MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

1300 North 17th Street ▪ Suite 1752
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

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Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-5060-P (Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests)

Dear Ms. Tavenner:

The Medical Imaging and Technology Alliance (MITA) appreciates this opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services (CMS) to implement Section 6002 of the Patient Protection and Affordable Care Act (the Proposed Rule).[1] As the leading trade association representing medical imaging and radiotherapy technology manufacturers, we have an in-depth understanding of the significant benefits to the health of Medicare beneficiaries that medical imaging, radiotherapy, and proton therapy provides. MITA looks forward to working with you to continue to improve the healthcare of Medicare beneficiaries through appropriate use of these technologies for the early detection, diagnosis, staging, therapy monitoring, and surveillance of many diseases.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, related imaging acquisitions, diagnostic ultrasound, and nuclear imaging (including positron emission tomography (PET)), and magnetic resonance imaging (MRI). Medical imaging is used to diagnose patients with disease, often reducing the need for costly

[1] 76 Fed. Reg. 78742 (Dec. 19, 2011).

medical services and invasive surgical procedures.[2] In addition, medical imaging equipment often is used to select, guide, and facilitate effective treatment, for example, by using image guidance for surgical or radiotherapeutic interventions.[3] MITA's members also develop and manufacture innovative radiotherapy equipment used in cancer treatment.

MITA strongly supported the enactment of Section 6002, commonly known as the Physician Payment Sunshine Act, and its goal of promoting transparency in the relationships between manufacturers and health care providers. We offer the comments below to assist CMS in implementing the Sunshine Act in a manner that is faithful to the statute and produces accurate, meaningful data for public consumption. Our comments include the following recommendations:

I. Timing of Compliance Obligation

- Delay the beginning of manufacturers' compliance obligations until at least 180 days following the publication of a final rule.

II. Definition of "Applicable Manufacturer"

- Limit reporting obligations to entities that are "operating in the United States."
- Limit reporting obligations of entities covered through "assistance or support" to payments having a direct nexus with the entity's "assistance or support."
- Allow affiliated manufacturers flexibility to report together even if they are independently covered as "applicable manufacturers."
- Clarify what activities constitute "assistance or support."

III. Reporting of Associated Product Name

- Permit reporting of associated products at the modality or system level for medical devices to reflect the realities of naming and marketing of medical devices and to make data on medical devices comprehensible to consumers.

IV. Reporting of Payments Made to Third Parties

- Revise the proposal regarding research payments in accordance with the statute's rules on reporting payments to third parties and create additional safeguards to ensure public understanding of the research payment reports.
- Provide end users with additional information about reports of payments made at the request of or designated on behalf of a covered recipient.

V. Report Content

- Finalize the proposal to allow manufacturers to submit an optional assumptions document and allow manufacturers to submit documentation of assumptions as to other aspects of their reporting obligations.

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[2] See, e.g., Perrier, et al., "Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," *New England Journal of Medicine*, 352(2005): 1760-1768.

[3] See, e.g., Jelinek, JS et al., "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223(2002): 731-737.

- Permit manufacturers to rely on and have notice of changes to NPI and specialty information published by CMS, and not require manufacturers to report an identifier other than NPI.
- Clarify certain issues related to reporting of date of payment.

VI. Nature of Payment Categories

- Provide further guidance on the scope and definition of the nature of payment categories.
- Allow manufacturers the option of reporting payments for activities that are associated with multiple segregable categories as a single payment.
- Implement the proposal to report all direct compensation for serving as a speaker under a single category.
- Revise the guidance on reporting group meals to ensure accurate reporting of which physicians received the meal.

VII. Exclusions

- Extend the exclusion for educational materials to all materials that have a genuine educational function for physicians.
- Clarify the scope of the employee health care exclusion and adopt an additional exclusion for bona fide employment interview expenses.

VIII. Review Period

- Notify covered recipients of the opportunity for review through CMS's own established means rather than requiring manufacturers to collect data on recipients' preferences.

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I. Timing of Compliance Obligation

CMS should delay the beginning of manufacturers' compliance obligations until at least 180 days following the publication of a final rule.

MITA appreciates CMS's recognition that the delay in publication of a final rule to implement the Sunshine Act necessitates a corresponding delay in the beginning of applicable manufacturers' obligations to begin tracking and collecting data on reportable payments or transfers of value.[4] However, we believe that CMS's proposal of 90 days following publication of the final rule would provide insufficient time for manufacturers to make the necessary adjustments to their systems, and we ask instead that CMS delay the beginning of compliance obligations until at least 180 days following publication of the final rule.

MITA's members have been planning and preparing to comply with the Sunshine Act since the law was enacted. As the Proposed Rule attests, however, the statute includes many

[4] 76 Fed. Reg. at 78743.

ambiguities and leaves many critical questions unanswered. Moreover, the Proposed Rule itself expands the scope of the statute in ways that manufacturers likely did not anticipate when they designed their reporting systems and raises multiple alternative approaches in a number of areas. Given the number of open questions, MITA's members are not currently in a position to finalize their compliance systems. We appreciate CMS's efforts to clarify many of these complex issues in the Proposed Rule and its openness to input from manufacturers and other interested parties as to how the statute should best be carried out. Nevertheless, the Proposed Rule leaves open numerous critical issues affecting nearly every aspect of manufacturers' compliance planning, from which entities must report and which entities are covered recipients to the allocation and attribution of payments and the review and publication of data. In total, CMS has sought feedback on a few dozen unresolved issues in the Proposed Rule and can expect comments from a variety of stakeholders in response to its solicitation of feedback on so many important questions. In addition, in a letter dated September 13, 2011,[5] in earlier comments following CMS's Open Door Forum,[6] and in meetings with CMS, MITA had requested clarification on and made recommendations regarding a number of unanswered questions, many of which were not addressed in the Proposed Rule and thus remain unresolved.

Moreover, after the final rule is published, manufacturers will need time to adjust and finalize their compliance systems and operations to comport with the decisions CMS has made. This final adjustment process will include multiple rounds of training and retraining of sales, marketing, research, legal, compliance, finance, and other personnel to ensure that they are prepared to collect and report data in accordance with the final rule. In many cases, manufacturers will also need to draft new policies to reflect changes and new interpretations and to implement adjustments to infrastructure and information technology systems to comport with the rule. Although manufacturers will continue to prepare in anticipation of CMS's resolution of the many outstanding questions, a great deal of this preparation cannot begin until the final rule is published. A period of at least 180 days following publication of the rule will give manufacturers the time they need to ensure that their employees, systems, and compliance infrastructure are fully prepared to comply with the statute.

II. Definition of "Applicable Manufacturer"

A. CMS should limit reporting obligations to entities that are "operating in the United States."

The Sunshine Act defines an "applicable manufacturer" as "a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a

[5] See Letter from MITA to Peter Budetti and Anthony Rodgers (Sept. 13, 2011), http://www.medicalimaging.org/2011/11/mita-comments-on-sunshine-reporting-requirements-for-drug-and-device-manufacturers/.

[6] See MITA Comments on Open Door Forum: Transparency Reports and Reporting of Physician Ownership or Investment Interests, http://www.medicalimaging.org/2011/04/comment-letter-to-cms-on-open-door-forum-on-physician-sunshine-act-reporting/.

territory, possession, or commonwealth of the United States."[7] A "manufacturer of a covered drug, device, biological, or medical supply" is defined in turn as "any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply."[8] CMS's proposed definition departs from the statute's definition in one key respect: it omits the requirement that an entity be "operating in the United States" and instead requires merely that the entity produce a covered product "for sale or distribution in the United States" or assist an applicable manufacturer with production, sale, marketing, promotion, or distribution of a covered product "for sale or distribution in the United States."[9]

MITA is concerned that CMS's proposed definition of "applicable manufacturer" would expand the statutory definition to cover foreign entities that Congress never intended the statute to cover. Congress's decision to set the "operating in the United States" requirement apart in a separate definition reinforces that an entity must be both a manufacturer of a covered product and "operating in the United States" to be covered as an "applicable manufacturer." The Proposed Rule, however, appears to disregard the "operating in the United States" requirement and instead shifts the emphasis of the definition from the extent of an entity's operations in the United States to the ultimate destination of a covered product, a concept that is absent from the statutory definition.

Although the Sunshine Act does not define the term "operating in the United States," we believe Congress is unlikely to have intended that the statute cover, for example, an entity that has no physical presence in the United States, has no employees in the United States, is not present in the United States for tax or corporate purposes, and has no additional contacts in the United States. Yet such entities would be drawn under the statute's coverage by the Proposed Rule's definition. Once covered, these entities would be required to report all payments to covered recipients, even if those payments relate solely to products sold exclusively outside the United States or otherwise have nothing to do with the provision of health care in the United States. Extending the statute's coverage to foreign entities also raises the possibility of conflicting obligations for entities subject to the jurisdiction of foreign laws, such as European Union privacy laws prohibiting the transfer of personal data to countries like the United States that the E.U. deems not to afford sufficient privacy protections. There is a well-established presumption when interpreting federal statutes that Congress did not intend to create such conflicts through the application of federal statutes outside the territorial limits of the United

[7] 42 U.S.C. § 1320a-7h(e)(2).
[8] Id. § 1320a-7h(e)(9).
[9] 76 Fed. Reg. at 78767 (Proposed 42 C.F.R. § 403.902).

States unless it affirmatively expresses its intent to do so.[10] Congress expressed the opposite intent in the Sunshine Act, which requires applicable manufacturers to be "operating in the United States."

MITA urges CMS to revise the proposed definition of "applicable manufacturer" to ensure consistency with the statutory requirement that an entity be "operating in the United States" to be covered. Specifically, we propose that the Proposed Rule's definition be amended to include the words "operating in the United States" as a separate and independent requirement applicable to both paragraphs of the definition, so that an applicable manufacturer would be defined as "an entity that is operating in the United States" and that satisfies either paragraph (1) or paragraph (2) of the proposed definition.

B. CMS should limit reporting obligations of entities covered through "assistance or support" to payments having a direct nexus with the entity's "assistance or support."

As noted above, the Sunshine Act defines an "applicable manufacturer" as an entity that is operating in the United States and that also fits under one of the two categories provided in the statute. The first category covers an entity that is "engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply" ("paragraph (1) entity").[11] The second category covers an entity "under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply" ("paragraph (2) entity").[12]

With respect to paragraph (2) entities, we believe that Congress's intent would be best carried out by a rule limiting reporting obligations to those payments and transfers of value that have a direct nexus with the activity that constitutes "assistance or support" to the paragraph (1) entity. Although the plain language of the statute establishes that Congress intended the law to reach some entities that do not themselves manufacture covered products, we think the Proposed Rule's definition extends too far.

Entities that manufacture covered devices and drugs often have multiple U.S. and global affiliates, many of which would be considered to provide "assistance or support" to the paragraph (1) entity with respect to production, promotion, sale, or distribution of the covered product. These affiliates also may make payments to covered recipients that would be reportable under the Sunshine Act if the affiliates were applicable manufacturers in their own right. Many of these payments, however, have no connection to the "assistance or support" for the paragraph

[10] See, e.g., EEOC v. Arabian American Oil Co., 499 U.S. 244 (1991); Morrison v. National Australia Bank Ltd., 130 S. Ct. 2869 (2010).
[11] 42 U.S.C. § 1320a-7h(e)(9).
[12] Id.

(1) entity that brought the affiliate within the statute's reach. For example, an affiliate may make payments to U.S.-licensed physicians for research regarding products that are not sold in the U.S. or are not covered by Medicare, Medicaid, or CHIP, or for research wholly unrelated to any drug, device, biological, or medical supply. Likewise, the corporate parent of a company with multiple divisions or affiliates serving multiple industry sectors may provide "assistance or support" to the health care division with respect to marketing, sale, or promotion of a covered product, but may also make payments and transfers of value to physicians or teaching hospitals to promote products made by a different division that are wholly unrelated to the provision of health care, such as lighting fixtures or furniture. Even a single joint sales call to a teaching hospital held by the health care division and another division or affiliate could conceivably qualify as "assistance or support" and thereby require the other division or affiliate to report payments or transfers of value associated with all future interactions with the hospital. Under the Proposed Rule, these payments or transfers of value would be reportable even though they have nothing to do with "assistance or support" with respect to a covered product.

Requiring paragraph (2) entities to report payments wholly unrelated to the "assistance or support" that brought them under the law would obstruct the statute's goal of collecting meaningful, transparent data that accurately reflects the relationships between manufacturers and providers. Congress's goal in adopting the Sunshine Act was to shed light on relationships between providers and manufacturers of covered products that might affect the provider's clinical decisions or contribute to an increase in health care costs. Payments that were neither made by a manufacturer of products reimbursable under Medicare, Medicaid, or CHIP, nor related to any entity's efforts to market, promote, sell, or distribute reimbursable products, are far removed from the core purpose of the law. Indeed, submission of data unrelated to a paragraph (2) entity's support of a paragraph (1) entity's efforts to produce, promote, or sell its products would impede the public's understanding of the true nature of manufacturers' interactions with providers and would make the public database less useful for those studying ways to reduce costs and maintain providers' clinical integrity. We therefore urge CMS to limit reporting by a paragraph (2) entity to payments that have a direct nexus with the activities performed in "assistance or support" of a paragraph (1) entity.

C. Affiliated manufacturers should have flexibility to report together even if independently covered as "applicable manufacturers."

MITA strongly supports CMS's proposal to allow a company to elect to report separately from or together with entities under common ownership with and providing "assistance or support" to that company.[13] We ask CMS to extend this permissive rule to all affiliated entities, even if each entity is separately covered under paragraph (1) of the Proposed Rule's definition of "applicable manufacturer," and to allow affiliated entities to select which entity will submit the affiliated group's report.

[13] 76 Fed. Reg. at 78744.

Allowing affiliated entities to report together both promotes public understanding of the reports by grouping entities that the public may recognize as related and facilitates accurate and consistent reporting by affiliated entities. Extending this rule to all affiliated entities that wish to report together, including those that are independently covered as "applicable manufacturers," will maximize the rule's benefit to public understanding and consistent reporting.

D. CMS should clarify what activities constitute "assistance or support."

Finally, MITA requests that CMS provide additional guidance on what activities constitute "assistance or support" to an applicable manufacturer sufficient to trigger coverage under paragraph (2) of the Proposed Rule's definition of "applicable manufacturer." As CMS recognizes,[14] many manufacturers of drugs, biologicals, and medical devices are global companies with multiple affiliates operating in cooperation to varying degrees and in varying ways. Additional guidance regarding which of these operations and what degree of cooperation satisfies the requirement of "assistance or support" will assist manufacturers in ensuring each affiliate's full compliance with the Sunshine Act.

III. Reporting of Associated Product Name

CMS should permit reporting of associated products at the modality or system level for medical devices to reflect the realities of naming and marketing of medical devices and to make data on medical devices comprehensible to consumers.

The Sunshine Act provides that if "the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply," then the manufacturer must report "the name of that covered drug, device, biological, or medical supply."[15] CMS proposes to implement this provision by requiring manufacturers to report the name "under which the product is marketed, since this name is probably most recognizable to the consumer." The Proposed Rule adds that if the product "does not yet have a market name, the applicable manufacturer should report the scientific name."[16]

This proposal would cause significant confusion for medical device companies and for members of the public hoping to learn about payments related to a particular medical device. MITA's members produce a broad range of complex medical devices, many of which have multiple reimbursable components or attachments. In some cases, the components or attachments may be marketed under unique names, but are also part of a larger system of products that is marketed under a different name. Moreover, while a patient sees the name of the drug her doctor has prescribed each time she picks up her prescription bottle, and patients frequently encounter market names for drugs in direct to consumer advertising, medical devices

[14] Id.
[15] 42 U.S.C. § 1320a-7h(a)(1)(A)(vii).
[16] 76 Fed. Reg. at 78747; see also id. at 78768 (Proposed 42 C.F.R. § 403.904(b)(8)).

like ultrasound machines are not commonly advertised to the public at large and in many cases are not known by their marketed name even to those patients who are treated with the device. The various components and adjunct parts are even less familiar to consumers and patients who may be reviewing the public reports. In addition, unlike drugs and biologicals, the marketed names of medical devices may change over time. Finally, the concept of a "scientific name," which is native to the world of drugs, has little meaning for device manufacturers and users. Devices like an ultrasound machine or MRI system have no specialized "scientific name." Because of these differences in how medical devices are named and marketed to the public, the proposed method of implementing the associated product requirement is inappropriate for most medical device manufacturers.

To achieve the purpose of the statute, CMS should revise the rule to permit medical device manufacturers to report the associated product name at the modality or system level. For example, Company X, which manufactures ultrasound devices, would report all of its payments for marketing, education, and research related to ultrasound devices as payments related to "Company X ultrasound devices." This alternative proposal would provide more coherent guidance to medical device manufacturers. Manufacturers will be responsible for training their sales forces to record the information necessary to comply with the statute, and the burden on sales representatives to report the required information accurately will be greatly eased if they are able to choose from a small number of modality or system names rather than hundreds of device and component names. It would also provide more meaningful data to patients, physicians, and other members of the public, who could research and aggregate payments made by each manufacturer with respect to the class of device that interests them without first having to research which of the many unfamiliar names and many different components of a given device should be included in the search. MITA urges CMS to adopt this alternative rule with respect to medical devices.

IV. Reporting of Payments Made to Third Parties

A. CMS should revise its proposal regarding research payments in accordance with the statute's rules on reporting payments to third parties and create additional safeguards to ensure public understanding of the research payment reports.

MITA has serious concerns about the special rules that CMS has proposed for the reporting of payments related to research. Under these proposed rules, applicable manufacturers would be required to report the full amount of any payment made pursuant to a written research agreement and research protocol not only under the name of the institution that actually receives the payment but also under the name(s) of the physician principal investigator(s) ("PIs") conducting the research trial.[17]

[17] Id. at 78749, 78768 (Proposed 42 C.F.R. § 403.904(e)).

MITA is deeply concerned that the Proposed Rule will create the public misperception that physician PIs are receiving large payments from manufacturers – perhaps totaling in the millions of dollars – when in fact the PI may be receiving only a small portion of the amount paid to the institution. Physicians who are apprehensive about such misunderstandings may in some cases decline to serve as PIs, reducing the pool of qualified physicians available to conduct vital clinical trials.

Moreover, CMS's proposed rules are inconsistent with the language of the statute, which provides that applicable manufacturers must report information related to any "payment or other transfer of value to a covered recipient (or to any entity or individual at the request of or designated on behalf of a covered recipient),"[18] and limits the scope of "covered recipients" to physicians and teaching hospitals. Under the statute, therefore, payments to non-teaching hospitals are reportable only if such payments are made at the request of or designated on behalf of a covered recipient. CMS proposes to require reporting of payments to these entities, even though the institutions are not covered recipients themselves and were not designated to receive the payments on behalf of a covered recipient.

MITA asks CMS to revise its special reporting rules for research to bring them into accordance with the statute and to avoid dissuading physicians from serving as PIs or potentially stifling important clinical research. When a manufacturer makes a research-related payment to a covered recipient, that payment should be reported only in the name of the covered recipient to whom the payment is made. Thus, under our recommended approach, a payment to a teaching hospital under a clinical trial agreement would be reported only as a payment to the teaching hospital, not as a payment to both the teaching hospital and the PI. A payment to a physician to carry out investigator-sponsored research in his or her own office would likewise be reported only as a payment to the physician. When a manufacturer makes a research-related payment to an entity that is not a covered recipient, such as a non-teaching hospital, that payment should be reportable only if it is made at the request of or designated on behalf of a covered recipient. If a physician PI is coordinating an investigator-sponsored study at a non-teaching hospital and directs the manufacturer to pay the hospital for expenses related to the study, those expenditures would be reported in the name of the PI under the statute's third party payment rules.

In addition, to provide further protection against public misperception of the nature and scale of research-related payments, MITA asks CMS to provide additional safeguards with regard to research payment data. In the Proposed Rule, CMS recognizes the potential for public misperception and proposes that research-related payments attributed to individual physicians under the special research reporting rules would not be aggregated with other payments reported for those physicians but would instead be published "separately."[19] Whatever reporting rules CMS adopts in its final rule, we believe it is vital that CMS take additional steps to help the public understand the amount and nature of payments being reported under a physician PI's

[18] 42 U.S.C. § 1320a-7h(a)(1)(A).
[19] 76 Fed. Reg. at 78749.

name and to minimize the possibility that these payments could be aggregated with other payments to the physician PI.

To that end, MITA suggests that research-related payments should be published in a separate database and a separate page of the public website or on a different website altogether. CMS could also discourage end users from improperly aggregating research payments that are attributed to an individual PI by providing a separate reporting template for research payments with an additional field for "Principal Investigator Name." In addition, the website and each downloaded report should be accompanied by a prominently displayed warning and explanation that the individual physician may not have actually received the full amount reported.

B. CMS should also provide end users with additional information about reports of payments made at the request of or designated on behalf of a covered recipient.

CMS has also proposed, in accordance with the statute, that payments made to a third party at the request of or designated on behalf of a covered recipient must be reported under the name of the covered recipient.[20] MITA urges CMS to provide additional information to end users regarding the nature of such payments.

We are concerned that a number of payments that must be reported under a covered physician's name will be misconstrued as having been paid directly to the physician. This includes not only amounts that a physician asks the manufacturer to pay to his or her physician group, which the Proposed Rule would require manufacturers to report in the "name(s) of the physician covered recipient(s),"[21] but also payments that a physician asks the manufacturer to pay to another corporate entity associated with the physician and even payments that a physician asks the manufacturer to pay to his or her favorite charity. In such cases, it is important that the public understand that the payment made by the manufacturer went not to the individual physician but rather to a third party designated or requested by the physician. To that end, we ask CMS to include a prominent notice on the public website and with each download that the aggregate total for a physician may include payments that were paid to entities other than the physician.

V. Report Content

MITA thanks CMS for its efforts in the Proposed Rule to anticipate operational issues that manufacturers may confront as they work to meet their obligations under the Sunshine Act. Nevertheless, the Proposed Rule raises a number of important questions about the content of the disclosure reports that may result in uncertainty or inconsistent reporting among manufacturers. We ask that CMS provide further guidance on these issues in its final rule.

[20] Id. at 78768 (Proposed 42 C.F.R. § 403.904(b)(10)).
[21] Id. at 78746.

A. CMS should finalize its proposal to allow manufacturers to submit an optional assumptions document and allow manufacturers to submit documentation of assumptions as to other aspects of their reporting obligations.

MITA appreciates CMS's proposal to offer manufacturers the opportunity to submit a document detailing their reasonable assumptions about which nature of payment category is appropriate.[22] The ambiguities in the nature of payment categories and the benefits of submitting an assumptions document will likely motivate many manufacturers to submit such a document voluntarily. Other manufacturers, however, may not need to submit such a document because they report only a limited set of relatively clear payment categories, and therefore we do not believe it is necessary to require manufacturers to submit such a document.

MITA also asks CMS to allow manufacturers the opportunity to submit documentation of other assumptions that the manufacturer has made in collecting and reporting data. For example, a manufacturer may wish to document its assumptions regarding its decision to report the payments of several affiliates together in one report, its method of reporting associated product names, or its decision as to how to value equipment loans or other transfers of items that do not have an obvious value. We believe that both CMS and manufacturers will benefit from documentation of such assumptions for the same reasons that CMS identified with regard to the nature of payment, and we ask CMS to allow manufacturers to submit any such assumptions that they believe would be helpful in explaining their reports.

B. Manufacturers should be able to rely on and have notice of changes to NPI and specialty information published by CMS, and should not be required to report an identifier other than NPI.

The Sunshine Act requires manufacturers to report, "in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient."[23] In the Proposed Rule, CMS "suggest[s]" that manufacturers use the National Plan & Provider Enumeration System ("NPPES") database of physician NPIs to report NPI, as well as the "provider taxonomy" field of the NPPES database to report a physician's specialty.[24] The database is maintained and updated frequently on CMS's public website.

To facilitate accurate reporting of physician NPI and specialty, MITA asks that CMS notify manufacturers when updates to the NPPES database are issued. With notice of each update to the database, manufacturers will be in a better position to adjust their reports (to the extent possible) to reflect the most recent information available from CMS. Additionally, in light of the ongoing updates to the NPPES database, we urge CMS to provide a defined range of dates for which a given version of the database may be relied on for manufacturers' reports. In

[22] Id. at 78748.
[23] 42 U.S.C. § 1320a-7h(a)(1)(A)(ii).
[24] 76 Fed. Reg. at 78746-78747.

the absence of such guidance from CMS, manufacturers will have no way of ascertaining whether the NPI and specialty information posted for a physician at the time they make their report will be the same information that CMS may later use to measure compliance with the requirements of the law. Finally, we ask that CMS archive all published lists of physician NPIs and specialties on a public website for a period of at least five years, so that in the event of an audit manufacturers and CMS will have access to the data on which manufacturers relied in reporting this information.

CMS also solicits comment on whether manufacturers should be required to report a physician identifier other than the NPI, such as a state license number, for physicians who do not have an NPI.[25] MITA recommends that CMS not require any additional information as a substitute where NPI is unavailable. Physicians without an NPI will already be identifiable in manufacturer reports by their name and business address. Requiring manufacturers to record and track a separate identification number for physicians without an NPI would impose an additional cost and administrative burden that is not mandated by the statute and does little to make the reports more accessible or comprehensible to the public.

C. CMS should clarify certain issues related to reporting of date of payment.

In cases where a payment is provided "over multiple dates, such as a consulting agreement with monthly payments," CMS proposes that manufacturers have discretion to report the total payment on the date of the first payment as a single line item or to report each individual payment as a separate line item.[26] MITA supports this proposal to give manufacturers greater flexibility in reporting and asks that CMS finalize this proposal in the final rule.

In addition, when manufacturers use their discretion to report multiple payments as a single line item, we suggest that CMS not require manufacturers to assign a specific date to the group of payments. As a matter of accurate reporting, these payments are made on multiple dates and assigning a single payment date to the entire batch of payments would be misleading.

If CMS instead requires manufacturers to report multiple payments in a single consistent manner, we recommend that CMS require consistency only within a nature of payment category rather than consistency across all nature of payment categories. Manufacturers structure payments to providers differently depending on the nature of the payment (e.g., speaking agreement, research agreement, or educational grant). As a result, any rule mandating consistency in reporting the date of payment must take account of these differences and apply only to a particular nature of payment category.

Finally, we ask that CMS clarify in the final rule that the scope of the manufacturer's discretion to report multiple payments as a single line item is limited to those payments that

[25] Id. at 78746.
[26] Id. at 78747.

occurred within the current calendar year, so that, for example, only current year payments under a multi-year consulting agreement would be reportable as a single line item.

VI. Nature of Payment Categories

A. CMS should provide further guidance on the scope and definition of the nature of payment categories.

MITA appreciates CMS's proposal to give manufacturers the flexibility to determine which nature of payment category is appropriate for each payment and permit them to make "reasonable determinations" about which category to report.[27] We are concerned, however, that inconsistent interpretation of the nature of payment categories will lead to confusion among manufacturers and the public and will produce less meaningful data about manufacturers' relationships with physicians.

In particular, categories such as "Honorarium," "Gift," and "Compensation for services other than consulting" are broad, ill-defined, and may overlap with or encompass other categories. In such cases, although manufacturers may make reasonable assumptions about which nature of payment category is appropriate, other manufacturers will likely make different reasonable assumptions, so that a consumer seeking to aggregate payments for "Gifts" may collect a largely incoherent set of data. Moreover, the consumer will bring his own reasonable understanding of a "Gift," which may be different from the manufacturer's reasonable understanding of a "Gift" and may lead to confusion and misperception of the actual nature of the manufacturer-provider relationship. Further, although we agree with CMS that each of the nature of payment terms has a comprehensible dictionary definition, many terms in the nature of payment categories carry particular weight in the payment disclosure context. For example, the term "Gift" has statutory meaning under state reporting laws that may color how that term is read by manufacturers, covered recipients, and the public.

For all of these reasons, we ask CMS to provide additional guidance on the proper scope of the nature of payment categories, particularly with regard to terms such as those mentioned above that are likely to overlap or encompass other categories or have the potential to mislead the public as to the nature of relationships between manufacturers and providers.

B. CMS should allow manufacturers the option of reporting payments for activities that are associated with multiple segregable categories as a single payment.

When a single payment is made for various expenses related to a single activity, CMS proposes to require manufacturers to segregate the payments and report each payment under a separate category.[28] For example, if a lump sum payment is made to cover the costs of travel,

[27] Id. at 78748.
[28] Id. at 78747.

meals, and consulting fees for a meeting, CMS would require the manufacturer to identify the expenses associated with each category of payment and report them separately. CMS also seeks comments on an alternative approach in which a manufacturer would report such a payment as a single lump sum, rather than segregating the components of the payment into separate categories.[29] MITA recommends that CMS allow manufacturers the option of using this alternative approach. CMS correctly recognizes that this approach "may be more compatible with existing business processes,"[30] and we believe it would significantly reduce manufacturers' administrative burdens associated with the reporting obligation. CMS could require that manufacturers who elect to not segregate their payments must be prepared to provide the segregated amounts if they are audited.

C. CMS should implement its proposal to report all direct compensation for serving as a speaker under a single category.

CMS proposes to interpret the "Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program" category broadly to "encompass all instances in which applicable manufacturers pay physicians to serve as speakers, and not just those situations involving 'medical education programs.'"[31] MITA supports this approach and we agree that having a single category for all speaker fees will help to minimize inconsistencies across manufacturers' reports. We ask CMS to implement this proposal in the final rule.

D. CMS should revise its guidance on reporting group meals to ensure accurate reporting of which physicians received the meal.

MITA thanks CMS for its efforts to provide greater clarity on the issue of reporting group meals provided in group settings. We agree that this is an area that creates a particular risk of inconsistent reporting among manufacturers and misperception in the public. We are deeply concerned, however, that the method proposed by CMS for allocating the cost of group meals to specific covered recipients will lead to inaccurate reporting and misleading reports, and we urge CMS to adopt an alternative rule.

CMS proposes that manufacturers providing group meals in group settings should report "the cost per covered recipient receiving the meal (even if the covered recipient does not actually partake of the meal)."[32] The Proposed Rule goes on to suggest, by way of a number of examples, that each member of the group or practice that receives the meal should be reported as having received the meal, regardless of whether the physician was present when the meal was provided.

[29] Id.
[30] Id.
[31] Id. at 78750.
[32] Id. at 78748.

MITA asks CMS to reconsider any proposal that would allocate the cost of group meals to all physicians in a group practice even if the physician is not present at the meal. To begin with, such a rule would indisputably lead to inaccurate reporting: if manufacturers are required to report every member of the practice as a recipient, there will be numerous cases where a physician who was out of the office, chose not to attend, or was otherwise absent will be reported as having received a benefit that he or she never received. This will result in the publication of fictional information that will falsely attribute benefits to physicians that were never actually received. This will confuse and mislead users of the data and undermine the transparency objectives that Congress intended the statute to achieve.

Additionally, CMS has provided little guidance on what constitutes a "group" or "practice." Requiring manufacturers to bear the burden of determining the contours of a particular group will likely lead to inconsistent, inaccurate, and misleading reports. For example, in a multi-specialty practice, the Proposed Ruled does not explain whether a group meal provided only to one group of specialists should be allocated to the entire practice or only to physicians in that specialty group. Manufacturers are likely to draw competing reasonable assumptions on such points.

A rule that allocates the cost of a group meal to all members of the group regardless of attendance would have other potential negative effects as well. When a manufacturer provides a meal to members of one specialty in a multi-specialty practice, and the manufacturer is promoting a product that has FDA-approved indications for conditions treated only by that specialty, there is a risk that requiring the manufacturer to report the meal as a payment to all members of the practice would create the appearance of off-label promotion to the other specialties in the group. In addition, many physicians affirmatively choose not to attend meals provided by manufacturers. To require manufacturers to report the names of such physicians anyway would not only be inaccurate but would also cause easily avoidable disputes between manufacturers and physicians, which both manufacturers and physicians would bear the cost of resolving.

As an alternative method of allocating the cost of meals, MITA proposes that only those physicians who actually attend the meal (regardless of whether they actually consume any food or drink) should be reported as having received a payment. This rule would allow manufacturers to collect accurate information about which physicians actually attended, would preclude any inadvertent appearance of off-label promotion, and would avoid reporting of the names of physicians who did not receive any benefit from the meal and may have affirmatively decided not to attend.

Finally, MITA strongly supports CMS's proposed exclusion of payments to provide buffet meals, snacks or coffee at booths at conferences or similar events.[33] We agree that this is a

[33] Id. at 78748-49.

reasonable exclusion in light of the very small per-recipient value of these items and the administrative difficulty in capturing the name of each covered recipient in such situations.

VII. Exclusions

A. The exclusion for educational materials should extend to all materials that have a genuine educational function for physicians.

The Sunshine Act excludes from reporting obligations all "[e]ducational materials that directly benefit patients or are intended for patient use."[34] In the preamble to the Proposed Rule, CMS requested comment on whether materials that are provided to physician covered recipients primarily for their own education and that are not given to patients should be included as "materials that directly benefit patients."[35]

MITA strongly supports including within the educational materials exclusion all materials that have a genuine educational function for physicians, regardless of whether such items are intended for patient use or are given directly to patients. These materials would include medical textbooks, journal article reprints, anatomical models used for educational purposes, and any other item that serves a genuine educational function for physicians. Such items directly benefit patients by providing physicians with disease and treatment information they need to make appropriate clinical decisions, educate their patients, and keep themselves informed of the latest clinical developments relevant to their patients' treatment. We strongly recommend that all such items be excluded from reporting under the final rule.

B. CMS should clarify the scope of the employee health care exclusion and adopt an additional exclusion for bona fide employment interview expenses.

MITA appreciates the guidance offered by CMS in the Proposed Rule regarding certain statutory exclusions and generally supports the list of exclusions as proposed by CMS. In addition, however, we urge CMS to clarify in the final rule the scope of the existing exclusion for employee health care costs and to exercise its discretion in implementing the statute to add an exclusion for payments to a physician as reimbursement for costs associated with an interview for a bona fide employment opportunity with the manufacturer.

The Sunshine Act provides that, "[i]n the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan" are not reportable.[36] We would like CMS to clarify whether this exclusion would also apply to other payments made by manufacturers to covered recipients as payment for health care services provided by the covered recipient to employees of the applicable manufacturer. For example,

[34] 42 U.S.C. § 1320a-7h(e)(10)(B)(iii).
[35] 76 Fed. Reg. at 78751.
[36] 42 U.S.C. § 1320a-7h(e)(10)(B)(x).

manufacturers frequently hold health fairs, screening events, or on-site health clinics for the benefit of their employees. These events, though not paid for under a self-insured plan, are nevertheless paid for by the manufacturer for the benefit of its employees and not as part of any existing or hoped-for relationship with the particular physician who provides the services. MITA strongly believes that such payments for a physician's one-time medical services to a manufacturer's employees fit within Congress's intent in adopting the employee health care exclusion and should likewise be excluded from reporting under the final rule.

We also ask that CMS adopt in the final rule an additional exclusion for costs associated with an interview for a bona fide employment opportunity. The statute makes clear that payments to physicians as employees of the manufacturer are not reportable.[37] This exclusion recognizes that payments to employees are outside the scope of the statute because they are made to the individual as an employee and not as a potential prescriber or purchaser. Payments made to reimburse physicians for costs associated with an interview for a bona fide employment opportunity are similarly beyond the scope of the statute. These payments are made to the physician as a prospective employee, not as a health care professional in a position to purchase or prescribe the manufacturer's products. The relationship between manufacturers and their prospective employees, whether or not the candidate is eventually hired, is not the type of relationship that Congress was concerned about in enacting the Sunshine Act, and we ask that CMS adopt a rule excluding payments to reimburse expenses for bona fide interviews.

VIII. Review Period

CMS should notify covered recipients of the opportunity for review through its own established means rather than requiring manufacturers to collect data on recipients' preferences.

Finally, CMS confirms in the Proposed Rule that it plans to notify all applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors about the procedures for review of the aggregated data prior to publication.[38] CMS is considering several options for communicating with covered recipients, including use of CMS's list serves and public posting of information about the review period. CMS also solicits comments on an alternative approach in which manufacturers would be required to collect and report each covered recipient's preferred method of being notified of the review process, as well as the recipient's email address, if indicated.[39] MITA opposes this alternative method. It would be particularly burdensome for manufacturers to collect and report this information. In addition, any information collected by the manufacturer at the time the payment is made could be out of date by the time of the reporting period. We recommend that CMS not require manufacturers to collect and report this information, and instead the agency should notify covered recipients that

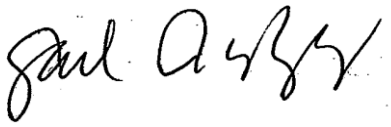
[37] Id. § 1320a-7h(e)(6)(B).
[38] 76 Fed. Reg. at 78754.
[39] Id. at 78755.

data is available for review through its well-established means of communicating with physicians and hospitals.

* * *

We appreciate this opportunity to submit these comments on the Proposed Rule and look forward to continuing our work with CMS on this important issue. If you have any questions or would like to discuss these matters further, please contact me at 703-841-3242.

Respectfully submitted,



Gail M. Rodriguez, Ph.D.
MITA Executive Director
NEMA Vice President