PhRMA

April 7, 2011

VIA EMAIL: PHYSICIANSUNSHINE@CMS.HHS.GOV

Barbara Cebuhar

Office of External Affairs and Beneficiary Services
Centers for Medicare & Medicaid Services

Re: Centers for Medicare & Medicaid Services Special Open Door Forum: Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Ms. Cebuhar:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) following the March 24 Special Open Door Forum on transparency reports and reporting physician ownership or investment interests. PhRMA is a voluntary, nonprofit association that represents the country's leading biopharmaceutical research companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. Last year, America's biopharmaceutical research companies invested $67.4 billion in researching and developing new medicines.

The purpose of the provisions in section 6002 of the Affordable Care Act (ACA), Transparency Reports and Reporting of Physician Ownership or Investment Interests[1] (the "Sunshine Provision"), is to ensure that patients have meaningful and relevant information about the relationships between biopharmaceutical and medical device companies and health care providers. PhRMA supports the need for transparency in interactions with health care providers and looks forward to working with CMS to help ensure that the Sunshine Provision is implemented effectively and consistent with these goals. We trust the following comments will be useful to CMS as it prepares a proposed rule to implement the Sunshine Provision.

PhRMA also respectfully requests a meeting with CMS to discuss these issues and our comments in greater detail in the next few weeks. In particular, PhRMA members can provide CMS with specific information about the operational challenges companies face in implementing the Sunshine Provision (based on experiences operationalizing similar state requirements), especially since such challenges facing the companies are also likely to present implementation challenges to CMS. We will be in touch shortly to schedule such a meeting.

[1] Pub. L. No. 111-148, codified at Social Security Act (SSA) § 1128G.

CMS should also consider whether to conduct additional outreach to stakeholders before issuing a notice of proposed rulemaking, consistent with the provisions in section 6002 of the ACA, as required by the Sunshine Provision, which provides that CMS must consult with "affected industry, consumers, consumer advocates, and other interested parties."[2]

I. Background

Ethical relationships and interactions with health care professionals are critical to our mission of helping patients by researching and developing new medicines. An important part of achieving this mission is ensuring that health care professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in health care.

Our companies' relationships with health care professionals are critical to achieving these goals because they enable us to:

- conduct clinical research, in collaboration with physicians, government, and private entities, to assess the safety and effectiveness of medications and new uses for existing medications;
- inform health care professionals about the benefits and risks of our products to help advance appropriate patient use;
- support or provide scientific and educational information about diseases, medical conditions, and treatments;
- support the general advancement of medical knowledge; and
- perhaps most importantly, obtain critical feedback, including real-world experience, and advice about the use of our products in patients through exchanges and consultation with physicians and other medical experts.

Company relationships with health care professionals are critical to achieving these goals because they help inform health care professionals about the benefits (as set forth in the FDA-approved labeling) and risks of approved products, provide physician access to other information that may be necessary to inform medical recommendations, and obtain feedback and advice from health care professionals.

In their interactions with the medical community, PhRMA member companies are committed to following the highest ethical standards and all legal requirements. The Food and

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[2] SSA § 1128G(c)(2).

Drug Administration and other federal and state agencies regulate company marketing activities, and companies devote substantial resources to compliance with government regulations and ethical standards. We firmly believe that a health care professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the health care professional's medical knowledge and experience. PhRMA has in place a voluntary "Code on Interactions with Health Care Professionals" (the "PhRMA Code"). Updated and strengthened most recently in 2009, the PhRMA Code seeks to ensure that biopharmaceutical company engagement with providers is professional, ethical, and educational—and, ultimately, provides physicians with some of the tools they need to give their patients the best care possible.[3] Similarly, PhRMA's "Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results," revised in October 2009, reflect our members' commitment to the safe and appropriate conduct of clinical trials and to the accuracy and integrity of clinical data.[4]

A recent telephone survey of more than 500 American Medical Association members, conducted by KRC Research and supported by PhRMA, clearly illustrates the benefits of interactions between physicians and biopharmaceutical company representatives. For example, more than 90 percent responded that interactions with representatives allow them to learn about new indications for approved medicines, potential side effects of medicines, and both emerging benefits and risks of medicines. In addition, 84 percent of physicians said that interactions with representatives allow them the opportunity to provide feedback to a pharmaceutical company about their experiences with a specific medicine. Large majorities also found information from company representatives to be up-to-date and timely (94 percent), useful (92 percent), and reliable (84 percent).[5]

The survey also revealed that physicians consider a broad range of factors in making their prescribing decisions, with almost all respondents relying on their clinical knowledge and experience as well as a patient's response to a particular medicine. More than 80 percent reported that they take into consideration a patient's insurance factors, such as formulary and prior authorization requirements. The survey also found that nearly 8 out of 10 physicians view pharmaceutical research companies and their sales representatives as useful sources of information on prescription medicines. The survey found that physicians consider a range of sources useful for staying informed about medicines. In addition to biopharmaceutical representatives and company-sponsored peer education programs, independent continuing medical education courses, peer-reviewed medical journals, and other physicians were also cited as useful sources of information.

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[3] http://www.phrma.org/about/principles-guidelines/code-interactions-healthcare-professionals.

[4] http://www.phrma.org/sites/default/files/800/042009_clinical_trial_principles_final.pdf

[5] http://www.phrma.org/sites/default/files/987/krcsurveyofphysicians_1.pdf.

CMS should consider including this information as part of its educational and contextual communications to the public on this issue.

II. General Comments

Given the complexity of information to be collected and aggregated, significant volume of data, and the difficulty of presenting this data to the public in an understandable and user-friendly manner, CMS's challenges going forward are great. For instance, one mid-sized pharmaceutical company expects to report approximately a million interactions involving approximately 300,000 physicians in the first year alone. Such reports suggest that the universe of data that will be submitted to CMS by all applicable manufacturers with respect to all covered recipients has the potential to be overwhelming.

Notice-and-comment rulemaking is essential to ensure an appropriate level of consistency in reporting across manufacturers and over time. As we have seen at the state level, issuing guidance rather than a regulation can result in the agency having to repeatedly reconsider issues and revisit guidance documents, activities that are resource-intensive for both the regulators and industry and make compliance more challenging. We were pleased to learn during the Open Door Forum that CMS expects to engage in notice-and-comment rulemaking and that it expects to issue a proposed rule this summer. Meeting the proposed summer timeline is critical to ensuring that the industry has time to prepare for implementing the requirements.

We therefore encourage CMS to promptly issue proposed, and then final, regulations that clarify the types of payments that are required to be reported, the universe of covered recipients, and the manner in which that information should be captured and reported. These regulations should focus on implementing the statute as written and on clarifying those parts of the statute that are ambiguous or incomplete. We do not believe that CMS should consider ways to expand the reporting requirements at this time, and we strongly encourage CMS to focus on the immediate implementation challenges, rather than expanding those challenges. In its proposed rule, CMS should clearly explain the rationale for the positions articulated, particularly to the extent that they deviate from or add to the requirements in the statute. This additional information will help stakeholders provide meaningful input. CMS should also ensure that final regulations are provided sufficiently far in advance of when companies will be required to begin tracking information so that there is adequate opportunity to change and/or develop the necessary systems to implement the regulatory requirements.

No matter how carefully CMS drafts its regulation, the agency will not be able to anticipate all of the various factual scenarios for which companies may be required to submit data. PhRMA therefore suggests that, for those situations where CMS has not issued definitive regulations, companies be permitted to make reasonable assumptions in compiling and submitting their data, provided that they document their assumptions. This approach would be consistent with CMS's approach regarding price reporting under the Medicaid Drug Rebate Program and Medicare Part B.

III. Definitions

A. "Applicable Manufacturer"

Critical to CMS's mission of providing clear direction is the need for comprehensive, unambiguous definitions of the key statutory terms. In particular, given the complexities of global organizations, including entities incorporated outside the United States, it is important for CMS to recognize the status of these foreign organizations as separate legal entities incorporated under the laws of other countries and not in all cases subject to the control of the U.S. entity. A clear reading of the statutory definitions of "applicable manufacturer" and "manufacturer of a covered drug"[6] is that, when a foreign affiliate not operating in the United States interacts with a U.S. physician, the interaction is not a covered transaction unless: (a) the foreign affiliate provides support to the U.S. entity in the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a "covered drug," or (b) the payment was directed or controlled by the U.S. entity.

The definition of "applicable manufacturer" should also address which entity should report payments made as part of a collaboration, such as a co-promotion agreement. In the case of a collaboration between two applicable manufacturers, the applicable manufacturer that makes the payment to the covered recipient should be responsible for reporting, unless the two manufacturers have contracted otherwise. In the case of a collaboration between an applicable manufacturer and an entity that is not an applicable manufacturer, payments made to covered recipients by the entity that is not an applicable manufacturer should be reported if the payment was made at the direction and control of the applicable manufacturer. As an example, a payment to a covered recipient by a contract sales organization operating under an agreement with an applicable manufacturer would be reportable.

B. "Covered Recipient"

Similarly, the definition of "covered recipient"[7] should contemplate how research payments made to a non-covered recipient, such as a contract research organization (CRO), site management organization (SMO), or other legal entity established by physicians to conduct clinical research, are to be handled under the statute. This issue is significant in view of the complex and evolving environment in which clinical trials take place. In many instances a clinical trial sponsor will delegate certain responsibilities, including the selection and payment of physician investigators, to an independent and unaffiliated CRO or SMO, which will then contract with institutions, individual investigators, and study staff, many of whom may meet the definition of "covered recipient."

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[6] *Id.* § 1128G(e)(2), (9).

[7] *Id.* § 1128G(e)(6).

PhRMA believes that, under a clear reading of the statutory definition, if a research payment is made by a manufacturer to a teaching hospital, it should be reported as a payment to the teaching hospital. To the extent that some portion of the payment is used to support research work by individual physicians at the teaching hospital (for example, to fund salaries), applicable manufacturers cannot and should not be required to attempt to apportion or trace funding down to the individual physician level. If a payment is made by an applicable manufacturer to a teaching hospital or a physician indirectly, through a contracted intermediary such as CRO or SMO, and attributable to a specified covered recipient , it should be reported as a payment to that covered recipient only after the intermediary informs the manufacturer of the covered recipient to whom the payment is made. Payments to institutions that are not teaching hospitals and are not earmarked for a specified covered recipient as defined in the Sunshine Provision are not reportable. This reading is consistent with the statute, which provides that transfers of value "made indirectly to a covered recipient through a third party in connection with an activity or service" are not reportable if "the applicable manufacturer is unaware of the identity of the covered recipient."[8]

Finally, payments made to a third party, such as a charitable organization, at the direction of a covered recipient should be reportable as payments to the covered recipient, consistent with the statutory requirement that "[i]n the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient."[9]

C. "Teaching Hospital"

The statute defines a "physician" by reference to the definition of "physician" in Title XVIII of the Social Security Act,[10] but it does not further define teaching hospitals. Without further definition, companies may use different standards for determining whether a hospital is a teaching hospital, which could lead to inconsistent and inaccurate reporting. Thus, PhRMA believes CMS should provide a master list of teaching hospitals and their tax identification numbers to ensure clear and consistent reporting by applicable manufacturers. This list should be updated by CMS annually.

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[8] *Id.* § 1128G(e)(10)(A).

[9] *Id.* § 1128G(a)(1)(B).

[10] *Id.* § 1128G(e)(11) (referencing SSA § 1861(r), which defines "physician" as, with some limitations, a medical doctor, osteopath, dentist, podiatrist, optometrist, or chiropractor).

D. "Physician"

Similarly, there are significant complexities associated with reporting payments to individual physicians. For example, multiple physicians may have the same name, a single physician may be licensed in multiple states, a physician may be retired or on a sabbatical, or a physician may have more than one, or no, National Provider Identifier (NPI). To simplify the process of data collection—and eventual aggregation and communication to patients—CMS should make available a master list of physicians, including state license numbers and NPIs, for whom payments must be reported, much like Massachusetts has done to facilitate compliance with its similar reporting requirement. Companies should be expected to check the list annually. PhRMA also believes that companies should be required to report only one NPI for each physician for which it is submitting data, regardless of how many NPIs are associated with the physician.

IV. Payment Categories

The statute lists 14 categories to be used by applicable manufacturers to describe the nature of a specific payment;[11] however, many of the payment categories potentially overlap and the parameters of many are unclear. PhRMA believes that an important public policy goal of CMS in implementing the Sunshine Provision of ACA should be ensuring that there is no double-counting of data; otherwise, the information could be confusing and misleading to the public. To that end, PhRMA believes that CMS must provide clear definitions for each category describing the nature of a payment under the law, specify that each category is mutually exclusive, and clearly recognize that some categories may have no or virtually no data submitted. For example, the term "honoraria" is an outdated term that is no longer commonly used in the biopharmaceutical industry; we request that CMS instead refer to a "fee for service," which more accurately describes the transaction. Further, the category "compensation for services for other than consulting" is duplicative of other categories specified in the statute. CMS should also consider whether some of the categories should be combined to facilitate reporting. For example, some meals and travel could be reported as expenses associated with consulting activities, rather than as individual line items.

CMS should also clarify that only items provided to physicians or teaching hospitals that clearly benefit the physician—such as textbooks or subscriptions to medical journals—are disclosable under the Sunshine Provision. Similarly, the statute exempts "[e]ducational materials that directly benefit patients or are intended for patient use";[12] however, other items are provided solely for patient use, such as sharps disposal containers provided with

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[11] *Id.* § 1128G(a)(1)(A)(vi).

[12] *Id.* § 1128G(e)(10)(B)(iii).

injectable drug products and other items provided as part of patient starter kits, which should also be excluded.

Still other items that may be technically considered "transfers of value" do not clearly fall within any of the enumerated statutory categories. For example, it is unclear under which category a medical textbook should be included. An argument could be made that it should be included under "educational materials," and clarity from CMS would promote consistent reporting.

V. Corrections of Reported Information

In order for the information collected from manufacturers and presented online to be useful to the public, the data must, at a minimum, be accurate. CMS must therefore provide adequate opportunity and an easy mechanism for manufacturers and covered recipients to correct any information submitted and/or published. The statute requires that CMS give manufacturers and covered recipients the opportunity to review and correct the information submitted for a period of not less than 45 days before it becomes available to the public.[13] CMS should ensure that manufacturers and recipients are able to review the information in the particular form in which it will be posted online, and it should provide notice of the start of the 45-day clock to physicians and teaching hospitals, who may not be aware that their information is scheduled to be posted. To facilitate the provision of notice, CMS will need to generate a mechanism for communicating with covered recipients, as well as a master list of covered recipients to be notified. As noted earlier, this same list should be provided to manufacturers to assist them in reporting their data.

In addition, CMS should provide manufacturers with an opportunity to provide CMS with amended or corrected information following submission of annual reports. The regulation should make clear that such amended information can be submitted without penalty to the manufacturer and will not be considered evidence of a failure or knowing failure to submit the original report. CMS may also wish to consider a materiality threshold to specify circumstances under which amended information can be submitted.

VI. Communication of Information to the Public

As noted above, the purpose of Sunshine Provision reporting is to provide information to the public about the relationships between their health care providers and medical device and biopharmaceutical companies. CMS will therefore need to carefully consider how best to aggregate, organize, and present the reported data for posting online. An essential element of this task will be providing plain English definitions of the relevant statutory terms and educational information about why these relationships exist and the benefits that result from such

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[13] *Id.* § (c)(1)(C)(ix).

interactions. Failure to provide adequate information about how these relationships advance patient care could harm relationships between patients and their physicians and could have a negative impact on the public health. It could also endanger relationships between manufacturers and physicians, which could in turn chill research regarding new treatments.

PhRMA would be pleased to assist CMS in developing this background information. PhRMA also recommends that CMS consider soliciting input from physicians and teaching hospitals about how this information can be presented and what explanatory or educational information should accompany the aggregated data.

VII. Submission of Data

PhRMA recommends that CMS develop a standardized template for manufacturers to use in providing and formatting data, so that information is submitted consistently and uniformly. This template should be included as part of the proposed regulation so that stakeholders will have the opportunity to comment on it during the rulemaking process.

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PhRMA appreciates the opportunity to comment on the initial request from CMS for input on the Sunshine Provision. We look forward to a further discussion with CMS on these important issues in the near term and will be in touch to schedule an in-person meeting shortly. In the interim, please feel free to contact us if you have further questions or if you would like additional information.

Sincerely,

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Marjorie Powell
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