same competitive disadvantages discussed above. An expansive reading of the definition of applicable manufacturer may suggest that such research activities are subject to reporting under the Sunshine Provisions. In such cases, competitors who do not operate within a corporate structure that includes medical manufacturer affiliates will have access to confidential and proprietary information regarding the research activities of a non-health care entity because such research is not related to medical technology or medical products and therefore not subject to delayed publication.

To the extent that payments and transfers of value by non-health care affiliates of diversified manufacturers are reportable, CMS should provide manufacturers with the flexibility to report at the holding company or commercial organization level, as discussed below. The non-health care affiliates potentially implicated will otherwise be responsible for implementing reporting systems and training employees at the divisional level, an endeavor not previously contemplated by entities not operating in the health care space.

- b) *Manufacturers should not be required to report payments by unaffiliated distributors which take title to products.*

As mentioned in our July 12, 2011 Letter, AdvaMed recommends that CMS clarify that manufacturers would not be required to report payments and transfers of value from distributors which take title to a product and which are not affiliated with or under common ownership with the manufacturer. Since they take title to the products, they are not acting as an agent for the applicable manufacturer. This position is consistent with the definition of applicable manufacturer as proposed by CMS. By contrast, manufacturers which use independently contracted sales representatives and/or distributors which do not take title to the product would be required to report payments and transfers of values made by those entities because they would be acting as an agent of manufacturers.

- c) *The definition of common ownership should be limited to at least 50 % of total ownership in two or more entities.*

AdvaMed recommends that CMS limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own at least fifty percent of total ownership in two or more entities. This recommendation is consistent with similar definitions used throughout the Internal Revenue Code.

For example, Section 1563(a) of the Internal Revenue Code defines the term “controlled group of corporations” for purposes of parent-subsidiary relationships using an “at least 80 percent” common ownership standard.³ Brother-sister corporations are considered to be “controlled

³ 26 U.S.C. § 1563(a)(1).

groups of corporations” if there is “more than 50 percent” common ownership.⁴ Both standards are used in numerous places throughout the Internal Revenue Code and this same “more than 50 percent” or “at least 80 percent” split also appears in tax regulations defining “common control” for purposes of the rules governing pension and profit sharing plans.⁵

CMS’ proposal to not limit common ownership, or to limit the term to five percent or more, would capture multiple entities for which reporting is not reasonable or necessary, and will not further the legislative intent of providing useable information for consumers. Instead, the proposed definition creates an unreasonable burden for entities not otherwise expecting to track and report payments. CMS has also not provided any guidance regarding how the phrase “provides assistance or support” is supposed to be interpreted. Without further clarity, the risk exists that manufacturers will interpret the requirement in different ways and reporting will not be consistent.

In addition, application of the five percent common ownership definition may have multiple unintended consequences across our highly diverse industry. First, the medical device industry is highly heterogeneous, dominated by smaller innovative companies dependent on private equity or venture capital financing. Application of this definition to the private equity firm or other investor diversified in distinct, independently operated, emerging growth companies across multiple sectors and technologies could require reporting across all medical technology portfolio companies where only one would qualify as an “applicable manufacturer.” Many of these portfolio emerging companies might not even have a commercial product, but invest significantly in research. The broad definition would unduly burden private equity and similarly held portfolio companies that otherwise would not be subject to the statute. Additionally, beyond private equity portfolio arrangements, it is common in this industry for larger device companies to invest minority non-controlling interests in smaller start ups. The reference to a five percent ownership definition in the Proposed Rule could render reportable transfers of value by these independently operated small device innovators. Further, in some cases, investment interests could be held by multiple large manufacturers, creating confusion as to whom the reporting obligations extend.

It is for the foregoing reasons that we recommend limiting the definition of common ownership to at least fifty percent of total ownership in two or more entities, consistent with the tax code.

- d) *Manufacturers should have flexibility to report at the holding company level, by division, by commercial organization, or by an organization structure that complies with the Sunshine Provisions as appropriate for the applicable manufacturer.*

Manufacturers’ corporate structures and organizations vary greatly. Many manufacturers include multiple divisions, business units, commercial organizations, and other operational structures. In

⁴ 26 U.S.C. § 1563(a)(2).

⁵ See 26 C.F.R. § 1.414(c)-2(b) and (c).

other cases, the legal entity structure may match these structures. In more cases, the legal entities may not match the operational structure as a result of acquisitions, divestitures, and tax considerations, among others.

In addition, as further discussed in Section II.4 and Exhibit B of this letter, and as a result of state requirements to track and report interactions with physicians and others, many manufacturers have already developed reporting systems. Some manufacturers track and report payments on a division or commercial organization basis, while others do so at the holding company level.⁶

To avoid the need for (and attendant costs of) complete system overhauls to comply with the Sunshine Act, we recommend that applicable manufacturers have the option to report according to the organizational structure that makes the most sense for that applicable manufacturer while also complying with the Sunshine Provisions and regulations. This flexibility becomes even more critical when considering the potential reporting obligations of foreign affiliates and related entities, discussed above. In either circumstance, applicable manufacturers would remain obligated to report all reportable payments and transfers of value, subject to the attestation statement proposed by CMS and the penalties authorized under the Sunshine Provisions.

2. Identification of Covered Recipients (Lists of Physicians and Teaching Hospitals)

<p>CMS Proposal:</p>	<p>CMS proposes to publish a list of teaching hospital covered recipients on the CMS website once per year. CMS proposes that this list would include the name and address of each teaching hospital.</p> <p>With respect to physician covered recipients, CMS proposes that in order to identify physician covered recipients, applicable manufacturers should use the National Plan & Provider Enumeration System (NPPES). If a physician is not listed in the NPPES NPI registry, the applicable manufacturer would be responsible for obtaining the physician's NPI directly from the physician, to the extent that the physician has an NPI. CMS is also considering whether it should require applicable manufacturers to report another unique identifier, such as a state license number, for physicians who are identified, but do not have an NPI.</p>
<p>AdvaMed Response:</p>	<p>AdvaMed recommends that CMS clearly identify each corporate entity that qualifies as a teaching hospital on the teaching hospital list and further identify a single taxpayer identification number associated with that corporate entity. For physician covered recipients, AdvaMed</p>

⁶ This variation between manufacturers is consistent with current state law reporting requirements. For example, Massachusetts allows manufacturers to either submit one overall disclosure report or several reports at the divisional level. See Office of Inspector General Frequently Asked Questions, available at <http://www.mass.gov/eohhs/provider/licensing/programs/pharm-code-of-conduct/background-information-about-the-code-of-conduct.html>.

	recommends that CMS create a single list assigning a unique national identifier to each physician covered recipient. In addition, AdvaMed recommends that CMS ensure that both lists of covered recipients are published at least 90 days prior to the beginning of each reporting year. Finally, AdvaMed recommends that CMS clarify the exception for physician employees as it related to the definition of covered recipients.
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Support for AdvaMed’s Response:

- a) *List identifying unique teaching hospital covered recipients is required to ensure accurate reporting and meaningful published information.*

As an initial matter, we appreciate CMS’ efforts to clarify the term “teaching hospital” by defining the term as it has proposed. We are also grateful that CMS has proposed publishing a list of teaching hospital covered recipients on its website once per year.

Teaching hospitals often are complex corporate organizations and the corporate structure of an organization varies greatly depending on the institution. Teaching hospitals names may also be significantly similar to names of other health care entities, particularly affiliated healthcare entities. In order to ensure that the list of teaching hospitals is useable and leads to consistent reporting across applicable manufacturers, AdvaMed recommends that CMS specifically identify each corporate entity that qualifies as a teaching hospital covered recipient and provide that entity’s taxpayer identification number (“TIN”). Identifying teaching hospitals by reference to name and address alone would not provide the necessary clarity for applicable manufacturers to track and report payments accurately. In many instances, the name associated with the teaching hospitals may also be associated with various components of the corporate organization that do not qualify as a teaching hospital covered recipient. For example, with respect to Mayo, there is a Mayo Foundation (at 200 1st Street SW, Rochester, MN); a Mayo Clinic (at the same address); a Mayo School of Continuing Medical Education (at 1311 8^{1/2} Street SE, Rochester, MN); and a Mayo Clinic (at 5777 E. Mayo Boulevard, Phoenix, AZ).

We also recommend that applicable manufacturers should be required to report only with respect to the specific corporate entities and TINs identified on CMS’ list of teaching hospital covered recipients.

If CMS does not intend to identify teaching hospitals by reference to the specific corporate entity and TIN, further guidance will be required regarding what specific corporate entity or component of a teaching hospital identified on CMS’ list of teaching hospital covered recipients constitutes a covered recipient.

AdvaMed also recommends that CMS ensure that the list of teaching hospital covered recipients is published at least ninety days prior to the beginning of each reporting year in order to allow applicable manufacturers sufficient time to identify those entities for which it will be required to

track payments and transfers of value for purposes of subsequent reporting, and to make necessary systems modifications for purposes of the same.

- b) *List identifying physician covered recipients is required to ensure accurate reporting and meaningful published information.*

CMS' proposal to utilize the NPPES system for purposes of identifying physician covered recipients is helpful, in that the NPPES system does include information for the majority of physicians. However, the NPPES system does not include all physicians, as CMS expressly notes. That is, the NPPES system contains NPI information for the majority of physicians who have an NPI, but some physicians' NPIs may not be included in the NPPES system, and some physicians may not have an NPI at all. In such cases, CMS proposes that applicable manufacturers must obtain a physician's NPI number directly from the physician, or report another unique identifier, such as a state license number, for physicians who do not have an NPI.

CMS' proposal will necessarily lead to inconsistent reporting and does not further the goal of ensuring that all reportable payments and other transfers of value are accurately and consistently identified on the public website. For example, it is possible that a physician may have more than one NPI and in such case, different applicable manufacturers may not use the same NPI in reporting to CMS payments to that physician. In addition, a physician may be licensed in multiple states and will therefore have multiple "unique identifiers." The state license number that one manufacturer relies on, may be different from the state license number another applicable manufacturer relies on. Accordingly, when CMS receives the information it will not be clear that both payments were made to the same physician covered recipient. Additionally, duplicate state license numbers may exist across states, therefore an applicable manufacturer would need to report the state of licensure and the state license number for the information to be meaningful to CMS as it attempts to aggregate data for each physician covered recipient. However, even reporting both state name and state license numbers will not ensure consistent reporting if the physician is licensed in multiple states.

In order to avoid this situation, AdvaMed recommends that CMS create a single list of national identifiers for all physicians. Each physician would be assigned a unique identifier. All applicable manufacturers would then use the same identifier for each physician, ensuring consistent reporting to CMS.

In addition, similar to the list of teaching hospital covered recipients, AdvaMed recommends that CMS ensure that the list of unique physician covered recipient identifiers is published at least ninety days prior to the beginning of each reporting year to allow applicable manufacturers sufficient time to prepare for necessary tracking and reporting.⁷ Applicable manufacturers would

⁷ With respect to the NPPES system, we note that the NPPES website states that it is updated daily. If applicable manufacturers will be required to rely on the NPPES system, CMS should make clear that covered recipients will be those with NPI information as of the date ninety days prior to the beginning of the reporting year.

only be required to report payments and transfers of value to physicians included on whatever list of physician covered recipients CMS finally decides to use.

Finally, as referenced in our July 12, 2011 Letter, AdvaMed recommends that CMS clarify that companies are required to report payments and transfers of value only for physicians who currently practice in the U.S. and who receive transfers of value for activities that occur in the U.S. Medical device innovation occurs on a global scale. That is, some medical technology arrangements span national borders, and the treatment of global collaborations presents significant complexities and administrative concerns for CMS and industry alike. To develop an administrable approach presenting meaningful data to patients, we suggest that applicable manufacturers should only be required to report with respect to U.S. covered recipients listed on the national, CMS-established list described above, and for activities that occur within the U.S.

- c) *CMS should clarify the exception for physician employees as it related to the definition of covered recipients.*

Finally, the definition of physician “covered recipient” should be modified to track the anti-kickback statutory exception for employees by adding the following underlined language: “Any physician, except for a physician who has a bona fide employment relationship with an applicable manufacturer”.... This would assure that physician-owned entities such as physician owned manufacturers and physician owned GPOs (as defined in the statute and clarified through guidance to include physician owned distributors) cannot avoid reporting requirements by simply styling a physician as an employee by excluding only “bona fide” physician employment relationships.

In addition, CMS should expand the covered recipient definitional exclusion for employee physicians to include board members of applicable manufacturers. The nature of the services board members provide, their relevant compensation, and the roles and responsibilities that they perform are consistent with employees of applicable manufacturers, which are expressly excluded from the definition of covered recipients. Similar to the reasoning behind excluding payments to employees, to report payments or other transfers of value to physician board members related to their roles and responsibilities as board members would be misleading to the general public and does not otherwise further the legislative intent of the Sunshine Provisions. Further, board member payments are disclosed in applicable manufacturers’ financial statements, already available to the public. Accordingly, disclosing board member payments and transfers of value pursuant to the Sunshine Provisions would not provide additional value or transparency.⁸

⁸ We note that Massachusetts has taken this approach of excluding from reporting payments to both employees and board members by defining the term “health care practitioner” to exclude “full time employees and board member of pharmaceutical and medical device manufacturers.” 105 CMR 970.004.

3. Payments and Other Transfers of Value Report Content: Associated Covered Drug, Device, Biological, or Medical Supply

CMS Proposal:	CMS proposes that if a payment or other transfer of value is “reasonably associated” with a particular covered drug, device, biological or medical supply, then the name of the specific product must be reported. The product should be reported using the name under which it is marketed or, if the product does not yet have a market name, the scientific name. As an alternative, CMS is considering allowing applicable manufacturers to report multiple products as related to a single payment or other transfer of value.
AdvaMed Response:	AdvaMed recommends that CMS allow applicable manufacturers to report the product category or therapeutic area in lieu of a market name or scientific name of a single component product or requiring a listing of multiple product names that have little to no meaning to patients, in order to ensure more meaningful and useful reporting.

Support for AdvaMed’s Response:

In our July 12, 2011 Letter, AdvaMed recommended that CMS allow companies to report according to a primary product category or therapy area, rather than based on the individual component product. To support our recommendation, AdvaMed presented a variety of considerations and examples specific to the medical device industry. In response to CMS’ proposal in this section, we reiterate our previous recommendations and incorporate by reference our comments in our July 12, 2011 Letter. We provide below additional examples and clarifications regarding why requiring reporting with respect to a specific product is not always feasible or useful in the medical device industry and why identifying all covered devices at the product level would not be meaningful or understandable to patients, CMS, Congress, the States, or other users.

- (a) *Many medical technologies contain multiple components or instruments, each of which on its own could be considered a “single product.”*

Relationships between medical technology companies and covered recipients may involve multi-component product systems, or products with related product components, tools or accessories. This is because a medical device is infrequently comprised of a single product, but rather more typically consists of multiple components, all of which may individually qualify as “covered devices.” For example:

- Heart lung machines are used with extensive catheter tubing, filters, and other accessories.
- A hip replacement involves multiple components of the implant (*i.e.*, stem, head, acetabular cup, and cement, among others) and specific equipment and supplies used in

surgery (*i.e.*, saw, drill, burs, blades, blood system, and protective equipment, to name a few).

- Intravenous (IV) pumps systems can vary based on associated disposables, different types of containers, needles, and administrative sets with large and small volume solutions, all of which have hundreds of codes associated within an applicable manufacturer's system.
- Large diagnostics lab equipment may test utilizing the test kits/reagents for 100 or more health issues (*e.g.*, a cardiac event or elevated cholesterol). Each piece of lab equipment includes consumables (*e.g.*, disposable containers and tips), replacement parts, accessories, software, etc. All of these items have individual item numbers and the vast majority of these items do not have brand names associated with them. These products are generally marketed as a single therapeutic group or category. In addition, patients are rarely aware of the market names of instruments and consumables used to analyze a patient's blood. For example, we do not believe that, in general, patients have knowledge of the market names of analyte testing instruments and the corresponding reagents used for diagnostic tests.

Any payment or transfer of value provided by a device manufacturer to a covered recipient "reasonably associated" with, for example, a heart lung machine or a hip replacement cannot be simply attributed to a single product, or even a certain number of multiple products.⁹ Instead, the payment or other transfer of value may be "reasonably associated" with any number of covered device components. However, all such covered devices will likely fall under the same product category or therapy area.

(b) Many marketing and educational interactions with covered recipients focus on a broad category of medical technologies—not just an individual product.

Similarly, medical device research, service and sales representatives typically work with broad portfolios that include multiple products, as opposed to just one or two products, as may be common in the pharmaceutical or biologics industries. Accordingly, interactions between medical device representatives and covered recipients usually involve several products, all of which may fit within a single product category or therapy area. As such, selection of a single or even multiple products for reporting purposes is extremely difficult if not impossible, as a practical matter. For example:

- Based on the interactive and integrated nature of many medical technologies, companies may provide education and training on multiple products as part of a single training program (*e.g.*, training on an implant may include imaging, and surgical technique using

⁹ CMS also seeks comments on its alternative proposal of allowing applicable manufacturers to report "multiple" covered products. We submit that this approach raises the same concerns and issues discussed herein with respect to reporting a single product.

multiple products). Accordingly, there is not one single product that is “reasonably associated” with the training payment, easily reportable to CMS.

- Medical device companies often utilize advisory panels of clinical experts to provide consultation on therapeutic areas (*e.g.*, ligament reconstruction or articular solutions), rather than individual medical devices.

To require a company to identify a single covered device, or even a certain number of covered devices, would inappropriately inflate the payments or other transfer of value “reasonably associated” with that covered device or covered devices, and ultimately lead to inaccurate and misleading information on the public website. That is, if a reportable payment or other transfer of value were reasonably associated with a heart lung machine and such machine were comprised of multiple components, each qualifying as a covered device, to report only one of those component covered devices would mean that a payment in fact reasonably associated with multiple covered devices, must now be reported as reasonably associated with only one covered device. Similarly, in the case of a reportable payment or other transfer of value related to a training course covering a number of covered devices, CMS’ proposal would require companies to assign the entire value of the training course to a single product, notwithstanding the fact the training effort related to several products. Reporting on these and other arrangements common in the medical device industry, as required under the Proposed Rule, would misrepresent the true nature of the payment or transfer of value, as well as the company’s actions and operations. Reporting based on product category or therapeutic class would ensure both accurate postings and avoid public misperception of the nature of these relationships.

(c) Most patients know the product category or therapeutic area of a medical device—not the market name of the device.

In the medical device and diagnostics industry, the market name of a product is often not recognizable or meaningful to the consumer. Device companies typically do not market their products to patients by trademarked names. Accordingly, patients are generally not familiar with the marketed names, much less the names of the specific components that make up their orthopedic implant; rather patients will know only that they have a “hip replacement” from XYZ Company¹⁰ or are “receiving IV medications” made by XYZ Company. In other words, a patient can identify a company and a general product category or therapeutic area (*i.e.*, “hip replacement”)—not a specific medical device name.

As a further example, commonly implanted devices such as pacemakers and defibrillators are manufactured by multiple companies, and each company has a variety of different brand names for the various versions of the pacemakers that they sell. Patients are generally not focused on the identity of the company that manufactured his or her pacemaker or defibrillator, he or she generally does not even know the market name of his or her particular pacemaker or defibrillator,

¹⁰ In fact, hip replacement patients often carry a medical implant alert identification card, which states that its bearer has an orthopedic implant and identifies the patient’s name, the implant type, and the doctor’s information.

but are generally more concerned by the medical conditions that necessitated the use of a device and the care they receive from their documents and other professionals.

(d) Medical devices in the development stage often do not have a scientific name.

Unlike in the pharmaceutical industry, there is often no scientific name associated with a medical device during the research and development stages. Instead, during such stages, manufacturers may utilize internal identifiers, such as project names or project numbers. To report such information would not be meaningful or understandable to patients, CMS, Congress, the States, or other users. Further, such information may be confidential and proprietary in that it represents internal company operations and naming practices.

(e) Requiring medical device companies to report a single product will result in significant and costly changes to internal tracking systems.

An additional consideration related to requiring device manufacturers to report at the level of the specific covered device relates to the practical effort of identifying, by covered device, those “reasonably associated” products. Currently, across multiple companies and divisions, manufacturers track and identify specific products in any number of ways. Some companies or divisions may track the information to a level as detailed as product number, while others may more broadly track product categories. Regardless of the current systems used, if CMS adopts its proposal with respect to associated products, applicable manufacturers will be required to adjust their systems to meet the reporting requirements. Even if systems are updated accordingly, requiring an applicable manufacturer’s employee to choose from the thousands of product SKUs that a large manufacturer will typically have could lead to error and inconsistency in reporting and would make the system very cumbersome to use.

In light of the foregoing concerns and to enhance transparency and public usage of this information, CMS should allow medical device manufacturers flexibility to report the product category or therapeutic area in lieu of a market name or scientific name of a single medical device. This will ease the reporting burden while providing clear and more accurate information to consumers.

4. Delayed Implementation

CMS Proposal:	CMS has delayed implementation of the Sunshine Provisions until after the publication of the final rule. CMS seeks comments regarding the length of time necessary to begin implementation after publication of the final rule and also suggests that a preparation period of 90 days following publication of the final rule might be appropriate given that Congress originally anticipated this amount of time.
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AdvaMed Response:	AdvaMed recommends that CMS provide applicable manufacturers ¹¹ 180 days after publication of the final rule to begin implementing the Sunshine Provisions. This recommendation is based on specific information and examples from various AdvaMed members regarding their expectations with respect to implementation time.
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Support for AdvaMed’s Response:

AdvaMed appreciates CMS’ willingness to allow applicable manufacturers additional time to prepare for implementation of the Sunshine Provisions, in light of the delayed release of the Proposed Rule. As CMS has recognized, implementation of the Sunshine Provisions is a large undertaking that requires extensive manufacturer resources, time, and money. However, we are concerned that CMS may not fully appreciate the extent of resources, time, and money associated with implementation of the Sunshine Provisions and continued compliance.

To support our recommendation that CMS provide applicable manufacturers 180 days after publication of the final rule to begin implementing the Sunshine Provisions, we attach as Exhibit B an illustrative timeline, outlining the specific length of time required for system development, implementation, testing, and training. As this information demonstrates, manufacturers will require more than the 90 days proposed by CMS in order to ensure accurate and compliant reporting under the Sunshine Provisions, especially in light of the annual certifications manufacturers will be required to submit.

To further support our recommendation, and emphasize the complex nature of implementing the Sunshine Provisions, including substantial internal systems and personnel challenges, we also include at Exhibit C information from our members regarding costs associated with implementation of and compliance with the Sunshine Provisions. Based on information provided by our members, we believe that CMS significantly underestimates the cost per year and number of full time equivalent (“FTE”) employees necessary to accurately collect and submit the information required under the Sunshine Provisions.

Finally, our recommended time period is supported by a variety of considerations, discussed below, including our members’ actual experiences in implementing and complying with state laws that currently require similar reporting.

- a) *CMS is proposing divergent options in more than 60 areas for comment, making meaningful preparation virtually impossible at this stage.*

¹¹ Certain aspects of the Sunshine Provisions apply equally to applicable manufacturers and applicable group purchasing organizations (“GPOs”). However, for purposes of our comments, we refer only to applicable manufacturers, as these are our members. With the exception of our comments relative to physician owned entities set out in Section II.9 of this letter, we express no view with regard to the application of the Proposed Rule to GPOs.

At this stage, it is virtually impossible for applicable manufacturers to prepare systems and personnel to the degree necessary to be fully compliant with the Sunshine Provisions within ninety (90) days of receipt of the final rule. Given the penalties and the inherent risks in publicly posting incomplete or inaccurate data, ensuring that applicable manufacturers have time to adequately prepare is of significant concern.

It is also extremely difficult for applicable manufacturers to begin substantive implementation the reporting requirements of the Sunshine Provisions in advance of the final rule because CMS is seeking comments on almost every aspect of the Proposed Rule and the Proposed Rule includes several divergent approaches that must be resolved before companies can make threshold systems implementation decisions.

For example, it remains unclear whether:

- An applicable manufacturer must report one or multiple covered products as associated with a payment or other transfer of value;
- Lump sum payments must be separated into distinct line items representing different natures of payment or can be reported as a single lump sum;
- CMS will notify covered recipients of the 45-day review period or if applicable manufacturers will be responsible for notification; and
- Food and beverage will be allocated per covered recipient in a group practice or hospital, by department, or otherwise.

The Proposed Rule also includes recommendations that were not previously contemplated by applicable manufacturers. For example, prior to release of the Proposed Rule, applicable manufacturers did not contemplate that the regulations would apply to foreign affiliates, as anticipated by the Proposed Rule.

Because there remain open questions and issues regarding the Sunshine Provisions, even following release of the Proposed Rule, manufacturers are limited in the steps they can take now to prepare for implementation following release of the final rule.

- b) *Effective implementation will require the development and roll-out of comprehensive training programs.*

Once the final rule is released and applicable manufacturers have more clarity regarding their obligations under the Sunshine Provisions, applicable manufacturers will then be required to begin the process of training personnel, potentially worldwide, in order to ensure that internal policies and procedures related to tracking and reporting are properly executed.

This training effort will represent a significant undertaking as compliance with the Sunshine Provisions necessarily implicates employees and personnel across multiple areas of a company. For example, our members expect to train personnel from the following departments:

- Sales
- Marketing
- Finance and Accounting
- Communications
- Research and Development
- Executive Management
- Legal
- Compliance
- IT/Data Analysts
- Internal Audit
- Human Resources
- Regulatory
- Clinical
- Product Managers
- Medical Science Liaisons aka Office of Medical Affairs

This list represents examples of the types of personnel that will need to be trained, but is not intended to be an exhaustive list. All of these individuals and possibly more, depending upon the manufacturer, will need to be effectively trained in order to ensure that applicable manufacturers can accurately and efficiently report information to CMS. One of our members, a large-size device manufacturer, reports that it expects to be training forty to fifty percent of its global employee base, or more than 3,700 employees world-wide, with respect to the Sunshine Provisions.

In addition, applicable personnel will need anywhere from two to four trainings in order to accommodate the Sunshine Provisions requirements. For example, applicable manufacturers may provide general transparency training, systems training, and remediation and reporting training, among others.

Even to the extent applicable manufacturers begin the training process prior to release of the final rule, additional training sessions may be required following release of the final rule in order to address new or revised requirements. That is, while many applicable manufacturers began addressing these training needs prior to the January 1, 2012 implementation date under the Sunshine Provisions, it has been virtually impossible to do so in an effective manner without the additional direction that final regulations will provide. Until regulations are finalized, applicable manufacturers cannot finalize the substantive content of the training, and any training that was conducted prior to issuance of the Proposed Rule is now at least partially incorrect or obsolete due to the new interpretations put forward by the Proposed Rule.

c) *Actual experiences in Massachusetts and Vermont support a longer implementation period.*

Based on actual experience in Massachusetts and Vermont, manufacturers need more implementation time. In complying with the reporting requirements in those states, our members found, for example:

- Initial and continued implementation challenges with respect to both states.

- Significant system challenges, with at least one year required to work through the challenges to ensure that all information was properly uploaded or accepted into the state's system.
- Continued questions regarding relevant definitions and categories. For example, one of our members reports significant challenges in reporting product-level detail to Vermont. The company categorizes its products by major families, but Vermont did not understand its product definitions. As a result, the company had to provide detailed descriptions of each product for all product categories. Because the company has over 6,000 sub-brands this was a tremendous challenge. This is the same challenge many company will face if CMS finalizes its proposal to require reporting of specific products.
- Finally, note that, as to certain state specific requirements, some manufacturers were able to moderate the time and resource commitment by isolating, when possible, state specific subsets of health care providers and/or transactions and developing practices that were designed to ensure state specific compliance. In some cases, because they were unable to implement in time, some manufacturers simply limited or ceased engaging health care providers located in these states altogether, even though such engagement would be for legitimate and appropriate purpose. This is not a feasible practice for the entire U.S.

Further, we note that in issuing its disclosure requirements, Vermont provided manufacturers with a six month grace period to prepare for implementation. That is, while the law went into effect on July 1, 2009, manufacturers were not required to begin tracking information for reporting purposes until January 1, 2010. Even with this six-month grace period, manufacturers still faced implementation challenges, notwithstanding the fact that Vermont reporting related to a relatively small number of physicians and other covered recipients. Implementing the Sunshine Provisions will be exponentially more challenging than Vermont implementation, since the Sunshine Provisions will require reporting on potentially all U.S. physicians and teaching hospitals.

As a result of the above considerations, applicable manufacturers will need more time than the 90 days proposed by CMS to ensure a timely, accurate, and complete reporting.

d) *CMS is proposing to expand the definition of "applicable manufacturer."*

As further discussed in Section II.1 of this letter, under the Proposed Rule, CMS is proposing to expand the definition of "applicable manufacturer" to include those manufacturers engaged in the production or preparation of a covered product sold or distributed in the United States, regardless of where the covered product is produced or where the entity is located or incorporated. This proposed definition is broader than the statutory definition and potentially implicates additional entities and divisions not previously expecting to track or report data pursuant to the Sunshine Provisions. Accordingly, if CMS adopts this expanded definition of applicable manufacturer as proposed, manufacturers will require additional time to ensure foreign affiliates are prepared for compliance with the Sunshine Provisions. Required

preparation time will be further complicated by currency, language, and privacy law barriers, among others.¹²

- e) *Agreements entered into before passage of the Sunshine Provisions will need to be assessed and managed.*

In our industry it is common for applicable manufacturers to have long-term agreements with covered recipients (e.g., royalty agreements), many of which would have been entered into prior to passage of the Sunshine Provisions. Together with other expansions in the Proposed Rule, particularly the applicability of the Sunshine Provisions to non-U.S. affiliates, and in further support of our request for implementation time, companies will need time to reassess and manage these contractual obligations. Specifically, applicable manufacturers will need sufficient time to work with covered recipients to amend applicable existing agreements consistent with the Sunshine Provisions, or to terminate such agreements and enter into new agreements consistent with the Sunshine Provisions.

5. Nature of Payment: Research

CMS Proposal:	CMS proposes to separate the classification of research payments to clarify whether the payment or other transfer of value went indirectly or directly to the covered recipient. For both direct and indirect research, CMS proposes that applicable manufacturers must report the entire payment amount for each research payment (whether to the covered recipient or a research institution), rather than the specific amount that was provided to the covered recipient. Indirect payment reports should also include the name of the entity or individual that received the payment or other transfer of value. For physicians, CMS proposes to publish the payment amount separately, and not aggregate the entire amount into the physician's total on the public website. For teaching hospitals, CMS proposes to aggregate the payment into the teaching hospital's total payment amount.
AdvaMed Response:	AdvaMed recommends that only research payments made to covered recipients should be reported. This is consistent with the language of the Sunshine Provisions. Where the research payment is not made directly to a physician covered recipient, but instead to a covered recipient entity (e.g., teaching hospital), manufacturers should also disclose the name of the covered recipient principal investigator(s), if

¹² For example, European data privacy laws may require written consent from covered recipients protected by these laws before the name and other personal information is provided to CMS. Other EU or country specific legal standards may apply as well.

	known at the time of payment.
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Support for AdvaMed’s Response:

Under the Sunshine Provisions, applicable manufacturers are required to report information regarding payments or other transfers of value to a “covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient).” Research organizations and other entities that are not covered recipients do not fall within this requirement because they are not covered recipients, nor were they designated by a covered recipient.

- a) *Only Payments Made Directly to Physician Covered Recipients or Teaching Hospital Covered Recipients Should Be Reported.*

As required by statute, AdvaMed recommends that payments made directly to a physician covered recipient be reported under that physician covered recipient’s name. With respect to payments made directly to a teaching hospital covered recipient, AdvaMed recommends that such payments be reported only with respect to the teaching hospital and not be reported as a separate line item for any physician covered recipient serving as a principal investigator. Any physician serving as a principal investigator could be identified within the line item attributable to the teaching hospital, to the extent that the manufacturer is aware of the identify of the principal investigator at the earlier of the contract execution date or the date of payment (for example, if the principal investigator is identified in the research agreement),¹³ but payment amounts should not be attributed to the physician covered recipient.

As you know, research payments cover a broad range of services performed by teaching hospitals well beyond physician services. Such services include nursing time, lab fees, patient care, medical supplies, statistician services, and institutional overhead, among others. Further, it is the teaching hospital, not the applicable manufacturer, that determines how much to pay the physician serving as a principal investigator. And if the principal investigator is an employee of the teaching hospital, he or she may receive no additional payment from the teaching hospital beyond his or her salary. If the physician serving as a principal investigator does receive additional funds from the teaching hospital, the amount of such funds is at the discretion of the teaching hospital, not the applicable manufacturer. To attribute the entire payment to the teaching hospital and to the physician serving as principal investigator as separate line items would be misleading to the public and has the potential to stifle future research. That is, when physicians are faced with patient and media inquiries about payments they did not actually receive, but which are attributed to them, they may be more reluctant to participate in clinical research, which is essential to clinical safety. This concern is especially significant in light of

¹³ The issue of manufacturer awareness arises in multiple contexts under the Proposed Rule and Sunshine Provisions, including with respect to third party payments and, as here, in the context of principal investigators. We discuss this issue further in Section II.8 of this letter.

proposals to increase the research that will be required for approval or clearance of medical devices.

b) *Payments Made to Non-Covered Recipients Should Not Be Reported.*

CMS' proposal to require applicable manufacturers to report payments made to non-covered recipients, such as non-teaching hospital research organizations, and CMS' intent to attribute those payments to physician covered recipients serving as principal investigators, is wholly outside the scope of the authority granted CMS in the Sunshine Provisions. In addition, to attribute an entire research payment made to a non-covered recipient to a physician covered recipient serving as principal investigator is misleading and may discourage physicians from participating in research projects.

During the development of the Sunshine Provisions, Congress considered the same direct and indirect approach CMS proposes in the Proposed Rule. However, Congress subsequently rejected this approach when it adopted the Sunshine Provisions as they currently exist. Accordingly, CMS oversteps its authority by proposing to require applicable manufacturers to report payments to non-covered recipients.

Aside from the plain language and the legislative intent of the Sunshine Provisions and CMS' authority thereunder, requiring applicable manufacturers to report payments to non-covered recipients, and attribute such payments to covered recipients, also would not further the policy objectives of the Sunshine Provisions, and would present significant operational challenges for manufacturers.

Medical device manufacturers enter into research agreements with institutions, which then exercise discretion over how payments from the manufacturers are allocated. In numerous cases, the physician covered recipient serving as a principal investigator receives no payment beyond his or her usual salary from the institution. More specifically, it is the institution—not the manufacturer—that determines how to compensate (if at all) a principal investigator in these cases. In addition, the physician covered recipient serving as a principal investigator may change over the course of a research agreement. Manufacturers may not be notified of this change and therefore will be unaware of the identity of the principal investigator.

To require applicable manufacturers to report the full amount of the payment to the institution to any physician covered recipients serving as principal investigators who (1) may not receive any of the manufacturer's payment or (2) receive a portion of the payment at the discretion of the institution, not the manufacturer, misrepresents the relationship between the applicable manufacturer and the physician covered recipient. In addition, it is inaccurate and misleading to attribute on the public website the entire research payment made directly to a research institution to a physician covered recipient serving as a principal investigator, since such physician likely received none or only a fraction of the entire research payment at issue. Finally, the approach proposed by CMS may require manufacturers and research institutions to audit their research agreements on a continuous basis to determine whether the principal investigators have changed, with such changes potentially occurring during a single reporting cycle.

For the foregoing reasons, we recommend that research payments made to non-covered recipients should not be reportable. In the event that CMS decides to follow an approach inconsistent with our recommendations above, we request that CMS provide an additional comment period with respect to such proposal.

6. Exclusions: Educational Materials that Directly Benefit Patients or Are Intended for Patient Use

CMS Proposal:	CMS clarifies that this exclusion is limited to “materials” (including, but not limited to, written or electronic materials) and does not include services or other items. CMS is also considering whether certain materials provided by an applicable manufacturer to covered recipients to educate the covered recipients themselves, but which are not actually given to patients (for example, medical textbooks), should be interpreted as education materials that “directly benefit patients.”
AdvaMed Response:	AdvaMed supports adoption of a policy whereby educational materials that serve a genuine educational function for covered recipients are deemed to “directly benefit patients” and thus excluded from reporting. AdvaMed further recommends that the educational materials exclusion should align with Section IX of the AdvaMed Code. Finally, AdvaMed recommends that CMS clarify that this exclusion includes time and overhead associated with education and training.

Support for AdvaMed’s Response:

AdvaMed recommends that the exclusion for educational materials that directly benefit patients or are intended for patient use should align with Section IX of the AdvaMed Code. Therefore, educational materials that serve a genuine educational function for covered recipients should be deemed to “directly benefit patients” because such materials ensure the safe and effective use of medical devices, and hence would not have to be reported. This would include, for example:

- Medical textbooks
- Anatomical models
- Disease-state reference guides
- Journal articles
- Wall charts
- Health care provider and patient training brochures and DVDs¹⁴
- Subscriptions
- Educational software applications
- Reprints

¹⁴ Manufacturers may distribute DVDs to health care providers for their own education and for distribution to patients. The DVDs demonstrate how a product works and provides instructions on how to use the product.

- Product labeling
- Product or procedure technique publications

This list represents examples of educational materials that benefit patients, common in the industry, and is not intended to be an exclusive list. Educational materials such as those noted above serve to educate a covered recipient and therefore also directly benefit patients. That is, patients directly benefit from a well-educated physician who has had the advantage of developing skills with respect to a particular medical device through educational materials.

In addition, even those educational materials that are primarily intended as educational materials for covered recipients may be shared with patients. For example, a physician covered recipient may refer to a medical textbook during a patient visit in order to provide the patient a better understanding, or visual representation, of his or her condition or scheduled procedure.

It is not clear what, if any, of the above-referenced educational materials would be excluded from CMS' definition of "materials" as "other items." However, AdvaMed recommends that CMS recognize as educational materials subject to exclusion those "items" that serve an educational function consistent with the language of the Sunshine Provision.

If CMS does require the reporting of certain educational items, such as journal articles, there are administrative considerations with respect to tracking and reporting such items that CMS should consider. Many applicable manufacturers currently provide journal articles that provide important clinical and other information to covered recipients pertaining to the safe and effective use of their products and the disease states that they treat. Manufacturers report that in most cases journal articles would have to be tracked manually. Accordingly, the administrative task of reporting journal articles would be especially unwieldy and may have the effect of discouraging applicable manufacturers from providing, and physicians from requesting or accepting, journal articles. Such a chilling effect would be unfortunate for both covered recipients and patients, since journal articles represent an important educational tool that ensures appropriate and thorough responses to covered recipient questions. In addition, assigning a value to journal articles would be difficult, and could lead to misleading data posted on the public database.

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Loading such materials onto a DVD or thumb drive is often more cost effective than providing the information in paper or book form.

7. Nature of Payment: Food and Beverage Allocation

<p>CMS Proposal:</p>	<p>With regard to group meals provided in group settings (<i>e.g.</i>, buffet-style food in a physician’s office), CMS proposes that applicable manufacturers should report the cost per covered recipient receiving the meal (even if the covered recipient does not actually partake of the meal). For example, if a sales representative brings in \$25 worth of bagels and coffee to a practice group that includes five physicians, CMS proposes that the per covered recipient cost would be \$5, regardless of whether all five physicians actually consumed any of the food provided. For large group practices or hospital-based physicians, CMS is considering whether to adopt a different approach, such as counting the number of physicians by department.</p>
<p>AdvaMed Response:</p>	<p>AdvaMed recommends that companies allocate the value of meals provided among all individuals who partook of the meal, regardless of whether the individual is a covered recipient. That is, in the example above, if three of the five physicians in the group practice were present at the meeting and partook of the \$25 worth of bagels and coffee that was served, and one non-physician office staff member and a manufacturer representative were also present, the applicable manufacturer would allocate the meal among these five attendees and the applicable manufacturer would then report only with respect to those three attendees that are covered recipients at a value of \$5 for each covered recipient.</p>

Support for AdvaMed’s Response:

Under CMS’ current proposal for food and beverage allocation, many covered recipients who do not partake of meals, or who deliberately choose to opt out of such meals,¹⁵ may be identified in applicable manufacturer reports as having received food and beverage, even though they in fact did not. In addition, in the event that non-covered recipients also partook of provided food and beverage, physicians may be identified as having accepted food and beverage from applicable manufacturers in excess of what they actually received. Such a result does not further the policy behind the Sunshine Provisions, will lead to the reporting of inaccurate information, and will significantly increase the number of disputed postings. The proposal may also create the incorrect appearance of inappropriate promotion of products to physicians who are part of the same practice, but who practice a specialty not covered by the product’s labeled indications

¹⁵ For example, a covered recipient may be present at a meeting where a meal is served, but may not partake of the meal either because of a legal prohibition, such as under Massachusetts law, or because of a personal decision not to accept meals from industry.

because CMS proposes attributing meal costs to all physicians in a practice group or department, even those who do not attend the event where the meal is served.

CMS' proposal also does not reflect the reality of meetings in which an applicable manufacturer may provide meals to covered recipients. CMS appears to assume that all members of a particular practice or department will attend an educational presentation where a meal is served. This may not be the case and, as stated, to allocate a portion of a meal to a physician who was not present and did not consume the meal is inaccurate, misleading, and may result in disputes between applicable manufacturers and covered recipients regarding information reported to CMS. In fact, our members note that, based upon their experience in Massachusetts, most questions and concerns raised by physicians relate to accuracy of meal reporting.

Many manufacturers now currently have policies and procedures in place to identify the number of individuals who receive meals and record the names of covered recipients present. For example, some manufacturers maintain sign-in sheets at meetings where food and beverage are served. As a result, applicable manufacturers are able to identify the total number of attendees to whom meal costs should be allocated for reporting purposes. To require applicable manufacturers to arbitrarily allocate meal costs across all physician covered recipients within a particular office, hospital, or department not only will lead to significant administrative challenges in identifying applicable covered recipients, but it also does not accurately reflect the true nature of the transfer of value.

Accordingly, we recommend that CMS allow applicable manufacturers to allocate the cost of meals among the total number of covered recipient and non-covered recipient attendees, including applicable manufacturer representatives, as appropriate. Applicable manufacturers would then be required to report the value associated with each individual covered recipient, to the extent required under the Sunshine Provisions.

Applicable manufacturers are currently reporting to Massachusetts consistent with this method.¹⁶ To require similar reporting to CMS not only ensures consumers receive accurate information regarding these transactions, but also allows applicable manufacturers to continue to employ the method with which they are familiar. Under our proposal, applicable manufacturers would not be required to attribute to covered recipients meals costs properly allocated to non-covered recipients. Applicable manufacturers would also not be required to attribute meal costs to covered recipients who are expected to attend an event but who do not in fact show up for the event. Such a result is more accurate and will reduce the number of disputes between covered recipients and applicable manufacturers.

¹⁶ See Office of Inspector General Frequently Asked Questions, *available at*: <http://www.mass.gov/eohhs/provider/licensing/programs/pharm-code-of-conduct/background-information-about-the-code-of-conduct.html>.

CMS should also provide manufacturers the flexibility to implement policies and procedures to exclude attendees from the allocation who do not, in fact, partake of the hospitality offered as a result of applicable state laws or a personal decision to not accept hospitality from industry.

8. Payments or Other Transfers of Value to a Third Party

<p>CMS Proposal:</p>	<p>CMS proposes that in those cases where a covered recipient requests that a payment or other transfer of value be transferred by the applicable manufacturer to another individual or entity instead of being provided directly to the covered recipient, the applicable manufacturer should report the name of the entity or individual that received the payment at the request of or designated on behalf of the covered recipient, in addition to the name of the covered recipient.</p> <p>CMS also addresses the issue of awareness in the context of indirect payments through third parties. CMS proposes that an applicable manufacturer be deemed aware of the identity of a covered recipient if the applicable manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient.</p>
<p>AdvaMed Response:</p>	<p>AdvaMed agrees with CMS’ proposal to require reporting when transfers involve third party <u>entity</u> recipients, <i>e.g.</i>, charitable institutions, but recommends that CMS not require applicable manufacturers to report third party recipients who are <u>individuals</u>. We also reiterate our previous recommendation that determinations as to what, if any, entity to report as a third party recipient should be guided by federal income tax policy and treatment.</p> <p>With respect to the awareness standard, AdvaMed recommends that CMS clarify that an applicable manufacturer’s awareness of the identity of a covered recipient should be measured as of the earlier of the time a contract is executed or the date the manufacturer makes a payment or other transfer of value to the third party. In addition, CMS should clarify that payments through third parties to covered recipients are not reportable if the covered recipient is not aware of the identity of the applicable manufacturer.</p>

Support for AdvaMed’s Response:

- (a) *CMS should require applicable manufacturers to report only third party entity recipients.*

In our July 12, 2011 Letter, AdvaMed recommended that with respect to issues of payments or transfers of value “at the request of or designated on behalf of” a covered recipient, CMS should be guided by federal income tax policy to facilitate a consistent treatment of this broad category

of arrangements. That is, where a transfer of value is reportable as gross income to a covered recipient, it should qualify for reporting under the Sunshine Provisions.¹⁷ In addition, we recommended that when a payment is not made directly to a physician covered recipient, the information to be reported should include: a) the amount of money paid; b) the name of the physician who performed the work; and c) the entity which received payment on behalf of the physician.

Consistent with our previous recommendations, we welcome CMS' proposal to require applicable manufacturers to report the name of the entity, *e.g.* charitable institutions, ultimately receiving the payment or other transfer of value as a result of a request or designation by a covered recipient. We do, however, recommend that CMS clarify that applicable manufacturers would not be required to report payments made to a charity selected by the applicable manufacturer, with no control or input from the covered recipient, after a covered recipient has waived his/her right to fees for services performed. In accordance with IRS tax rules, this type of donation should not be reportable because it is of no benefit to the physician, the physician has completely waived his/her right to income, and the charity was not selected by the physician.

We do not agree with CMS' proposal to extend the reporting requirement to include identifying individuals who may ultimately receive a payment or other transfer of value at the request of or designated on behalf of a covered recipient. Such requirement may present sensitivity issues, as well as privacy issues.

- For example, a physician covered recipient may have a royalty relationship with an applicable manufacturer that entitles the physician to significant royalty payments. The physician may in turn assign those royalty payments to his child. If the applicable manufacturer is required to report the name of the physician's child, and such information is made publicly available on the website, anyone will be able to see the potentially large amount of money tied to the child's name. Regardless of the child's age, such information may make him or her a target for bad actors. On a less extreme level, such information is highly sensitive and may expose the third party individual recipient to unwanted attention, especially in light of the fact that the child is not a covered recipient and will not have the option of reviewing the data to be made public about him or her.

We note that in discussing whether to require applicable manufacturers to report the name of an immediate family member of a physician who has an ownership or investment interest in the entity, CMS identified privacy concerns with reporting the name of the immediate family member publicly. We believe these concerns are warranted and also apply in the situation where an individual receives a payment from an applicable manufacturer at the request of or designated on behalf of a covered recipient.

¹⁷ See generally *Lucas v. Earl*, 281 U.S. 111 (1930) (holding that a taxpayer who possesses a current or future right to income cannot shift the tax on such income by transferring the right to receive the income to another taxpayer).

In the case of ownership or investment interests, immediate family members may be used to camouflage or hide the covered recipient's involvement. In this case, however, the payments are attributed to the covered recipient and it is not necessary to disclose the individual third party recipient's name in order for the public policy of the Sunshine Provisions to be met.¹⁸

In addition, notwithstanding CMS' reference in Section II.A.d of the Proposed Rule ("Payments or Other Transfers of Value") to reporting "the name of the entity or individual" that received the payment at the request of or designated on behalf of the covered recipient, CMS elsewhere in Section II.B.3 of the Proposed Rule ("Report Format") identifies the fields of information to be included in the report, and indicates an additional field for "Name of entity that received the payment or other transfer of value if not provided to the covered recipient directly." For the reasons discussed above, AdvaMed agrees with the latter approach identified by CMS and recommends that CMS not require applicable manufacturers to report individual third party recipients. We also reiterate our recommendation that determinations as to what, if any, entity to report as a third party recipient should be guided by federal income tax policy and treatment.

(b) CMS should clarify the awareness standard.

The issue of manufacturer awareness arises in multiple contexts under the Proposed Rule, including with respect to third party payments and in the context of research using principal investigators. Notwithstanding the guidance CMS provides in the Proposed Rule regarding awareness, open questions still remain with respect to the awareness issue, including the question of when a manufacturer's awareness should be measured. We recommend that in all cases where awareness is an issue under the Sunshine Provisions, an applicable manufacturer's awareness of the identity of a covered recipient should be measured as of the earlier of the time a contract for the services to be compensated is executed or the date the applicable manufacturer makes a payment or transfer of value to the third party.

If CMS declines to measure knowledge or awareness at a single, identified point in time, then applicable manufacturers will face situations in which they must continue to monitor transactions long after payments have been made in case the identity of a known recipient changes or an otherwise unknown recipient happens to become evident later. Such a requirement is unreasonable and overly burdensome. It also does not serve the purposes of the Sunshine Provisions as the identity of the covered recipient at the time of payment by the applicable manufacturer was unknown and therefore not a consideration.

CMS uses the example of an applicable manufacturer providing payment to a hospital to fund its department chairs, the identities of whom CMS assumes are publicly available. We submit that the applicable manufacturer's awareness of the identities of the department chairs should be measured only as of the time the manufacturer agrees to provide funding to the hospital for the department chairs. This is true even if the department chairs change after the payment has been

¹⁸ We note that our comments here with respect to ownership and investments interests are separate and distinct from our comments on physician owned entities in Section II.9 of this letter.

made and these new department chairs accordingly become indirect recipients of funds from the payment the applicable manufacturer previously made to the hospital.

CMS would allow a reporting exclusion for indirect payments through third parties, where the applicable manufacturer is unaware of the identity of the covered recipient. AdvaMed submits that this exclusion should also apply when indirect payments are made through a third party to a covered recipient, but the covered recipient is not aware of the identity of the applicable manufacturer, regardless of whether the applicable manufacturer is aware of the identity of the covered recipient.

A covered recipient cannot be influenced to use a manufacturer's products as a result of receiving a payment related to blinded research if the covered recipient does not know the manufacturer involved in the research. Disclosing these types of payments would not serve the public policy purpose of the Sunshine Provisions. If disclosure is required in this case, then the disclosure will be the first time the covered recipient learns which manufacturer is involved in the blinded research. Since the covered recipient was not aware of the source of the payment, including it in the disclosure may lead to increased covered recipient disputes because covered recipients will question a payment from a manufacturer that that they did not realize was involved.

Finally, AdvaMed recommends that CMS clarify that in cases where a manufacturer hires an entity, not the covered recipient, to perform work without specifying that any particular covered recipient conduct the work, the payment should be reported only as paid to the entity. In such cases, there is no direct financial relationship between the covered recipient performing the work and the manufacturer, and the applicable manufacturer was not aware of the physician who would conduct the work at the time the contract was executed. For example, an applicable manufacturer may contract with a hospital for the services of any physician in a particular specialty, not knowing which physician will provide the services at the time the contract with the hospital is executed. The applicable manufacturer may later incidentally learn the identity of the physician through receipt of an invoice. This should not constitute "awareness" as the applicable manufacturer was not aware of the identity of such physician when it entered into the arrangement with the hospital.

9. Applicability of Sunshine Provisions to Physician Owned Distributors, Physician Owned GPOs and Physician Owned Manufacturers

a) Definition of an "Applicable GPO"

CMS Proposal:	CMS proposes to define an Applicable GPO as an entity that (1) operates in the United States, or in a territory, 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, and not solely for use by the entity. This definition would include physician owned distributors (PODs).
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AdvaMed Response:	AdvaMed agrees that CMS should define Applicable GPO to include PODs. CMS, however, should remove the word “group” from the definition to ensure that all POD business models are captured. CMS should also modify the phrase “and not solely for use by the entity itself” in the definition.
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Support for AdvaMed’s Response:

AdvaMed fully concurs that the statutory language captures not only physician-owned GPOs, but also PODs. We attach as Exhibit D AdvaMed’s Statement on Transparency and Physician-Owned Companies for additional background on PODs, which may help explain the context for our recommendations in this area.

The statute in Section (e)(1) defines GPOs to include an entity that “purchases” or “negotiates the purchase of a covered drug or device.” As recognized by CMS, the language of the statute supports including both models of PODs within the definition of “applicable GPO”. CMS should make clear that the definition includes the “purchase and reselling” PODs as well as the PODs that “negotiate the purchase of a covered... device” in return for a commission from the supplying manufacturer.

In addition, as noted above, the physician-owned GPOs are not traditional GPOs, but as with other physician owned company (POC) models, are structured and operated with the intent to create additional revenue for the physician owners. While traditional GPOs may represent groups of buyers, a physician-owned GPO may arrange for the sale for only a single hospital or health system where the physician owners refer patients and thereby avoid reporting requirements. To that end, the language “for a group” should be deleted from part (2) of the definition of a GPO. The statutory language applies to all GPOs without limiting it to only those GPOs that represent groups. In the interest of mandating full reporting, the term “group” should be deleted from the final regulations.

Lastly, CMS should modify the phrase “and not solely for use by the entity itself” in the definition to be clear that only physician-owned providers that purchase and are the end users of the device in the implanting procedure are not included in the definition of applicable GPO. Because the POD owners also perform the implant procedures, the current language could permit a POD to structure a relationship with a hospital through service, lease or other arrangements, to be able to assert that the device is supplied for the POD’s own use. Under such arrangements, the hospital would still pay the POD for and the physician owners would still profit from the device referral and purchase, but the proposed language would permit the POD with such arrangements to assert that it is not an applicable GPO for reporting purposes. Instead, the definition should read, “and (1) is not a physician-owned provider, such as a hospital, ambulatory surgery center or group practice, (2) is the end-user of the device with patients and (3) bills for the device or the implant procedure.”

b) *Ownership or Investment Interests: Definition and Reporting*

CMS Proposal:	CMS proposes to define an ownership or investment interest in an applicable manufacturer or applicable GPO to exclude stock options received as compensation until they are exercised. CMS is also considering whether to require reporting of the name and relationship to the physician of any immediate family member holding an ownership or investment interest.
AdvaMed Response:	AdvaMed recommends that no distinction be made between stock options received as an ownership interest and stock options received as compensation. All stock options should be disclosed when granted. In addition, if an ownership or investment interest in an applicable GPO is held by a family member of a physician, the applicable GPO should be required to report the interest in the name of the physician covered recipient as well as the name and relationship of the family member to the physician.

Support for AdvaMed’s Response:

In the July 12, 2011 Letter, AdvaMed noted that stock options present complexities in reporting, and a uniform and administrable approach would be preferred. AdvaMed recommended that CMS allow companies to report stock options in the year granted, and we now recommend that this framework extend to the reporting of stock options as ownership or investment interests.

The language excluding stock options and convertible securities received as compensation until they are exercised should be deleted from the definition of ownership or investment interest. The statute does not include this limitation, but in fact Section (1)(a)(A) defines payment or transfer of value to include “stock options” and “current or **prospective** ownership or investment interests.” There is no basis in the statute for narrowing the definition of ownership interests to exclude stock options or convertible securities received as compensation, especially when such payments are provided to physicians by POCs. Given the purpose of POCs, once stock options or convertible securities are paid as compensation, a physician who has stock options or convertible securities in a POC, is in the position to and has a vested interest in growing the business of the POC in order to increase their value upon conversion.

In addition, because they are expressly included in the definition of payments and transfers of value, the list of categorization of payments, at least for POCs, should expressly include dividends, profit distributions or a return on investment. Otherwise, POCs could conceal these payments under “Other.”

Lastly, if an ownership or investment interest in an applicable GPO, to include a POD, is held by a family member of a physician, the applicable GPO should be required to report the interest in the name of the physician covered recipient as well as the name and relationship of the family member to the physician. Unlike a transfer of value to a third party at the direction of a covered recipient physician, or an ownership interest in an applicable manufacturer held by a family

member, in which the family member or other third party may have little or no connection to the relationship between the manufacturer and the covered recipient and thus disclosure is of limited benefit, an ownership interest in a POD or other applicable GPO may be held by a family member solely in order to avoid sufficient disclosure of the physician owner’s interest. To that end, if an immediate family member holds an interest in an applicable GPO, the name, the name and relationship to the family member should be reported. If an immediate family member holds an interest in an applicable manufacturer, identification of the physician covered recipient, with a notation that the interest is held by a family member, is sufficient.

c) Reporting of Transfers of Value by Applicable GPOs

CMS Proposal:	CMS proposes that applicable GPOs only report payments made to their physician owners or investors.
AdvaMed Response:	AdvaMed recommends that CMS require applicable GPOs to report payments made to all physicians, not just physicians with ownership or investment interests.

Support for AdvaMed’s Response:

With regard to manufacturers, the statute is quite clear that it is intended to require all payments to physicians under Section (a)(1)(A) as well as the ownership interests identified in Section(a)(2). Section (a)(2) states that “**In addition to the [payment reporting] requirement under paragraph (1)(a)(A),** any applicable manufacturer or applicable group purchasing organization shall submit” information regarding ownership interests. Section (a)(1)(A) clearly requires applicable manufacturers to report all payments to physicians, regardless of whether they have ownership. In addition, Section (a)(2) requires that an applicable manufacturer that has physician owners must report the ownership interests unless the manufacturer is publicly traded.

On the other hand, GPOs, including distributors, do not have to report payments under (1)(a)(A) **unless** they have physician owners and are not publicly traded. In other words, traditional non-physician owned GPOs or distributors are not subject to any reporting requirements under the statute. Physician-owned GPOs, including PODs, are covered and must report not only ownership interests, but also, based upon the quoted statutory language above, all payments to physicians, including non-physician owners. Accordingly, CMS’s proposal that applicable GPOs need only report payments to physician owners and not to non-owners, should be modified to require physician-owned GPOs, including PODs, to report all payments to non-physician owners as well as physician owners in keeping with the express language of the statute. Because POCs are created for the primary purpose of permitting physicians to earn additional revenue based upon purchases through or from the POC it is important that applicable GPOs who utilize payments to non-owners as a means of inducing their peers to use product supplied by the POC should be required to report such payments in keeping with the language and purpose of the statute. Otherwise applicable GPOs could utilize payments in lieu of or in addition to ownership

interests to create additional revenue for referrals to POCs and at the same time avoid reporting requirements.

10. Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations

<p>CMS Proposal:</p>	<p>CMS proposes that the “product research or development agreement” referenced in the statute include a written statement or contract between the applicable manufacturer and covered recipient, as well as a written research protocol. In addition, CMS proposes that a “clinical investigation” be narrowly defined as one which is memorialized in a written research protocol between the covered recipient and the applicable manufacturer.</p> <p>CMS also proposes that delayed publication should apply to payments to covered recipients for services in connection with research on, or development of, new drugs, devices, biologicals, or medical supplies, as well as new applications of existing drugs, devices, biologicals, or medical supplies. Conversely, CMS proposes to limit delayed publication for payments in connection with clinical investigations for new drugs, devices, biologicals, or medical supplies.</p> <p>Finally, CMS proposes that if a report includes a date of payment 4 years prior to the current year, then the payment or other transfer of value would be automatically published.</p>
<p>AdvaMed Response:</p>	<p>AdvaMed recommends that “product research or development agreements” and “clinical investigations” not require a written research protocol, or in the alternative, we recommend that CMS clarify that the definitions of “product research or development agreement” and “clinical investigation” include arrangements involving written research protocols that may take a variety of forms.</p> <p>In addition, AdvaMed recommends that delayed publication should be available for payments related to clinical investigations of new applications of existing medical technology.</p>

Support for AdvaMed’s Response:

- a) *The proposed definitions of “product research or development agreement” and “clinical investigations” inappropriately exclude certain arrangements related to bona fide product development and research.*

AdvaMed recommends that CMS revisit the definitions of a “product research or development agreement” and a “clinical investigation” for purposes of delayed publication. As proposed, CMS’ definitions extend beyond the express requirements of the statute and could be interpreted to exclude certain valid development and research arrangements that should be subject to delayed publication in order to protect company trade secrets and proprietary information, while furthering medical technology advancements. As drafted, the Sunshine Provisions do not expressly require that product research or development agreements and clinical investigations, subject to delayed publication, include a written research protocol. Accordingly, we recommend that CMS not finalize this proposed regulatory requirement.

Alternatively, we recommend that CMS clarify that the definitions of “product research or development agreement” and “clinical investigation” include arrangements involving written research protocols that may take a variety of forms. Applicable manufacturers often enter into agreements with covered recipients related to bona fide research and development activities. Such arrangements include a written statement or contract between the parties, in the form of a written agreement, and may also include additional documentation evidencing the process and objectives of such research and development activities. We submit that this secondary document qualifies as a “written research protocol,” even though it may not necessarily follow the format of a clinical investigation protocol, as such a protocol may not be required or appropriate under the circumstances. In particular, protocols such as those used in clinical investigations are not common in the case of medical device development agreements, as development agreements are more project-based than certain research agreements. That is, while drugs may be primarily developed through clinical investigations, devices are frequently primarily developed before clinical investigations and the development process for devices can take a variety of forms, including, for example:

- Surveys, market research, advisory panels and customer meetings to better understand clinical needs;
- Design groups and meetings that collaborate on the clinical needs;
- Cadaver labs to test development prototypes;
- Clinical evaluations; and
- Testing on materials, wear, and certain features of the design.

As a result, written research protocols may take a variety of forms, depending on the nature of the bona fide research and development at issue. Regardless of the form of the research protocol, all of the preceding activities are highly confidential and the agreements with the physician consultants typically include non-disclosure provisions.

We submit that arrangements such as those above that may involve protocols different from the form expected for clinical investigations nonetheless qualify as bona fide research subject to delayed publication. These are the type of development activities that the industry wants to ensure were subject to delayed publication since disclosing that a company is even working with

certain physicians may disclose to its competitors that it is engaged in a development project and flag the type of development project. In addition, to not allow delayed publication for these activities would place U.S. companies at a distinct disadvantage because it would provide overseas competitors with valuable information about the companies' confidential research and development activities. To fail to protect these arrangements disadvantages applicable manufacturers and may discourage valid research and development arrangements.

- b) *Delayed publication should be available for clinical investigations for new applications of existing products.*

AdvaMed also recommends that CMS extend delayed publication to clinical investigations for new applications of existing devices and not limit protection for clinical investigations only with respect to new products. The distinction CMS makes between clinical investigations related to new products and clinical investigations related to new applications of existing products is not only arbitrary, but it also does not align with the reality of industry operations. Clinical investigations with respect to new applications are essential for innovation and advancement within the medical technology industry and are a huge part of the research activities our members engage in. Failing to protect company trade secrets and proprietary information related to these clinical investigations is certainly harmful to applicable manufacturers, but more importantly, it is harmful to consumers as it may discourage important clinical investigations

While we realize there may be a basis for making the distinction CMS has made as a result of the language of the Sunshine Provisions, there is no meaningful distinction between clinical investigations related to new products and clinical investigations related to new applications of existing products in terms of the purpose of delayed publication. The purpose of delayed publication is to avoid manufacturers being placed at a competitive disadvantage as a result of disclosing new products or improvements to existing products. The reasons for granting delayed publication of clinical investigations for new products apply equally to clinical investigations for new applications of existing products. Accordingly, we recommend that CMS extend delayed publication to clinical investigations for new applications of existing products.

- c) *At the time that research payments are published, there may not yet be a specific product associated with such payment.*

We also note that by virtue of the nature of research and development activities undertaken by medical device manufacturers, even at the time that a research payment may be publishable, because four years has passed, there may not be a specific product associated with such payment. Many medical device research projects extend well-beyond four years, as product research and development is an extremely complex undertaking. Even after four years and until a product receives FDA approval, licensure, or clearance, there may be no associated product linked to the research activities as applicable manufacturers may not know what the ultimate approved product will be. Thus, even after expiration of the four-year delay, it may still not be possible to attribute a product name to the payment. We note that the statute specifies that only a product name "if any" must be reported.

11. 45-Day Review Period for Applicable Manufacturers, Applicable GPOs, and Covered Recipients

CMS Proposal:	CMS proposes a 45-day review period to allow applicable manufacturers and covered recipients the opportunity to review the data submitted prior to such data being made available to the public.
AdvaMed Response:	AdvaMed submits that 45 days is not sufficient time for the required review and correction to occur. Instead, we recommend a review period of 90 days during the first year of implementation, and 60 days each year thereafter. In addition, we recommend that the review period be segregated into distinct phases, each to be assigned a specific time frame, to occur sequentially. We also recommend that notifications to CMS regarding disputes, if any, should be made by the applicable manufacturer only—not by covered recipients.

Support for AdvaMed's Response:

Based on discussions with our members, we believe that 45 days is not sufficient time for the required review and correction to occur. Instead, we recommend a review period of 90 days during the first year of implementation and 60 days each year thereafter. This conclusion is based on the fact that the review period serves multiple purposes, as discussed below, and the fact that the first year of implementation will necessarily present unique challenges and issues that all parties involved will need to address and work through. A longer review period is also essential in order to ensure that the information reported by applicable manufacturers is accurate and complete, especially in light of the significant penalties authorized under the Sunshine Provisions.

a) The review period must allow for review of data by applicable manufacturers.

The review period must first allow applicable manufacturers the opportunity to review the data intended to be published, as identified by CMS, to ensure that such data is consistent with the data as submitted by the applicable manufacturer. This review will be important as any number of mistakes may result during the transmission process, through no fault of any party. Our members reported this experience with respect to both Massachusetts and Vermont submissions.

b) The review period must allow for review by covered recipients and physician owners and investors.

Next, the review period must offer covered recipients and physician owners and investors a meaningful opportunity to review data expected to be published with respect to payments and transfers of value they received during the applicable reporting period.

c) The review period must allow for dispute identification and resolution.

Finally, to the extent that a covered recipient or physician owner or investor disagrees with any of the data identified with respect to them, the review period must allow the covered recipient or physician owner or investor to work with the applicable manufacturer to resolve the dispute.

Because the review period is intended to serve so many purposes, and each such purpose will require specific resources and time, it is our position that the review period should be extended.

d) The review period should be segregated into distinct phases.

Regardless of whether the time for the review period is extended beyond the currently proposed 45 days, we recommend that CMS segregate the review period into the following three distinct phases, each to be assigned a specific time frame, to occur sequentially:

1. Review of CMS aggregation by applicable manufacturers;
2. Review of CMS aggregation and identification of disputes by covered recipients; and
3. Resolution of disputes between applicable manufacturers and covered recipients.

Alternatively, CMS may combine the first and second phases identified directly above to create a two-phase review period.

Dividing the review period into distinct phases will allow applicable manufacturers to address general clerical errors and issues separate and apart from payment disputes. In addition, without a phased approach, which includes a cut-off time period for each phase, applicable manufacturers face situations in which covered recipients contact them at or near the end of the review period. In such cases, applicable manufacturers will not have adequate time to respond to and properly address the issue. As CMS makes clear, the dispute will therefore remain unresolved until the next reporting period.

Additionally, we recommend that CMS consider not posting disputed transactions until the following year. Alternatively, manufacturers would need the ability to correct such disputed transactions throughout each year in order to avoid having incorrect information posted on the website.

Manufacturers should not be required to collect and report how the covered recipient would like to be notified of the start of the 45 day review period, nor should manufacturers be required to obtain the covered recipient's e-mail address. Requiring manufacturers to obtain this information is overly burdensome and would require significant systems capabilities and resources to not only obtain the information initially but to maintain and update it on a going forward basis. Additionally, such process will undoubtedly result in CMS receiving different and sometimes out-dated information related to a particular covered recipient from different manufacturers.

e) Applicable manufacturers should be the only entities to notify CMS regarding disputes.

CMS also proposes in the Proposed Rule that in the event of a dispute, at the end of the review period, at least one of any entity involved (applicable manufacturer or covered recipient) must report to CMS that a payment or other transfer of value, or ownership or investment interest, is disputed and the results of that dispute. We recommend that such notification to CMS, if any, should be made only by the applicable manufacturer. Such a requirement would alleviate issues with multiple parties reporting, and potentially reporting contradictory information. In addition, it is reasonable for applicable manufacturers to report the results to CMS as they were the original parties to submit the data.

12. Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program.

CMS Proposal:	CMS proposes that this category be interpreted broadly to encompass all instances in which applicable manufacturers pay physicians to serve as speakers, and not just those situation involving “medical education programs.” CMS notes that this interpretation does not allow for differentiation between continuing medical education (CME) accredited speaking engagements and all other speaking engagements. CMS is considering whether to limit this category to CME-accredited speaking engagements and report other speaking engagements in another category.
AdvaMed Response:	It appears that CMS may not fully understand manufacturer support for independent medical education programs. We provide below additional background and context for CMS’ consideration. AdvaMed recommends that CMS clarify that applicable manufacturers are not required to report payments to ACCME-accredited program sponsors when the applicable manufacturer is not selecting and directly compensating the covered recipient faculty/speaker.

Support for AdvaMed’s Response:

The Proposed Rule’s discussion of independent medical education programs does not appear to accurately reflect the reality of these programs. For example, all independent Medical Education Programs accredited by the Accreditation Counsel for Continuing Medical Education (ACCME), the main accreditation body for CME courses, prohibit industry from selecting or influencing the selection of the program content or faculty. As a result, there should not be any ACCME accredited programs for which applicable manufacturer directly compensate faculty or speakers. The educational grants that applicable manufacturer provide to such programs may be used for the ACCME-accredited program sponsor to pay faculty and speaker travel and lodging costs and an honorarium. However, applicable manufacturers do not designate which faculty or speakers

their educational grants will be used to support. Accordingly, AdvaMed recommends that CMS clarify that applicable manufacturers are not required to report payments to any program sponsors that utilize an independent selection process for speakers, including ACCME and other applicable continuing education and continuing education recognition programs, when the applicable manufacturer is not selecting and directly compensating the covered recipient faculty/speaker.

13. Background Information on Industry-Physician Relationships

CMS Proposal:	CMS proposes that in addition to the information required to be included on the public “transparency” website under the statute, including background or other helpful information on relationships between the drug and device industry and physicians and teaching hospitals, the website will also clearly state that disclosure of a payment or other transfer of value on the website does not indicate either that the payment was legitimate or represented a conflict of interest or any wrongdoing. CMS states that it welcomes comments regarding the details and format for how this information should be displayed on the Web site.
AdvaMed Response:	AdvaMed provides below an overview of the background relevant to medical device company-physician interactions for each statutory transfer of value. We recommend that CMS publish proposed background text for public review and comment in advance of final promulgation. In addition, we ask that CMS not limit the background information to industry-physician relationships, because teaching hospitals are also covered recipients, and context of transfers of value to teaching hospitals is equally important.

Support for AdvaMed’s Response:

The legislation requires CMS to establish a clear and understandable website reporting the required information, including background information on industry-physician relationships. This background ensures the reported data is meaningful and helpful in patient decision-making. Further, the context of reported transfers of value is critical to ensure patients do not form mistaken impressions that all payments to physicians are suspect.

Viewed simply as columns of numbers and “transfer of value” categories, the planned transparency reports described in the proposed regulation tell very little in terms of real world impact and are subject to a wide variety of positive and negative interpretations. As patients, caregivers and others review the posted “payment or other transfer of value” data, it will be important to understand the practical nature of these transfers and how they benefit patients, the nation’s health care system and medical advancements.

Given the importance of the background text on industry-covered recipient relationships, we encourage CMS to publish proposed background text for public review and comment in advance of final promulgation. In addition, we ask that CMS not limit the background information to industry-physician relationships, because teaching hospitals are also covered recipients, and providing the context of transfers of value to teaching hospitals will be equally important.

We offer the following overview of the background relevant to medical device company-physician interactions for each statutory transfer of value:

There are numerous ways in which medical innovation companies compensate physicians, academics and healthcare professionals for their time, expertise and intellectual property, in connection with the development of new medical technologies, the improvement of existing technologies, and training and education of other health care professionals in the safe and effective use of medical technology, among other beneficial services. These arrangements fuel advances in medical technology, and improve medical care and the quality of healthcare available to American patients and consumers. Specific examples are below.

- **Consulting Fees** are both common and essential in the physician-industry innovation-focused relationship. Physician expertise is critical in the development of new medical technologies as well as the refinement and improvement of existing medical devices. Physician input into the device development process assures that an innovation will be of practical use to medical practitioners and will improve patient outcomes. For example, implanted medical devices can sometimes be reshaped to make it easier for physicians to implant. Such an adjustment can save time and prevent potential complications. An improvement such as this cannot be done without the input of physicians who have real-world experience with the device. Consulting fees are also paid for a variety of other activities, including training sales staff and other physicians on safe and effective use of an applicable manufacturer's products.
- **Honoraria** may be paid when physicians provide their time, preparation and expertise to conferences or medical congresses to share research, provide input on new innovations, and highlight clinical challenges with existing technologies. These discussions are critical to educating physicians, advancing the science of medicine, and ensuring the efficacy of new products. Additionally, honoraria may be paid for instructing company personnel, such as medical science liaisons and research development professionals about the clinical challenges faced in a particular practice area. Physicians deserve compensation for the time taken away from their practice to help with these efforts for the common good. Honoraria therefore may be paid for the same types of activities as consulting fees, although, honoraria are typically used when the physician is expected to provide a limited number of services during a year, and an honoraria agreement may be entered into for each service. Since honoraria are a subset of consulting arrangements and we recommend that companies have flexibility to report these payments as "consulting services."

- **Education** is an essential component of the innovative process. When a new device is developed, or an existing technology improved, physicians and other health care professionals often require training on the correct technique, application and usage of the technology. In fact, in many cases, the FDA requires product specific training and education for new devices.
- **Research** is bedrock of advancing medical progress. To bring a new, beneficial health care innovation from concept to the patient may require years of research and development, at substantial expense. Manufacturer research payments compensate physicians, health care professionals, research institutions, and members of the academic community who bring their unique expertise and perspectives to the research and development process. Research payments and grants offset a variety of other expenses related to research and development, such as IRB preparation and approval, patient informed consents, patient follow-up visits for designated periods of time, reimbursement of certain patient expenses, submission of required data, adverse event reporting, investigator meetings, monitoring visits to confirm compliance, and publication of clinical results.
- **Royalty or license.** In many cases, a new product or an improvement of an existing technology springs from the mind of the health care professional. As practitioners in the field, physicians regularly generate new ideas, designs or prototype technologies. In exchange for the physician's intellectual property rights and know-how, companies and physician-innovators may enter into agreements that grant the physician innovators royalties or other payments based on sales of products that use the physicians' intellectual property.
- **Direct compensation for serving as a faculty or a speaker.** Physician-to-physician sharing of medical and scientific knowledge is vital to disseminating information on the most effective uses and applications of new medical innovations, and in training other practitioners on the safe and effective use of technology. As addressed in Section II.12 of this letter, manufacturer typically do not compensate faculty for accredited programs. Instead, they typically compensate physicians serving as faculty for manufacturer programs through consulting or honoraria agreements.

In addition, CMS should provide companies an option to provide additional explanation and content surrounding each transfer of value that is reported. While the Sunshine Provisions require companies to provide a description of the nature of the payment (*e.g.*, consulting fees, honoraria, travel, etc.), companies should have the opportunity to provide additional context about the specific nature of the payment. For example, CMS should consider including an optional link to an applicable manufacturer's designated website.

III. Open Issues Not Addressed in the Proposed Rule

We appreciate that CMS, through the Proposed Rule, has provided manufacturers some additional guidance with respect to several provisions of the Sunshine Provisions. However, there are several issues that are not addressed at all in the Proposed Rule. We reiterate below those recommendations and comments previously submitted to CMS in our July 12, 2011 Letter, not otherwise addressed or discussed in the Proposed Rule. These recommendations remain important to our members, and we ask that CMS address these issues in subsequent rule making, including the final rule.

1. Definition of an “in-kind service”

In general, CMS should require companies to report an “in-kind” service according to the existing categories that are specified in the legislation. Reimbursement, coverage and technical information furnished by companies to covered recipients should be exempted from reporting. As medical technologies have become increasingly complex, so have payor coverage and reimbursement policies. Consequently, a company may provide objective technical, coverage, reimbursement, and health economic information regarding its medical technologies.

Companies also may collaborate with health care professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patient access to medical technology. These items and services have no independent economic value and should be exempt from reporting. Section X of AdvaMed’s Code of Ethics establishes guidance on the ethical provision of such information.

2. Recommendation on Acquisitions

Acquisitions present unique technical challenges for companies as they work to comply with the Sunshine provisions. Acquisitions most likely will not coincide with the close of a Sunshine reporting period, and the parties to the acquisition may use different tracking programs, which must be integrated post-transaction to enable single reporting by the consolidated entity. In addition, it is possible that the acquiring company will need to address problems in the tracking system of the acquired company. It will take time and resources for the acquiring company to merge multiple tracking programs into a seamless system. Therefore, CMS should provide a grace period in the case of an acquisition, merger and similar corporate transactions so that companies have sufficient time to harmonize tracking systems following the acquisition. Specifically, we recommend that applicable manufactures have at least a six month grace period for acquisitions of non-applicable manufactures, and even more time in the event that CMS finalized the definition of applicable manufacturer to include non-U.S. affiliates.

Finally, companies should not be held liable for the past reporting failures of a newly acquired company. An acquiring company would be obligated to report payments made by the acquired company only after the date that the acquisition becomes complete.

3. Definition of “product samples”

CMS should clarify in regulatory guidance that for purposes of the Sunshine Provisions, there are two general types of product samples in the medical device industry exempt from reporting:

- Single Use and Disposable Devices. Companies provide physicians and/or patients with samples of single-use and disposable devices, such as advanced wound care bandages, catheters, and contact lenses. Since a patient’s condition might not respond to a particular device, drug, or other treatment, a physician may want to provide a patient with samples to evaluate the patient’s response. In addition, these products may be used in connection with a larger treatment protocol using other manufacturers’ devices, and it therefore is necessary to evaluate compatibility. In other cases, device samples or starter kits are furnished directly to patients, for example a short term supply of testing strips may be provided to a patient who has just learned of a diabetes diagnosis.

Single use disposable samples serve a genuine educational or evaluative function, and have no economic value.

- Demonstration Devices. Generally, in discussing treatment options or when preparing a patient for surgery, a physician will describe the procedure, the surgical approach, the use and function of implantable devices and other treatment factors. If the patient is to receive an implantable device, such as a spinal implant, artificial knee or hip, it is crucial to demonstrate how the implant will fit within the human structure, how the implant will function, and describe the overall implantation procedure.

Demonstration devices serve a genuine educational function and have little independent economic value. These are typically labeled SAMPLE and “Not for Implant” and are clearly not intended for actual clinical use, but rather to educate the patient and facilitate optimal medical decision-making.

In all cases, samples are provided to educate patients, ensure use of the most appropriate technology or otherwise enhance patient care and safety and do not provide any direct benefit to the physician. Device samples do not have an economic value and should be exempt from reporting. In fact, the administrative costs associated with tracking and reporting device samples would discourage the use of beneficial device samples. (Some companies have opted to no longer provide demonstration devices to Vermont-licensed HCPs due to the administrative costs and impracticalities of tracking in connection with that state’s transparency law.)

Further, to ensure that medical device sampling is in the best interests of patient care, 2009 amendments to the AdvaMed Code provides substantive guidance to medical device companies to ensure the propriety of sampling practices. For example, the Code states that companies should provide health care professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products, and furnish samples only to the extent necessary to allow a reasonable evaluation.

4. Preemption of State Laws

Federal preemption of duplicative state laws is a critical component of the Sunshine provisions. It is essential that patients have a single, comprehensive source of information about industry relationships with covered recipients; not only will such a system provide a clearer understanding to patients about the nature of these arrangements, it will also make public reporting more efficient for companies.

CMS should clarify the scope of preemption afforded by the statutory text; in other words, CMS should annually clarify exactly which state laws (or parts of state laws) it considers to be preempted by the federal law. This will ensure a clear and predictable environment for covered recipients, companies and state legislatures. AdvaMed recommends that CMS should establish a process to proactively monitor state laws and assert preemption where appropriate. CMS should also provide a process for companies who become aware of a duplicative state law to bring that state law to the attention of CMS.

5. Additional Exclusions

- a) *Payments for services available to the general public should not be reportable.*

CMS should not require reporting of payments to physicians or teaching hospitals for commodity purchases at fair market value. For example, if a manufacturer rents a room (at established rates applicable to all outside parties, regardless of industry) at a hospital for purposes of conducting a training and education event at the hospital, that should not be reportable.

- b) *Recruiting costs should not be reportable.*

Company costs and recruitment fees incurred in connection with the recruitment, interviewing and review of covered recipient candidates for employment, should not be treated as transfers of value, and therefore should not be subject to reporting. If this information were to be reported, it would impede a physician's ability to look for a new position because his or her employer would become aware of the physician's job search activities by viewing the data on the public website.

- c) *Products or services provided as part of a product recall should not be reportable.*

While recalls of medical technologies are uncommon, there are a variety of services companies must provide if a recall does occur, including additional training for physicians, which should not be considered a "transfer of value." In some cases, that training may involve travel to a centralized training facility, which would normally trigger a reporting obligation under the Sunshine statute. However, in the case of a recall, physicians may be uncomfortable about being identified in a public database that otherwise lists voluntary activities involving physicians and industry and public disclosure might discourage physician participation that may be critical for patient care. Given that activities pursuant to a recall are a matter of FDA compliance and patient safety, payments related to such activities should be exempt from reporting.

- d) *Payments for services required and provided by a covered recipient should not be reportable.*

To avoid any confusion presented by ministerial business transactions, we recommend that CMS should not require reporting of payments for administrative services provided to the reporting company by the covered recipient, such as professional services (drug tests, vaccinations, health & wellness fairs, etc.), vendor credentialing (including credentialing required by the institution), online RFQ fees, administrative fees, and other vendor fees required by the institution.

- e) *Payments to physicians who provide review and evaluation of disability claims for human resources departments should not be reportable.*

AdvaMed recommends that payments by applicable manufacturers to physicians who provide review and evaluation of disability claims for human resources departments should not be reportable. This type of activity is part of the administration of a company's day-to-day employment management activities and should not be made public. This type of service is distinct from serving on an industry advisory board and should not be reportable.

- f) *Payments for services provided by an on-site physician who staffs a clinic for employees at the manufacturer's site should not be reportable.*

This type of activity is sometimes offered to employees to maintain their health and welfare. Providing this type of primary care is often what the physician does for his or her living. This is distinct from physicians who practice in private clinics or hospitals and also serve on industry advisory boards. Therefore, it should not be reportable.

6. Additional Comment Period

As noted throughout this letter, implementation of the Sunshine Provisions will necessarily be complicated and we expect that as applicable manufacturers prepare and actually submit their first reports to CMS, questions and concerns not previously anticipated may arise. This has been the experience of our members with respect to reporting in Massachusetts and Vermont. Therefore, following the initial reporting period, CMS should provide another opportunity for stakeholders to provide input and comment to CMS to enable CMS to provide additional clarification or procedures where needed to ensure consistent application among all reporting entities and accurate understanding of the information by consumers.

* * *

AdvaMed appreciates the significant complexities associated with implementation of the Sunshine Provisions and is grateful to CMS for its efforts in providing manufacturers additional clarity with respect to multiple aspects of the Sunshine Provisions through the Proposed Rule. We thank you for your consideration of these comments and recommendations as you work towards finalizing regulations for the Sunshine Provisions.

Sincerely,

A handwritten signature in black ink, reading "Stephen J. Ubl". The signature is written in a cursive style with a large initial 'S' and 'U'.

Stephen J. Ubl
President and CEO
The Advanced Medical Technology Association

Exhibit A

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July 12, 2011

Via Email and United States Mail

Donald M. Berwick, M.D., Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Re: AdvaMed Comments on Implementation of Sunshine Provisions Of the Affordable Care Act

Dear Administrator Berwick:

On behalf of the members of the Advanced Medical Technology Association (“AdvaMed”), we thank you for convening the March 24, 2011 Open Door Forum to collect stakeholder comments on implementation of Section 6002 of the Affordable Care Act (the “Sunshine Provisions”). We were pleased to learn during the Open Door Forum that CMS will develop regulatory guidance to ensure effective implementation through a public notice and comment process. We look forward to working with CMS through that process. Also, thank you for meeting with AdvaMed representatives on April 12, 2011. The interactive dialogue was helpful in further developing our policy recommendations.

Further to our verbal comments offered during the Open Door Forum and our meeting of April 12, we submit the following recommendations for CMS consideration.

Background

AdvaMed is the world’s largest trade association of medical device manufacturers who produce the medical technologies that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed represents approximately 370 manufacturers of medical devices, diagnostics, and health information systems, ranging from the largest to the smallest medical technology innovators and companies. With over \$136 billion in domestic sales in 2008, AdvaMed members manufacture roughly 60 percent of U.S. sales of medical technology.

AdvaMed supports and has proactively embraced appropriate disclosure of relationships between medical technology companies and physicians. We and our member companies recognize that

strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals to produce the world's most advanced medical technologies. AdvaMed and our member companies take very seriously our responsibility to ensure ethical interactions with our physician partners. We recognize that adherence to ethical standards is essential to the industry's ability to continue its collaboration with health care professionals. That is why AdvaMed developed a Code of Ethics on Interactions with Health Care Professionals¹⁹ ("AdvaMed Code" or "Code") to distinguish interactions that result in bona fide contributions to the advancement of medical technology, from interactions that may inappropriately influence medical decision-making. AdvaMed has taken aggressive steps to educate the industry and health care professionals about the Code, ethical interactions, and compliance.

The medical technology industry is fueled by intense competition and the innovative energy of our member companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Physicians and teaching hospitals are partners in many aspects of innovation. They are often the inventors of new devices, and it is critical that our industry work closely with them to move their innovative ideas from concept to reality. Physicians make valuable recommendations on how to improve existing devices and provide ongoing consulting to provide expert technical assistance and feedback to companies in the development and refinement of those improvements. In short, physician expertise, feedback, and experience are critical to ongoing advances and innovations in medical technology, and the Sunshine provisions must be implemented in a manner that does not discourage physicians from participating in bona fide collaborations that fuel medical device innovation.

In addition, device companies forge important training arrangements with physicians and teaching hospitals, essential for the safe and effective use of medical devices. How well a medical device works depends, in large part, on the skill and training of the physician utilizing the technology. In fact, the FDA often requires device manufacturers to provide product specific education and training to physicians as *a condition of* FDA clearance. The technique-specific nature of devices also makes physician involvement crucial to the training and education required after market approval, as specific techniques often need to be taught, and physician operators are best suited to provide this training to their fellow physicians. Some training on medical technologies requires travel to central facilities that can accommodate large medical technologies or to specialized training facilities, such as simulated operating rooms.

Physician and teaching hospital innovation and collaboration with the device industry have led to

¹⁹ Available at: <http://www.advamed.org/MemberPortal/About/code/>.

groundbreaking advances in patient care that benefit millions of American patients. These innovations have helped fuel a robust, competitive U.S. medical technology industry that is the global leader. We applaud President Obama's focus on innovation as the key to our nation's economic future, and our industry stands ready to play a key role. The Sunshine provisions should be implemented in a manner that serves the legislative intent to provide patients with clear, meaningful information concerning industry relationships, but implementation should not discourage beneficial interactions critical to the development and safe and effective use of innovative medical technologies. For this reason, in our comments below, we offer recommendations in certain areas to provide clear rules and definitions to facilitate a common approach by manufacturers and to ensure the data is meaningful.

1. Covered Recipients

A. "Teaching Hospital"

AdvaMed recommends that CMS define "teaching hospitals" based on the definition set forth in 42 C.F.R. § 415.152:

"Teaching hospital means a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry."

Approved graduate medical education (GME) program means one of the following:

- (1) A residency program approved by the Accreditation Council for Graduate Medical Education of the American Medical Association, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medicine Education of the American Podiatric Medical Association.
- (2) A program otherwise recognized as an "approved medical residency program" under §413.75(b) of this chapter."

To effectively implement this provision, we recommend that CMS publish annually a list of teaching hospitals that CMS has determined meet the criteria of this definition. Further, we recommend that CMS publish the unique identification numbers for those teaching hospitals that companies must utilize in their reporting. An annual list of teaching hospitals and unique identifiers from CMS will ensure uniformity and accuracy of reporting and that the public database contains information clear to patients. A single national list of covered recipients is necessary to ensure efficient administration of the new database by CMS, by establishing certainty among the many stakeholders, and will help CMS avoid numerous downstream administrative and management burdens associated with the receipt, management and posting of separately identified covered recipients. Such a list will also make it more efficient for companies to comply. Moreover, teaching hospitals may hold multiple provider and supplier numbers, and use of a single CMS-assigned number would facilitate accurate reporting.

Further, we recommend that CMS publish the list no later than October 1st of each year to facilitate integration of this key data into company tracking systems (and validate those systems) before the next calendar year reporting begins. Of course the identification of covered recipients will present ongoing maintenance and administrative concerns, as new covered recipients are licensed or accredited, and other covered recipients no longer qualify under the technical definitions. For this reason, AdvaMed recommends that CMS establish an administrable and regular process to update the list (e.g., quarterly), and allow companies a reasonable period after inclusion on the list to incorporate new covered recipients into their tracking systems.

B. “Physician”

Similar to the approach described above, AdvaMed recommends that CMS publish annually a list of the specific individuals that CMS has determined meet the definition of “physician” under Section 1861(r). This statutory reference includes a wide variety of disciplines (e.g., MD, D.O., DMD, DDS, DPM, optometrist, chiropractor) furnishing professional services within the scope of licensure and covered under Medicare and state health care programs. CMS should also publish the unique identification numbers for those individuals meeting the definition of “physician” that companies must utilize in reporting, as some physicians may not have an NPI number or may have multiple NPI numbers. As noted in the section above, the list should be published no later than October 1st of each year so that companies can integrate the information into tracking systems and have time to validate those systems before the next calendar year reporting begins.

Finally, we wish to emphasize that medical device innovation occurs on a global scale. That is, some medical technology arrangements span national borders, and the treatment of global collaborations presents significant complexities and administrative concerns for CMS and industry alike. To develop an administrable approach presenting meaningful data to patients, we suggest that for any covered recipient listed on the national CMS established list described above, CMS should require companies to report transfers of value only for physicians who currently practice in the U.S. and who receive transfers of value for activities that occur within the U.S.

C. “At the Request of or Designated on Behalf of”

This legislative text is likely to present implementation uncertainties and inconsistencies and, for that reason, is particularly in need of clarification by CMS. Where possible, CMS should be guided by federal income tax policy and treatment to facilitate a consistent treatment of this broad category of arrangements. That is, where a transfer of value is reportable as gross income to a covered recipient, it should qualify for reporting under the sunshine provisions.²⁰

²⁰ See generally Lucas v. Earl, 281 U.S. 111 (1930) (holding that a taxpayer who possesses a current or future right to income cannot shift the tax on such income by transferring the right to receive the income to another taxpayer).

Based on this approach, CMS should provide guidance that “on behalf of” occurs in the following circumstances:

- a) Under the doctrines of constructive receipt, assignment of income, and economic benefit, a service provider may be taxed currently on a particular income because the service provider has discretion over the timing of the receipt and/or form of the benefit. Thus, when the physician requests that his/her payment is made to a specific charity of the physician’s choice, that payment should be reported as a payment to the physician.²¹ CMS should require that the payment record reflect that the physician directed the payment to a specific charity so it is clear to the public that the physician did not personally receive the funds. In this case, the physician would be issued a 1099 by the manufacturer.

By contrast, no report should be required when a payment is instead made to a charity that the manufacturer has selected, provided that the physician has waived his/her right to the fees in writing in advance of the services being performed and has no control over the choice of charity. This type of donation should not be reportable because it is of no benefit to the physician, the physician has completely waived his/her right to the income, and the charity was not selected by the physician. In this case, the physician would not receive a 1099 from the manufacturer.

- b) In the case where a physician requests that the payment be made to another person or entity such as his/her private practice or consulting business, this payment should be considered as being made “on behalf of” the physician and should be reported as further described below.

Absent this interpretation, it would be altogether too easy for a physician to simply request that a payment owed be directed to the physicians’ private LLC or small practice group as opposed to the physician him/herself to prevent the payment from being reportable under Sunshine. In order to avoid such an outcome, we recommend that when a payment is not made directly to the physician, the information to be reported should include: a) the amount of money paid; b) the name of the physician who performed the work; and c) the entity which received payment on behalf of the physician.

- c) By contrast, in cases where a manufacturer hires an entity, not the physician, to perform work without specifying that any particular HCP conduct the work, the payment should be reported only as paid to the entity to the extent required by the legislation because there is no direct financial relationship between the physician

²¹ See generally, Charles K. Kerby, “Discretionary Choices Among Compensation and Benefits: Possibilities for Avoiding Current Taxation,” NYU 57th Institute on Federal Taxation, Chapter 3 (1999); Private Letter Ruling 9325023 (March 24, 1993).

and the manufacturer in this case.

- d) In the case of a clinical trial, when a physician payment is bundled together with an overall payment made to an institution, only the total payment to the institution would be reported to the extent required by the legislation. The reason for this is that clinical trial payments cover a broad range of services made by an institution well beyond physician services. Such services include nursing time, lab fees, patient care, medical supplies, statistician services, etc. Further, it is the institution, not the manufacturer, who determines how much to pay the physician. The payment to the physician is often one small component of an overall payment made to an institution.

D. Physician-owned distributors

The emergence of companies with equity investments by physicians, who are also major revenue generators for the companies, raises important legal and policy issues relating to the potential effect on clinical decisions by physicians. These entities include physician-owned manufacturers, distributors, and group purchasing organizations that sell devices to hospitals at which the physician-owners treat patients.

As opposed to the collaborations among physicians and industry, which yield advances in medical technology, these arrangements instead seek to leverage device purchasing into income generating opportunities for investing physicians. AdvaMed is concerned that at least some of these entities for which physicians generate substantial revenues have the potential to create conflicts of interest between physicians' responsibility to provide the best care and physicians' equity interests which may compromise (or appear to compromise) the physician-patient relationship and could further serve to restrict patient access to the most appropriate advanced medical technologies.

Moreover, five U.S. Senators recently called for an investigation into physician owned distributors, citing concerns with the underlying incentives and overall legality of these arrangements. We support the Senators' recommendation that CMS include physician owned distributors within the scope of the Sunshine legislation.²² The HHS Office of the Inspector General stated in correspondence to AdvaMed²³ that these arrangements should

²² See Senate Committee on Finance Letter to Donald Berwick, M.D., Admin'r, Ctrs for Medicare and Medicaid Services (June 9, 2011) <http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c>.

²³ See AdvaMed Letter to the Dep't of Health & Human Services' Office of Inspector Gen. /Industry Guidance Branch, requesting guidance concerning Certain Physician-Device Firm Arrangements (Sept. 6, 2006) <http://www.advamed.org/NR/rdonlyres/443A95E4-D3F4-4217-A5AA2909A073DFE6/0/Sept2006AdvaMedLtrtoOIGreMDOwned.pdf>; and Office of the Inspector Gen. response letter (Oct. 6, 2006) <http://www.advamed.org/NR/rdonlyres/82C1FE82-C014-4C9A-896B-8804CD17B2B4/0/OIGResponse10606reMDOwned.pdf>.

be closely scrutinized under the fraud and abuse laws. Given the intent of the Sunshine Provisions to provide patients with clear information about all such relationships, we believe the legislative text can and should be interpreted to apply to the distributor model of these physician-owned entities.

While the Sunshine Provisions include express reporting obligations for two of these corporate models, CMS should issue guidance clarifying that physician-owned distributors are included in the scope of those entities that are required to comply with the reporting requirements.

The Sunshine Provisions require reporting of certain transfers for physician owned entities. These entities include “Applicable Manufacturers” and “Applicable GPOs.” The Sunshine Provision defines Applicable GPO as follows:

The term ‘applicable group purchasing organization’ means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

The plain language of the statute delegates to the Secretary the authority to define the term GPO. Specifically, the phrase “as defined by the Secretary” grants the Secretary the authority to determine the meaning of GPOs as he or she deems appropriate for the purposes of the Sunshine Provisions.

2. Payments and Other Transfers of Value

A. Education and training; technical support

AdvaMed suggests that CMS consider defining a grant as funds transferred to a covered recipient in support of bona fide independent educational activities. This definition is consistent with the appropriate support of third party educational conferences under Section IV of AdvaMed’s Code of Ethics. Companies should not be required to impute a value to a training or education program, technical/case support, information on reimbursement, or report overhead, educational materials or supplies utilized in an education or training setting, including protective gear. Reporting should be limited to tangible and material support to covered recipients such as travel, food, and hospitality.

During our April 12th meeting, CMS inquired as to whether it would be possible to require companies to report the duration of each training program. Our member companies indicate that reporting systems are typically set up to track and capture dollar amounts associated with transfers of value, and not the duration of the education and training programs provided. In addition, reporting the duration of education and training would not add meaningful information to patients about the quality or importance of the program, as programs vary depending upon the device that is the subject of the training and the level of training involved (i.e. basic vs. more advanced training).

B. Reporting payments for activities that fall into more than one category

As a threshold point, to avoid situations where a transfer of value could be attributed to multiple categories, we propose CMS provide a limited number of categories with very clear definitions understandable to manufacturers and that provide the context of the transfer of value to consumers. CMS must avoid the situation that occurred with Massachusetts disclosure reporting pursuant to the 2009 Massachusetts Pharmaceutical and Medical Device Code of Conduct legislation where payments were categorized inconsistently causing concern by physicians and potential misunderstanding by consumers. There should not be overlap between categories and there should not be a hierarchy of categories (categories and subcategories) because that is most often where overlap and ambiguity occurs.

In some cases, a transfer of value to a covered recipient could be attributed to more than one reportable category outlined in the law (e.g. a two-day training program where travel, lodging, and meals are all included; a consulting contract that includes food and travel for meeting with company engineers that are working on the product development team).

In such cases, CMS should allow companies flexibility to segregate expenses into various categories **or** to report transfers of value under a single category that represents the *dominant purpose* for the transfer of value. For example, if the dominant purpose of the payment was for consultant work on an IDE protocol, then the company may report all transfers of value related to that rather than fragmenting into individual components.²⁴ AdvaMed suggests that consolidated reporting based on the dominant purpose should be at the election of the manufacturer, which may submit additional context relative to such transfers of value in the annual transparency reports to explain the nature of the arrangement.

C. Payments for services available to the general public

CMS should not require reporting of payments to physicians or teaching hospitals for commodity purchases at fair market value. For example, if a manufacturer rents a room (at established rates applicable to all outside parties, regardless of industry) at a hospital for purposes of conducting a training and education event at the hospital, that should not be reportable.

D. Payments for services required and provided by a covered recipient.

To avoid any confusion presented by ministerial business transactions, we recommend that CMS should not require reporting of payments for administrative services provided

²⁴ Similarly, in the case of consultant travel, an itinerary might include multiple legs, attributable to different purposes.

to the reporting company by the covered recipient, such as professional services (drug tests, vaccinations, health & wellness fairs, etc.), vendor credentialing (including credentialing required by the institution), online RFQ fees, administrative fees, and other vendor fees required by the institution.

E. Definition of “honoraria”

Honoraria are a subset of consulting arrangements and companies therefore should have flexibility to report these payments as “consulting services.” Absent this flexibility, CMS should provide a clear definition of “honoraria” to distinguish “honoraria” from other categories of payments (such as consulting).

F. Timing of reporting of consultant payments

For consultant contracts in which covered recipients perform many services over an extended period of time, CMS should require companies to report a payment to that covered recipient on the payment date (rather than on the date the covered recipient performs each service pursuant to the contract). It is often the case that payment is made after the provision of services, based upon proof of service documentation. In addition, often there is not a specific, single date upon which services are performed; services are frequently performed over several months or even across calendar years.

G. Identifying payments that are related to a specific device or medical supply

In many cases, relationships between medical technology companies and covered recipients may involve multi-component product systems, or products with related product components, tools or accessories. For example, companies may provide education and training on multiple products as part of a single training program. Moreover, in the medical device and diagnostics industry, the specific brand name of a product is often not recognizable or meaningful to the consumer. In the case of a reportable activity that is related to a specific technology, CMS should allow companies to report according to a primary product group or therapy area, rather than based on the individual component product. For example, a heart lung machine must also be used with extensive catheter tubing, filters, and other accessories. The primary product, however, is the heart lung machine so payments should be reported in conjunction with that product only in order to avoid duplicate reporting and confusion. This will ease the reporting burden while providing clearer and more accurate information to patients.

H. Secretarial discretion to require reporting of “other categories of information the Secretary determines appropriate.”

Before adding additional categories, CMS should better define existing categories so that companies fully understand what is expected. Should CMS consider adding additional categories, it should provide companies with sufficient lead time to provide comment and adjust internal tracking systems to incorporate the new category.

I. Definition of an “in-kind service”

In general, CMS should require companies to report an “in-kind” service according to the existing categories that are specified in the legislation. Reimbursement, coverage and technical information furnished by companies to covered recipients should be exempted from reporting. As medical technologies have become increasingly complex, so have payor coverage and reimbursement policies. Consequently, a company may provide objective technical, coverage, reimbursement, and health economic information regarding its medical technologies. Companies also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patient access to medical technology. These items and services have no independent economic value and should be exempt from reporting. Section X of AdvaMed’s Code of Ethics establishes guidance on the ethical provision of such information.

J. Reporting of stock options

Stock options present complexities in reporting, and to establish a uniform and administrable approach, AdvaMed recommends that CMS provide guidance such that companies report in the year granted.

3. Exclusions

A. Definition of “product samples”

CMS should clarify in regulatory guidance that for purposes of the Sunshine statute, there are two general types of product samples in the medical device industry exempt from reporting:

- Single Use Disposable Devices. Companies provide physicians and/or patients with samples of single-use disposable devices, such as advanced wound care bandages and catheters. Since a patient’s condition might not respond to a particular device, drug, or other treatment, a physician may want to provide a patient with samples to evaluate the patient’s response. In addition, these products may be used in connection with a larger treatment protocol using other manufacturers’ devices, and it therefore is necessary to evaluate compatibility. In other cases, device samples or starter kits are furnished directly to patients, for example a short term supply of testing strips may be provided to a patient who has just learned of a diabetes diagnosis.

Single use disposable samples serve a genuine educational or evaluative function, and have no economic value.

- Demonstration Devices. Generally, in discussing treatment options or when

preparing a patient for surgery, a physician will describe the procedure, the surgical approach, the use and function of implantable devices and other treatment factors. If the patient is to receive an implantable device, such as a spinal implant, artificial knee or hip, it is crucial to demonstrate how the implant will fit within the human structure, how the implant will function, and describe the overall implantation procedure.

Demonstration devices serve a genuine educational function and have little independent economic value. These are typically labeled SAMPLE and “Not for Implant” and are clearly not intended for actual clinical use, but rather to educate the patient and facilitate optimal medical decision-making.

In all cases, samples are provided to educate patients, ensure use of the most appropriate technology and otherwise enhance patient care and safety and do not provide any direct benefit to the provider. Device samples do not have an economic value and should be exempt from reporting. In fact, the administrative costs associated with tracking and reporting device samples would discourage the use of beneficial device samples. (In fact, some companies have opted to no longer provide demonstration devices to Vermont-licensed HCPs due to the administrative costs and impracticalities of tracking in connection with that state’s transparency law.)

Further, to ensure that medical device sampling is in the best interests of patient care, 2009 amendments to the AdvaMed Code provides substantive guidance to medical device companies to ensure the propriety of sampling practices. For example, the Code states that companies should provide health care professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products, and furnish samples only to the extent necessary to allow a reasonable evaluation.

B. Definition of “educational materials that directly benefit patients or are intended for Patient use”

AdvaMed recommends that explanatory patient brochures among other educational materials should not be reportable. Under Section IX of AdvaMed’s Code of Ethics, a company occasionally may provide items to health care professionals that benefit patients or serve a genuine educational function for health care professionals. This would include, for example, patient educational brochures or posters, used for educational purposes, among others. These items do not have independent market value and should be excluded from reporting.

C. Services provided by an on-site physician who staffs a clinic for employees at the manufacturer’s site.

This type of activity is sometimes offered to employees to maintain their health and welfare. Providing this type of primary care is often what the physician does for his/her living. This is distinct from physicians who practice in private clinics or hospitals and

also serve on industry advisory boards. Therefore, it should not be reportable.

C. Payments to physicians who provide review and evaluation of disability claims for human resources (“HR”) departments.

As noted above, this type of activity is part of the administration of a company’s day-to-day employment management activities and should not be made public. This type of service is distinct from serving on an industry advisory board and should not be reportable.

E. Products or services provided as part of a product recall

While recalls of medical technologies are uncommon, there are a variety of services companies must provide if a recall does occur, including additional training for physicians, which should not be considered a “transfer of value.” In some cases, that training may involve travel to a centralized training facility, which would normally trigger a reporting obligation under the Sunshine statute. However, in the case of a recall, companies may provide such training to physicians. In those cases, physicians may be uncomfortable about being identified in a public database that otherwise lists voluntary activities involving physicians and industry and public disclosure might discourage physician participation. Given that activities pursuant to a recall are a matter of FDA compliance and patient safety, payments related to such activities should be exempt from reporting.

F. Recruiting Costs

Company costs and recruitment fees incurred in connection with the recruitment, interviewing and review of covered recipient candidates for employment, should not be treated as transfers of value, and therefore should not be subject to reporting.

4. Delayed Publication for Payments Related to Clinical Investigations and Product Development Agreements

A product development agreement should be defined as one in which an applicable manufacturer or distributor engages a covered recipient for the purpose of making an explicitly defined contribution to (1) the research and/or development of a new product or technology or (2) an improvement to or new application of an existing product or technology.

To ensure uniformity and certainty, CMS should develop guidance that the reporting obligation is triggered by the payment date. Because companies are in the best position to know when products are approved/cleared by FDA, companies should have the obligation to report to CMS, by the next reporting deadline, once the company receives notice of FDA approval/clearance for the relevant product developed or the agreement. Whether publication is triggered by a company report of FDA approval/clearance, or CMS determines that the 4-year delayed publication period has been reached, CMS should have the responsibility for notifying companies, no less than 45 days in advance, when payment information subject to delayed publication will be publicly released. Manufacturers should be required to track the product approval date for all clinical

study related transactions.

Once the delayed publication period has expired and before the payment information is posted to the public database, CMS should allow a reasonable pre-posting period for covered recipients to review and verify, and for manufacturers to confirm, the payment information. Finally, when CMS posts payments for which delayed publication was in effect, CMS should identify those payments on the website in a clear manner so that the information and context surrounding those payments are understandable to patients. Consistent with the statutory language, payments subject to the delayed posting should be exempt from FOIA until they are posted.

In developing guidance to implement this section, CMS should allow flexibility to account for the wide variety of arrangements structured to develop new medical technologies. For example, for certain product development agreements, payments may be structured on a milestone basis, with multiple payments made over the course of a single agreement. In the case of product development agreements of a long duration, expiration of the delayed disclosure period for a single payment should not trigger disclosure of all subsequent related payments.

Last, CMS should publish the procedures and controls it will use to ensure data furnished by manufacturers will be separated from other data, and reserved for delayed reporting. These procedures should ensure that there is a clear option for manufacturers to choose indicating that a particular payment should be subject to delayed disclosure.

5. Background Information on Industry-Physician Relationships

The public database should include a dedicated statement that describes the value of interactions between covered recipients and manufacturers of medical technologies. The statement should discuss the various forms of interactions that occur and should identify the benefits of these interactions to patients and to continued innovation in medical care. CMS should seek stakeholder input before proposing this statement and provide an opportunity for public comment before finalizing the language in the statement.

In addition, CMS should provide companies an option to provide additional explanation and content surrounding each transfer of value that is reported. While the Sunshine Provisions require companies to provide a description of the nature of the payment (e.g. consulting fees, honoraria, travel, etc.), companies should have the opportunity to provide additional context about the specific nature of the payment.

6. Definition of “Manufacturer”

Companies should not be required to report transfers of value from distributors who take title of the product and who are not affiliated with or under common ownership with the manufacturer. By contrast, manufacturers who use independently contracted sales reps and/or distributors who do not take title to the product should be required to report transfers of values made by those entities because they are acting as an agent of manufacturers. Similarly, activities of a manufacturer’s contractors and agents who are involved in the sales, marketing or promotion of the manufacturer’s products should be reportable when such contractor or agent is acting at the

direction of the manufacturer and the manufacturer has knowledge of the identity of the physicians receiving the transfer of value.

7. Recommendation on Acquisitions

Acquisitions present unique technical challenges for companies as they work to comply with the Sunshine provisions. Acquisitions most likely will not coincide with the close of a Sunshine reporting period, and the parties to the acquisition may use different tracking programs, which must be integrated post-transaction to enable single reporting by the consolidated entity. In addition, it is possible that the acquiring company will need to address problems in the tracking system of the acquired company. It will take time and resources for the acquiring company to merge multiple tracking programs into a seamless system. Therefore, CMS should provide a grace period in the case of an acquisition, merger and similar corporate transactions so that companies have sufficient time to harmonize tracking systems following the acquisition. Additionally, companies should not be held liable for the past reporting failures of a newly acquired company. An acquiring company would be obligated to report payments made by the acquired company only after the date that the acquisition becomes complete.

8. Preemption of State Laws

Federal preemption of duplicative state laws is a critical component of the Sunshine provisions. It is essential that patients have a single, comprehensive source of information about industry relationships with covered recipients; not only will such a system provide a clearer understanding to patients about the nature of these arrangements, it will also make public reporting more efficient for companies.

CMS should clarify the scope of preemption afforded by the statutory text; in other words, CMS should annually clarify exactly which state laws (or parts of state laws) it considers to be preempted by the federal law. This will ensure a clear and predictable environment for covered recipients, companies and state legislatures. AdvaMed recommends that CMS should establish a process to proactively monitor state laws and assert preemption where appropriate. CMS should also provide a process for companies who become aware of a duplicative state law to bring that state law to the attention of CMS.

9. Implementation/Operational Issues

CMS should give reporting entities an opportunity, no less than 45 days before payments are publicly posted, to preview the payment information that will be posted. Such preview should be secure so that manufacturers cannot view other manufacturer's data. That preview date should be the date that triggers the 45-day correction period. Similarly, covered recipients also should be provided a process to check information that has been reported by industry for them before it is publicly posted, and CMS should publicize this opportunity so that covered recipients receive notification and reminders to check their information. The preview data should be in a downloadable format with the ability of companies and covered recipients to extract their individual data so they may verify it.

This preview period is essential to achieve the statutory intent of protecting confidential, proprietary company information on research and development. Providing an opportunity to preview the information will also protect covered recipients from the release of inaccurate information that would be viewed by the public. In addition, given the tremendous volume of information that CMS will be receiving and managing, CMS should include in its regulations a section detailing what systems companies will be required to utilize in submitting data, and extensive testing is needed before the public website goes live.

After the 45-day correction period expires, it is possible that there will be circumstances in which companies discover good faith errors or misidentified transfers of value. In these cases, CMS should provide companies with a process for resolving such errors in a reasonable period of time.

Also, there may be instances in which a covered recipient disputes the transfer of value amount or other content reported by a manufacturer. If the covered recipient raises an issue during the 45-day correction period, or after that correction period has expired, CMS should refer the covered recipient to the manufacturer to resolve the issue.

CMS should publish guidance describing exercise of agency discretion in the application of its sanction authority. The guidance should clarify that penalties will not automatically apply for good faith errors, misclassifications, or under- or over-reporting, even if those errors are uncovered after the 45-day correction period. That is, guidance should distinguish administrative actions applicable to innocent mistakes after reasonable diligent efforts vs. intentional abuse/disregard. In addition, the correction period should begin on the date the error is discovered by the company or covered recipient, not the date the error was made.

The Secretary is required to consult with HHS OIG, industry, consumers, consumer advocates, and other interested parties. We were pleased to learn during CMS's Special Open Door Forum that it plans to proceed with implementation of the Sunshine provisions through a formal notice and comment rulemaking. We agree that in order to ensure broad stakeholder input, CMS should propose implementing guidance, standards, definitions and procedures under a formal notice and comment rulemaking with at least 60 days for public comment before finalizing the regulation.

In addition, following the initial reporting period, CMS should provide another opportunity for stakeholders to provide input and comment to CMS to enable CMS to provide additional clarification or procedures where needed to ensure consistent application among all reporting entities and accurate understanding of the information by consumers.

* * *

AdvaMed appreciates the enormous technical and other complexities associated with implementation of the Sunshine provisions. We thank you for considering these comments and recommendations, and AdvaMed looks forward to actively engaging in continued dialog with the Administration and CMS as the guidance process proceeds.

Centers for Medicare & Medicaid Services
Letter to Administrator Donald M. Berwick
July 12, 2011

Sincerely,

A handwritten signature in black ink that reads "Stephen J. Ubl". The signature is written in a cursive style with a large initial 'S' and a distinct 'U'.

Stephen J. Ubl
President

cc: Anthony Rodgers, Deputy Administrator and Director
Peter Budetti, Deputy Administrator and Director
Christopher L. White, Esq., AdvaMed
Leah Kegler, AdvaMed

Exhibit B

IMPLEMENTATION TIMELINE

AdvaMed recommends that CMS provide applicable manufacturers 180 days after publication of the final rule to begin implementing the Sunshine Provisions. This recommendation is based on specific information and examples from various AdvaMed members regarding their expectations with respect to how much time they will need to implement the Sunshine Provisions once the final rule is released.

In order to support this recommendation, this Exhibit B outlines (1) general considerations related to the implementation of the Sunshine Provisions, (2) phases, tasks, and timelines associated with developing and enhancing necessary tracking and reporting systems, and (3) specific timelines associated with activities manufacturers will be required to undertake upon release of the final rule.

General Considerations

Manufacturer Variation.

There is great variety between applicable manufacturers in terms of current system capabilities, if any, and where in the process such manufacturers are in system development and enhancement. Accordingly, the information and timelines we provide herein are intended to represent a realistic portrayal of implementation expectations, but the specifics may vary by applicable manufacturer.

Multiple Systems.

Multiple systems are involved in implementing a process to track and report payments and other transfers of value under the Sunshine Provisions, including expense systems, accounting systems, master data systems, and aggregate spend systems.

System Integration.

In addition, all of these systems need to be integrated in order to allow accurate reporting. The project length for such integration would match the longest timeline for any one of the types of systems at issue which, in the following examples, is 300 days.

System Variation Within a Single Organization.

Moreover, many of our members operate across various business entities and geographic locations, complicating matters related to development and enhancement of necessary systems. For example, an applicable manufacturer may use multiple expense and/or accounting systems across businesses. Accordingly, enhancements will need to be done for all systems across all businesses.

Additional Work Following Release of the Final Rule.

Applicable manufacturers have been working diligently to develop and revise policies, procedures, and systems as necessary in response to the Sunshine Provisions, but much work still remains in light of the Proposed Rule and anticipated final rule. We include below a specific discussion of the activities, and associated timelines, manufacturers expect to undertake upon release of the final rule. These activities will relate to both communications and training for company personnel, as well as systems enhancements, all to ensure compliance with the Sunshine Provisions. These activities cannot begin to occur until release of the final rule.

Company-Wide Training.

Finally, all new systems and enhancements will require company-wide training, possibly on a global scale. Generally, development of training for new systems, from start to finish, is 45-60 days, and development of re-training for updates to the requirements and how it affects company personnel may be just as long. The time needed to deploy and conduct necessary training can range from 45-90 days.

Required Systems

We include herein a discussion of the potential types of systems involved in implementing a process to track and report payments and transfers of value under the Sunshine Provisions. These systems are not exclusive and the type and number of systems used will vary by applicable manufacturer. The systems timelines discussed below represent overall time requirements. As noted, many manufacturers are currently working through this process, even as they await the final rule. Moreover, the development and enhancement of the various systems at issue will likely operate on parallel paths. Accordingly, although an entire system development or enhancement process may be estimated to take, for example, 300 days, and applicable manufacturers may be making simultaneous changes to multiple types of systems, our understanding is that many applicable manufacturers have already started the process of system development and enhancement, even as they await release of the final rule and the necessary clarity it will offer.

We also emphasize that the following discussion relates generally to system development and enhancement. In fact, companies may undertake several stages of systems changes, as additional guidance and regulations are released. For example, many of our members are currently in the process of updating systems in light of the Proposed Rule. Such members expect the design, building, and testing of systems enhancements in response to the Proposed Rule to take nine months. We expect even more systems changes will be required following release of the final rule, as further discussed in the next section.

- ***Expense Systems:*** These source systems have the potential to be enhanced to capture additional data as required by the Sunshine Provisions. Attached as Attachment 1 is a project plan that illustrates the phases and tasks involved in rolling out a particular set of enhancements to an expense system. **Estimated project length is approximately 300 days.**

- **Aggregate Spend System:** Aggregate Spend Systems will need to be reconfigured and enhanced in order to allow for (i) different information coming through from the source systems; (ii) integration with additional systems; (iii) reconfiguration of business rules; (iv) reconfiguration of reporting modules, (v) reconfiguration of manual entry mechanisms, (vi) the possible creation of new system portions, such as a loaner/sample module; and (vii) reconfiguration of third party portals. Attached as Attachment 2 is a project plan that illustrates the phases and tasks involved in rolling out a particular set of enhancements to an aggregate spend system. **Estimated project length is approximately 220 days.**
- **Accounting Systems:** These source systems have the potential to be enhanced to capture additional data as required by the Sunshine Provisions. Attached as Attachment 3 is a project plan that illustrates the phases and tasks involved in rolling out a particular set of enhancements to an A/P system. **Estimated project length is approximately 150 days.**
- **Master Data System:** Master Data Systems will need to be enhanced in order for applicable manufacturers to be able to capture additional information from the source systems and provide for more detailed look-ups on covered recipient data. Attached as Attachment 4 is a project plan that illustrates the phases and tasks involved in rolling out a particular set of enhancements to a master data system. **Estimated project length is approximately 90 days.**

Required Activities Following Release of Final Rule

We recommend that CMS set forth a preparation period of 180 days following release of the final rule to allow applicable manufacturers to make necessary policy, procedure, and system changes and enhancements in response to the information provided in the final rule. Manufacturers will also be required to finalize systems for purposes of ensuring complete, accurate, and efficient implementation of the Sunshine Provisions.²⁵

The following charts outline the activities manufacturers will be required to engage in upon release of the final rule, and related details regarding estimated amounts of time needed to complete such required activities.

Sunshine Communications and Training		
Activity	Duration	Timeline
Regulations Issued		Day 1
Analysis of regulations and impact to internal	30 days	Days 1-30

²⁵ For those companies who do not have the resources to develop their own tracking and reporting systems, vendors are just now beginning to create suitable tracking systems for compliance with the Sunshine Provisions. We anticipate that once the final rule is released, the limited number of vendors currently working in this space will be faced with requests from multiple manufacturers for assistance in quickly implementing new systems or updating existing systems. We note that in addition to the time necessary to choose an appropriate system, companies will also need reasonable time to integrate and deploy such system.

Sunshine Communications and Training		
Activity	Duration	Timeline
processes		
Implement any required changes to internal processes	60 days	Days 31-90
Development and deployment of internal communications (creation, review, and approval)	30 days	Days 61-90
Development and deployment of external communications (creation, review, approval, and printing)	60 days	Days 61-120
Development of training	45 days	Days 91-135
Deployment of training (live trainings)	45 days	Days 136-180

* * *

Sunshine Systems Implementation		
Activity	Duration	Timeline
Regulations Issued		Day 1
Analysis of regulations and impact to systems. Identify business requirements and develop changes for system.	60-90 days	Days 1 - 90
Systems Change Implementation	30-60 days	Days 91-150
Report Development & Testing	60 days	Days 151 - 210

Attachment 1 - Expense System

TASK NAME
Phase 1 - Discovery
Discovery <ul style="list-style-type: none">Includes development of project request, proof of concept, and project charter.
Phase 2 - Planning
Planning <ul style="list-style-type: none">Includes defining project repository; creating master checklist, issues log, and contact list; capturing business requirements; and developing a project plan and project management plan.
Phase 3 – Execution Phase
Development <ul style="list-style-type: none">Includes performing setups/configurations; code development; development of design specifications; updates to configuration documents; finalizing the project plan; and developing test scripts and the test plan.
Development Testing <ul style="list-style-type: none">Includes performing setups/configurations; developing and reviewing a promotion document; performing user testing cycles; making fixes and changes; and training.
Testing <ul style="list-style-type: none">Includes migrating codes; performing setups/configurations; performing user testing cycles; and updating and reviewing the promotional document.
Phase 4 – Deployment
Deployment <ul style="list-style-type: none">Includes developing a production support plan, production release, and system description; performing setups/configurations; migrating codes, and shakedown testing.
Go Live <ul style="list-style-type: none">Includes technical post production support and functional post production support.
Phase 5 – Close Phase
Close Phase <ul style="list-style-type: none">Includes lessons learned.

Attachment 2 - Aggregate Spend System

TASKS
Step 1 - Discovery
<p>Discovery Prep</p> <ul style="list-style-type: none"> Includes project kick-off; solution overview; establishment of team roles and responsibilities; development of project charter; and documentation of charter and roles and responsibilities.
<p>Discovery</p> <p>Determining Organizational Master Data</p> <ul style="list-style-type: none"> For direct payments, indirect payments, product/materials shipments, etc. Includes identifying source systems, covered entity characteristics, tracking/updating mechanism, and internal policies and procedures; determining process for inclusion in master data; identifying exception processing; and documenting business requirements. <p>Determining Organizational Spend</p> <ul style="list-style-type: none"> For grants and charitable contributions, consulting, gifts/educational materials, product samples, research studies and clinical trials, royalty payments and licensing fees, employee expenses, events and meetings, etc. Includes identifying source systems, spend elements, remediation and policy changes, and itemization rules; and documenting business requirements. <p>Determining System Outputs</p> <ul style="list-style-type: none"> Includes identifying output systems and output elements; and documenting business requirements. <p>Environment and Hosting</p> <ul style="list-style-type: none"> Includes finalizing, reviewing, and approving business requirements.
Step 2 – Implementation
<p>Implementation Prep</p> <ul style="list-style-type: none"> Includes review of high level implementation plan and system map; identifying resources; determining URL/authentication mechanisms; identifying user roles and responsibilities; identifying security requirements and data partitioning; identifying data versioning requirements; documenting, reviewing, and approving functional requirements; and preparing preview environment. <p>Importing/Exporting Data in the System</p> <ul style="list-style-type: none"> Includes implementing system master data, system master feeds, system data exports, and system data portals; and conducting data system tests. <p>Analyzing Data in the System</p> <ul style="list-style-type: none"> Includes expense detail and audit reconciliation; compliance and legal requirements;

TASKS
performance metrics and user analysis; and data system tests.
Using and Reporting Data within the System
Step 3 - Test
Testing <ul style="list-style-type: none"> • Includes preparing test hardware; installing test environment; deploying the test environment; reviewing and approving “test scripts”; preparing “integration scripts”; and reviewing and approving integration scripts; systems/integration testing; ad-hoc testing; and performing a cleansed data load.
Step 4 - Training
Training
Step 5 – Deployment, On-going Support and Maintenance
Deployment, On-going Support and Maintenance

Attachment 3 - Accounting System

TASKS
Configure Accounts Payable Enhancement Development
AP Enhancement Integration Testing
User Acceptance Testing
Define / Enable General Ledger Account Codes
Finalize Business Process Changes & Update Forms
Populate Vendor Values - Covered Recipient Transactions (Physician/Teaching Hospital/Third Party)
Accounts Payable Enhancements Confirmed in Production System
Validate Existing Vendor Data in current system
Load vendor data into Master Data Management System (Round 1)
Local Updates to Covered Recipient Database Load (for missing Covered Recipient vendors)
Matching (auto/manual) (Round 1)
Load Covered Recipient Database data into Master Data Management System (Round 2 if necessary)
Matching (auto/manual) (Round 2 if necessary)
Validate Flagged Enterprise Resource Planning Vendors = current system = Master Data Management System
Automate current system to Master Data Management System Data Load

Attachment 4 - Master Data System

TASKS
Pre-Project Preparation <ul style="list-style-type: none">• Includes review of contract, statement of work, and solution architecture; transfer of knowledge to project team; introduction meeting; drafting of data plan; and software fulfillment.
Requirements Analysis <ul style="list-style-type: none">• Includes hardware sizing and recommendations; review of attribute requirements; complete attribute mapping; review of operations requirements; preparing company requirements document; and completing a requirements analysis.
Project Kickoff Meeting <ul style="list-style-type: none">• Includes preparation for kickoff meeting, conducting the kickoff meeting, and performing kickoff meeting wrap-up with the distribution of meeting notes and action items.
Project Plan <ul style="list-style-type: none">• Includes preparing, submitting, finalizing, and publishing a project plan.
Review Solution Architecture <ul style="list-style-type: none">• Includes developing, reviewing, and finalizing solution architecture; and developing and finalizing a data model.
Data Preparation <ul style="list-style-type: none">• Includes creating draft data extract guides.
Implementation Approach Document <ul style="list-style-type: none">• Includes developing, reviewing, and publishing an implementation approach document.

Exhibit C

Cost of Implementation and Compliance

CMS Analysis

The assumptions set out in CMS' Proposed Rule estimate the average total implementation cost per manufacturer will be \$169,815 in the first year of reporting. CMS estimates that smaller manufacturers will need to dedicate 50% of one full-time equivalent (FTE) employee to implementation, while larger companies will require an average of 10 FTEs to comply with reporting requirements. With 150 large firms and 1000 smaller firms assumed in the CMS calculation, CMS derives an industry average of 1.74 new FTE per company to implement the statutory tracking and reporting obligations. CMS assumes that most of the data collection and reporting will be performed by compliance officers, calculated to each cost \$97,595 yearly, including fringe benefits and overhead ($1.74 \times 97,595 = 169,815$). CMS thereby estimates the total industry cost as \$195,288,000 for the first year. CMS believes costs will decrease 25% in year two and onward, once procedures and systems have been modified. Calculations are based on the estimated time and effort consumed by collecting the data, compiling reports to send to CMS, and registering and submitting data to CMS. Also taken into account are the theoretical "potentially substantial savings" registrants may realize with the ability to query CMS for guidance, and receive technical assistance and useful information on low cost methods of compliance through a listserv.

AdvaMed Comments

To better understand industry implementation costs, AdvaMed conducted an informal survey of its membership. The companies responding to our informal survey indicated anticipated investment in compliance systems, training and personnel substantially in excess of the CMS estimates.

- We asked companies to estimate their implementation expenditures. Some 6.5% of respondents projected start-up costs of less than \$75,000, while 80% anticipate spending at least \$200,000, and 60% projected start-up costs of over \$500,000. Some companies reported incurring expenditures exceeding \$1 million already, to design, construct, implement and train on new data management, tracking and reporting systems. Note that these estimates are based on companies' understanding of the system requirements as stated in the statutory text alone and do not yet reflect changes necessary as a result of the proposed rule.
- We also asked companies to estimate their annual cost of maintaining a fully implemented compliance program with staff, maintenance, and support. Company responses and commentary reveal they do not expect any cost reductions or savings over initial first year start-up costs. Responses show 60% expect to continue spending more than \$500,000 annually to maintain compliance programs.

Survey respondents strongly disagreed with CMS' FTE equivalency estimates, suggesting 2-3 new FTEs (versus .5 FTE) for smaller companies. Larger companies also strongly expressed that the FTE estimates are significantly undervalued, and noted that many secondary functions will

require increased headcount to accommodate the new tracking and reporting systems—such as new IT, systems, finance and training personnel.

Further, some respondents expressed that CMS’ “fully loaded” \$97,000 estimate assigned to compliance employees is significantly below market value. A 2008 survey by the Health Care Compliance Association found average salary for Chief Compliance Officers was \$147,843, while Compliance Officers averaged \$99,261 (applying inflation updates, and including fringe benefits and overhead, would increase these figures significantly.)

Exhibit D

AdvaMed Statement on Transparency and Physician-Owned Companies

The Advanced Medical Technology Association (AdvaMed) represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities in order to enable patients to live longer and healthier lives. AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative medical technologies make toward achieving these goals.

The first duty of health care professionals is to act in the best interests of patients. AdvaMed recognizes that companies can serve the interests of patients through beneficial collaborations with health care professionals. Interactions between companies and health care professionals must be conducted in an ethical manner to ensure that medical decisions are based on the best interests of the patient.

To ensure that interactions between companies and health care professionals meet high ethical standards, they must be conducted in a *transparent* manner and they *must comply with applicable laws, regulations and government guidance*. To that end, AdvaMed developed its Code of Ethics on Interactions with Health Care Professionals.¹ Importantly, AdvaMed's Code of Ethics distinguishes interactions that contribute to the advancement of medical technology from interactions that may be perceived to inappropriately influence medical decision-making.

AdvaMed supports and has proactively embraced appropriate disclosure of relationships between medical technology companies and physicians. We recognize that strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals to product the world's most advanced medical technologies.

OIG and CMS Express Concerns About Physician-Owned Entities

The emergence of companies with equity investments by physicians, who are also major revenue generators for the companies, raises important legal and policy issues relating to the potential effect on clinical decisions by physicians. These entities include physician-owned manufacturers, distributors and group purchasing organizations that sell devices to hospitals at which the physician-owners treat patients.

As opposed to the collaborations among physicians and industry, which yield advances in medical technology and include safeguards to prevent against fraud and abuse, these

¹ Available at: <http://www.advamed.org/memberportal/about/code>. The principles of the Code are derived from a variety of authorities, including the federal Anti-Kickback Statute. Throughout the Code, we refer to the concept of an "unlawful inducement" to reflect Anti-Kickback Statute prohibitions.

arrangements instead, seek to leverage device purchasing into income generating opportunities for investing physicians. Both the Office of Inspector General of the Department of Health and Human Services (OIG), and the Centers for Medicare & Medicaid Services (CMS) have expressed legal and programmatic concerns with physician-owned entities.² In October 2006, OIG indicated it was “aware of an apparent proliferation” of physician-owned entities and stated that “[g]iven the strong potential for improper inducements between and among physician investors, the entities, device vendors, and device purchasers,” the OIG believed “these ventures should be closely scrutinized under the fraud and abuse laws.”³ In February 2008, OIG officials indicated in Congressional testimony that PODs and other physician-owned companies “raise substantial concerns that a physician’s return on investment from the venture may influence the physician’s choice of device.”⁴

In July 2010, the OIG entered into a \$7.3 million Civil Monetary Penalty settlement with physician- owned enterprise United Shockwave Services, United Prostate Centers and United Urology Centers. Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services was quoted in the OIG’s July 8 press release as stating, “This settlement sends a strong message that companies, including those with physician-owners, cannot use Federal health care beneficiary referrals to line their pockets by securing business from hospitals or other providers. We continue to have serious kickback concerns when companies link investment opportunities to the ability to generate business and offer returns on investment that are disproportionate to business risk.”⁵ More recently, in its September 13, 2011 response to a Senate letter calling for an OIG inquiry on PODs, OIG said “... it has been OIG’s longstanding view that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute an illegal inducement under the Federal Anti-Kickback Statute.”⁶

Similarly, CMS has been critical of these entities, and has considered amending its Stark

² The OIG stated its concerns regarding physician-owned joint ventures, noting that “[t]hese subject joint ventures may be intended ... to back up a stream of referrals from the physician investors and to compensate OIG directly for their referrals.” Special Fraud Alert. Issued in 1989 and re-issued in 1994. In addition, the OIG expressed concerns that hospital incentive programs “used to compensate physicians (directly or indirectly) for referring patients to the hospital” implicate the Anti-Kickback Statute and cause conflicts of interest, overuse of services and referrals to less appropriate hospitals. 1994 Special Fraud Alert. See also, OIG Special Advisory Bulletin on Contractual Joint Ventures.

³ Letter from Vicki Robinson, Chief, Industry Guidance Branch, HHS Office of Inspector General (Oct. 6, 2006), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20%282%29.pdf>.

⁴ Testimony of Gregory Demske, Assistant Inspector General for Legal Affairs, before the U.S. Senate Special Committee on Aging Examining the Relationship Between the Medical Device Industry and Physicians (Feb. 27, 2008), available at http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

⁵ Office of Inspector General News, July 8, 2010 Press Release available at http://oig.hhs.gov/publications/docs/press/2010/United_Shockwave_Press_Release.pdf.

⁶ Letter from Daniel R. Levinson, Inspector General, HHS Office of Inspector General (September 13, 2011) available at <http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c>.

physician self-referral regulations to address physician-owned distributors (“PODs”) and like entities more specifically.⁷

Discussing PODs along with similar physician-owned entities, CMS has stated that these entities “serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician-investors use on their own patients,”⁸ and that in many instances such physician-owned entities “would not satisfy the requirements of the exception for indirect compensation arrangements in [42 C.F.R.] § 411.357(p), and would, therefore, run afoul of the physician self-referral [Stark] statute.”⁹

AdvaMed shares the concerns expressed by the OIG and CMS that at least some of these entities from which physicians generate substantial revenues have the potential to create conflicts of interest between physicians’ responsibility to act in the best interests of patients and physicians’ equity interests. We believe this may compromise (or appear to compromise) the physician-patient relationship and could further serve to restrict patient access to the most appropriate advanced medical technologies. For these reasons, AdvaMed in 2006 requested guidance on physician-owned entities, and in 2010 advocated for the Physician Payment Sunshine provisions of the health care reform bill to include measures ensuring transparency in these arrangements.

Senate Calls for Inquiry into Physician-Owned Distributors, Citing Concerns

A bi-partisan group of five U.S. Senators led by the Senate Finance Committee Leadership recently called for OIG and CMS to analyze physician-owned distributors (PODs). The Senators’ letter to the Agencies followed an analysis by the Senate Finance Committee Ranking Minority into the complicated issues arising from PODs. The analysis included a review of more than 1,000 pages of documents and discussions with more than 50 people. The Report¹⁰ issued from the analysis concluded that “[t]he lures of financial incentives and lack of regulatory oversight appears to be driving huge increases in the number of PODs so that they are now a significant national presence.” The Senators cited concerns with the underlying incentives and overall legality of these arrangements.

⁷ Department of Health and Human Services, Centers for Medicare and Medicaid Services, Medicare Program; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23528, 23695 (April 30, 2008).

⁸ Centers for Medicare and Medicaid Services, Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23527, 23694 (April 30, 2008).

⁹ 73 Fed. Reg. 23695.

¹⁰ Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight. An Inquiry by the Senate Finance Committee Minority Staff, U.S. Senator Orrin Hatch, (R-UT), Ranking Member; June 2011, *available at*: <https://finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c>.

All of the POD business models reviewed in the Report “appear to be designed in a manner in which the physicians in the POD in various levels of directness, profit from their use of the products that they are selling.” The Report also appropriately notes that “a physician’s decision as to whether to use one product over another cannot in any way be based on the physician receiving payment for using a particular product,” as such a basis would raise serious Anti-Kickback Statute violation concerns.

The Report concluded that” [t]he very nature of the PODs seem to create financial incentives for physician investors to use those devices that give them the greatest financial return and that, in the process, patient treatment decisions may be based on personal financial gain. This is especially troubling given the numerous concerned allegations provided to the Committee that, due to their financial interest, physician investors in PODs may perform more procedures than are medically necessary or may use implants of inferior quality or that are not best suited for the procedure.”

The Report concluded that “[w]ith the POD structure, the surgeon is acting as the seller, buyer, and person making the decision about what is best for the patient, on its face this appears to be entirely inconsistent with the fundamental tenets of healthcare compliance that have shaped the medical device industry over the last decade, and the POD structure has generated significant conflict of interest and anti-kickback concerns. However, in the absence of more clearly articulated guidance on the legality of these arrangements, those affiliated with this aspect of the medical device industry are faced with walking away from a significant amount of business that will be absorbed by companies who are willing to engage in this practice, or acquiesce to the POD structure that, in many cases, is potentially unethical and/or illegal.”

The Report concluded that, “in absence of clarity, hospitals are in a position in which surgeons, who work in their hospital, generating income for the hospital, are approaching the hospital as a supplier and claiming that they are lowering healthcare costs by offering a lower price for products. This model seems inconsistent with the concepts of fraud and abuse law to think that a hospital can enter into a contract with their own physicians to purchase products that the hospital is paying for and that the physicians are selling and using.”

AdvaMed strongly supports the Senators’ position on this issue and their opinion that current guidance is “not adequate to protect against the risk of PODs abuse.” AdvaMed also supports the Senators’ call for an inquiry on PODs and their recognition of the need for increased safeguards to protect from potential conflicts of interest that can result in harmful patient outcomes.