Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

April 7, 2011

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
physiciansunshine@cms.hhs.gov

**Re: Comments on Section 6002 of the Affordable Care Act**

Dear Sir or Madam:

BIO appreciates the opportunity to comment on the implementation of the Physician Transparency and Reporting provisions enacted in 2010 as part of the Affordable Care Act (ACA). BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,100 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. Corporate members range from entrepreneurial companies developing a first product to Fortune 500 multinationals. We also represent state and regional biotech associations, service providers to the industry, and academic centers.

## General Comments

Section 6002 of the ACA requires manufacturers to report certain payments to physicians and teaching hospitals, beginning with data collected for the 2012 calendar year. BIO supports the goals of the ACA in providing greater transparency regarding financial relationships with healthcare providers. BIO recognizes the challenges faced by the Centers for Medicare & Medicaid Services (CMS) in implementing the statutory provisions requiring manufacturers to report payments or other transfers of value made to physicians and teaching hospitals. This challenge is particularly difficult because the statute requires that CMS must establish procedures for the submission of manufacturer reports by October 1, 2011. BIO hopes that CMS appreciates that manufacturers also face significant challenges in developing and implementing policies, procedures and information systems to facilitate the mandatory collection of data that begins January 1, 2012.





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BIO believes that the goals of the ACA will be best achieved by:

- implementation of the statutory provisions with clear definitions and standards to ensure consistency in the collection, characterization and reporting of information;
- interpretation of the statutory provisions to preclude duplicate reporting that might create confusion; and
- provision of appropriate educational context to improve the public's understanding of the information provided and the need for collaboration between U.S. physicians and the life sciences industry.

The March 24 Open Door Forum (Forum) and this opportunity for submission of written comments are important first steps in the implementation process. However, BIO believes that additional opportunities are necessary to enhance CMS' understanding of the complicated nature of developing internal company systems for tracking this information and identify questions that must be answered to enable consistent and accurate manufacturer reporting. BIO believes that notice and comment rulemaking is necessary to fully and fairly address the issues raised by these statutory provisions--issues that are complex and largely of first impression in the federal arena. We are pleased that the moderator of the Forum stated that CMS plans to issue a Notice of Proposed Rulemaking (NPRM) in the near future.

CMS' notice announcing the Forum sets forth six categories of information for stakeholder feedback. In several of these categories, CMS queries whether a particular aspect of the ACA reporting requirements should be expanded. As we stated in the Forum, we see no areas that warrant expansion. Further, there are fundamental definitional issues that must be addressed. BIO strongly believes that the existing statutory requirements must be clearly interpreted and addressed in regulations before considering any expansion.

Additionally, many manufacturers are already subject to state laws that require information collection and reporting regarding financial interactions between manufacturers and certain health care providers. Compliance with these requirements has demanded significant investment in the development of policies and procedures as well as the acquisition of information systems. We hope that CMS will consider consistency with these local requirements in interpreting ACA requirements.

Further, we hope CMS will request comment on how the information provided by manufacturers should be presented by CMS to the public. Determining how this information will be presented to the public is a very important part of implementation. The statute requires that information regarding payments for clinical research be listed separately from other payment data. BIO suggests that direct compensation or fees for services also be presented separately from reimbursement for travel, valuation of meals provided and similar in-kind payment. Distinguishing between these payment types will prevent duplicate reporting and will provide a non-misleading disclosure to consumers, that can serve to avoid misperceptions regarding spending.

## COMMENTS REQUESTED

### Other Forms of Payment or Transfers of Value

Section 1128G(a)(1)(A)(v) lists the forms of payment or other transfers of value currently recognized by the biopharmaceutical industry. We are not aware of any additional forms of payment for which coverage is needed or appropriate.

It is critical that CMS clarify how the fifteen enumerated categories of payments will be interpreted. Additionally, it would be useful for CMS to clarify how the "amount of the payment or other transfer of value" provided by an applicable manufacturer to a covered recipient, as referred to in Sec. 1128G(a)(1)(A)(iii) will be determined where such value is not static, or otherwise clearly stated.

### Nature and Types of Payment or Other Transfers of Value

Section 1128G(a)(1)(A)(vi) lists types and natures of payment or other transfers of value currently used in the biopharmaceutical industry. No additional types are warranted.

We note, however, that the types of payments currently listed already involve considerable overlap. For example, consider whether payments for consulting on research projects should be treated as "consulting fees" or "research", or whether "honorarium" may be duplicative of "consulting fees" in some instances. Clear definitions will help provide certainty and consistency among reporting manufacturers. Similarly, physicians may provide expertise on research with regard to a specific drug as well as on general areas of research at the same meeting. CMS should prevent duplicative reporting and help manufacturers report this information in a meaningful and consistent manner.

### Additional Categories of Information to Report

Section 1128(a)(1)(A) lists specific categories of information to be reported. The intent of the statute is to communicate clear and understandable information to the general public on financial interactions between manufacturers and certain health care providers. Collecting and publicly disseminating additional information may obscure the reporting of the most relevant information and complicate CMS' efforts to make the current information understandable. The current reporting obligations imposed by the statute should be implemented by CMS before any additional categories are considered.

### Average Consumer Information

CMS requests feedback regarding the type of information to be reported to the public, including background on industry-physician relationships, as well as how the data collected from manufacturers can be presented in a way that is most understandable to consumers. The reporting provisions direct the Secretary to consult with stakeholders, including consumers and affected industry, as part of the process of establishing procedures for submission availability, to "ensure that the information made available to the public is presented in the appropriate overall

context." Section 1128G(c)(2). This is an important provision, highlighting the need to assure that the information to be provided publicly is preceded and accompanied by clear, objective background, directed to the target audiences, and that the information presented is clearly defined and explained. The information presented by CMS should focus on improving the public's understanding of the need for collaboration between U.S. physicians and the life sciences industry.

As BIO has stated in comments to other agencies within the Department where information is to be provided to patients and consumers, it is advisable to conduct focus group research and consult with experts to assure that the information presented is useful and not misleading. BIO strongly recommends that CMS conduct such research here, and also establish a taskforce comprised of representatives from industry, the provider community and public advocacy groups to advise on the development of the required background information on industry-physician relationships to be posted on the website.

**Reporting of Data**

CMS requests feedback regarding mechanisms to assure accurate, efficient reporting, including electronic format, and correction of reported data. These are significant and extremely complicated issues that will require an enormous amount of data to be organized, collected, and posted, presenting major challenges for both industry and CMS.

As an initial comment, BIO strongly recommends that a standardized template be developed and provided for use in providing and formatting data to ensuring consistent reporting. If CMS intends to adopt this, the template should be included in its proposed rule, for purposes of stakeholder notice and comment. It would also be important to have a confirmation mechanism to acknowledge the receipt of data.

CMS should provide a reasonable amount of time for manufacturers to correct data that has been reported, as well as an opportunity to seek correction of data or information once posted by CMS, in the event there are questions at that point regarding accuracy. This opportunity to correct data should be limited to the corrections and not a complete resubmission, as the quantity of data would be burdensome for both CMS and the manufacturer. Given the challenges inherent in developing internal manufacturer systems that will support the collection and reporting of substantial amounts of data to CMS, BIO requests that the Agency provide additional opportunities to communicate on these issues.

## KEY AMBIGUITIES AND CONCERNS

In addition to our responses to CMS' specific questions, BIO has initially identified several areas in the ACA provisions that warrant clarity, including the pivotal terms: "applicable manufacturer" and "covered recipient." Further clarification of these and other key terms is critical to enable manufacturers to adequately prepare for and begin compliance activities and to provide that information in a consistent manner.

**"Applicable Manufacturer"**

A majority of BIO members are start-up companies that only have development stage drugs and biologicals. Some of these companies engage in co-development activities with established companies that may have other marketed products. BIO members also include a number of companies that operate as a corporate affiliate, including as affiliates of parent companies located in other countries. Member companies also routinely have co-marketing or co-promotion agreements with other companies to jointly develop, market, or promote a product. Clarification is needed as to how the reporting requirements apply to these situations, including foreign parents, partners, and ex-U.S. affiliates.

Section 1128G(e)(2) defines "applicable manufacturer" as 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." BIO believes that, in defining the scope of applicable manufacturer, the focus should be on the company engaging in activities in the United States in support of marketed products. We recommend the following:

- CMS should clarify that a manufacturer is not subject to the reporting provisions unless or until the manufacturer has a product that has been approved for commercial distribution in the United States (including territories, possessions and commonwealths).

  Such a clarification is consistent with the definition of "covered drug, device, biological, or medical supply" as including only such products reimbursed under Medicare, Medicaid or the Children's Health Insurance Program, as products must generally be approved by the Food and Drug Administration before such programs will cover the product. Such a clarification is also consistent with the intent to enhance transparency in financial relationships between the makers of marketed health care products and the prescribers of the products. There is useful precedent for this, as states with existing disclosure requirements, such as Massachusetts, have not applied the disclosure requirements to manufacturers with no approved products.

- Manufacturers that operate outside the geographic boundaries established by the statute, and that do not own entities performing certain supporting activities pertaining to a covered drug as identified by the statute within those geographic boundaries, should not be subject to the statute. If covered drugs are sold to an independent third party, such as a distributor, that distributes and markets the covered drugs in the United States, that third party should be the applicable manufacturer, not the company that manufactures the covered drugs outside the United States.

- Similarly, corporate affiliates of manufacturers subject to the statute should not be equated with the manufacturer and made subject to the statute simply by virtue of that corporate affiliation.

  This is particularly true of affiliates that operate outside of the United States and have operations unrelated to the U.S. manufacturing, distribution and marketing of drugs, devices, biological or medical supplies. Application of the reporting provisions to such corporate

affiliates would be inconsistent with the statutory language and would not further the intent of the statute. The one provision in the definition of manufacturer addressing corporate affiliates --an affiliate of a manufacturer under common control with the manufacturer that operates in support of the manufacturing, distribution or marketing activities of the manufacturer -- demonstrates the intent to include in the scope of applicable manufacturer only those corporate affiliates essentially acting as agents for the manufacturer. In that case, the manufacturer should determine whether to report on behalf of the affiliate or if the affiliate should separately report.

- CMS should clarify which manufacturer has responsibility for reporting when more than one manufacturer is involved in promoting a product. BIO believes that transparency is not served by having two different manufacturers separately report the same payment. We propose that the manufacturer that actually made the payment report the payment, unless the terms of a written agreement between the parties provides otherwise.

**"Covered Recipient"**

Section 1128G(e)(6) defines "covered recipient" to include physicians and teaching hospitals. A payment or other transfer of value is reportable if the transfer is made by an applicable manufacturer directly to a covered recipient, or indirectly to an entity designated by the covered recipient. An indirect payment made to a covered recipient through a third party is excluded from reporting if the manufacturer is unaware of the identity of the recipient. Section 1128G(a)(1)(A).

There are many situations where there are payments and transfers of value made to third parties, some of which may benefit covered recipients, without identifying or designating the covered recipient. In some cases, the manufacturer may not determine or have knowledge of the specific amount of the payment ultimately made to the covered recipient. The payments may be made directly to a contract research organization (CRO) or other entity involved in research and clinical trials. In these cases, the recipient is not a covered physician or teaching hospital, but is engaged in contracting with other entities, some of whom may be covered recipients. These situations could involve payments from a CRO or other research organization to a physician or teaching hospital. Other examples would be a fellowship or grant awarded to non-teaching hospital or professional society to fund training for physicians; participation in meetings by physicians selected by the hospital or society without input from the manufacturer; or compensation paid to a marketing/survey firm to undertake market research using physicians selected by that firm. BIO recommends:

- If an applicable manufacturer has requested or directed that the research organization or other entity retain a specific physician or teaching hospital as part of the clinical trial or research service, the downstream payment should be considered to be a covered payment, (i.e. a payment made by the manufacturer, for purposes of reporting). If however, a manufacturer has not requested or directed that the payment from a CRO or other research organization be made to a specific physician or teaching hospital, that payment should be excluded from the reporting obligation. This should also be the case where the applicable manufacturer establishes general standards for selection, but does not make the selection.

The term "physician" also raises important administrative issues in Section 1128G(e)(6)(A)(i). The status of an individual as a physician can be confirmed by checking state licensure records. A manufacturer, however, would have to separately check the licensure records of all fifty states to confirm status as a physician. The effectiveness of such checks would be imperfect because some physicians may have the same name (e.g., Dr. Mary Smith), have multiple business addresses, or may hold licenses in many states.

While the ACA states that a "National Provider Identifier" (NPI) should be reported for each covered recipient to whom a payment is made, BIO understands that some physicians may not have a NPI, for example if the physician does not prescribe covered products. Further, it is possible for a physician or an entity such as a group medical practice or academic medical center to have multiple NPI numbers assigned. This concern leads to challenges for both reporting and aggregating information. Accordingly, we recommend:

- CMS should create a database of covered physicians with unique identifiers that would allow manufacturers to run a single query and rely on the results of that query. Some states have established such databases in implementing analogous state disclosure laws. Alternatively, CMS should allow the manufacturer to rely on the licensing status of the state in which the physician resides or practices, rather than all 50 states.

The term "teaching hospital" is open to interpretation in Section 1128G(e)(6)(A)(ii). Hospitals may engage in teaching activities to a greater or lesser extent – from hospitals that sponsor medical residency programs to hospitals that may from time to time accept rotations of single residents. Some hospitals may be involved in teaching medical residents or providing advanced teaching and education to practicing physicians or both. Also, a hospital engaged in teaching activities may represent one unincorporated component of a single entity that also houses other components such as a college or medical school. Manufacturers thus may not be able to readily detect whether hospitals are engaged in teaching activities. BIO recommends that:

- CMS should define teaching hospital clearly by creating a database or list of teaching hospitals. That list presumably would reflect all hospitals eligible for and claiming graduate medical education funding from CMS (or under the Children's Hospital Graduate Medical Education Payment Program). CMS would have ready access to such information.

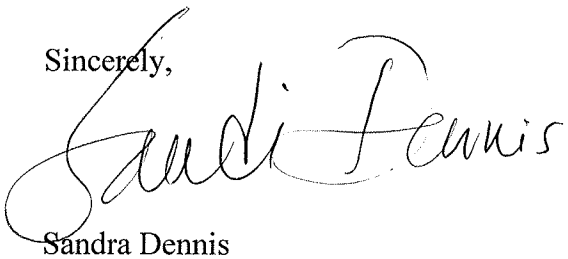
  Alternatively, CMS could define teaching hospital as a hospital that sponsors medical residency programs as identified by the Accreditation Council for Graduate Medical Education (which posts such information on its website). Payments to teaching hospitals should include those payments directed to the teaching hospital and, if the hospital is a component of a larger entity, not payments to universities or other parent organizations.

BIO respectfully requests that CMS consider the clarifications BIO proposes for key definitions in Section 6002. Absent clarification, the scope of the reporting obligations will remain unclear and may result in markedly different data submissions that will be difficult for CMS to aggregate and difficult for consumers to understand.

**Conclusion**

BIO appreciates this opportunity to comment on Section 6002 of the ACA. We request a meeting to further discuss these important and timely issues. We will contact you to follow up. If you have any questions regarding these comments, please contact me at 202-962-6673 or sdennis@bio.org.

Sincerely,



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