May 8, 2014

Via Electronic Delivery and United States Mail

Shantanu Agrawal, M.D., Deputy Administrator and Director
Center for Program Integrity
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Open Payments; Public Website Background Information/Context

Dear Dr. Agrawal:

On behalf of the members of the Advanced Medical Technology Association ("AdvaMed"), we write regarding Open Payments, the program implementing Section 6002 of the Affordable Care Act ("ACA"); specifically the background information to be included on the public website to provide context regarding relationships between the drug and device industry and physicians and teaching hospitals.

We appreciate the open dialogue we have shared with the Centers for Medicare & Medicaid Services ("CMS") and legislators regarding Open Payments and offer these comments in the same spirit of continued constructive cooperation.

We are writing to stress our views on the critical importance of CMS furnishing, in any future Open Payments disclosures, clear background information and context regarding industry relationships. We believe providing context – giving patients understandable, meaningful information concerning industry relationships – is extremely important in ensuring that the legislative intent of Open Payments is met, without discouraging beneficial interactions critical to the development and safe and effective use of innovative medical technologies. Indeed, we have commented on this issue before\(^1\) and by this letter reiterate our recommendations regarding website context information. Our comments below apply to any public release by CMS of information submitted by manufacturers pursuant to Open Payments, including the public release of aggregate data submitted by manufacturers as part of Phase I, Step 2 of the data registration and submission process.

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\(^1\) See, e.g., AdvaMed’s letter dated July 12, 2011 to Dr. Berwick regarding implementation of Section 6002 of the ACA; AdvaMed’s letter dated February 17, 2012 commenting on the proposed rule implementing Section 6002 of the ACA; AdvaMed’s letter dated April 9, 2013 commenting on the final rule implementing Section 6002 of the ACA.
Website Context Information Generally

Open Payments requires CMS to establish a clear and understandable website that reports the required data and payment provisions, but also includes background information on industry-physician relationships. As we noted in our previous comments, such background ensures the reported data is meaningful and helpful in patient decision-making. Further, providing context for reported payments and other transfers of value is critical to ensuring patients do not form mistaken impressions that all payments to physicians are suspect. Further still, for the information posted on the website to be clear and understandable, the website CMS designs and develops must be functional for both those reporting information and those reviewing reported information.

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

Indeed, the public reaction to CMS’ recent release of Medicare provider utilization and payment data for physicians and other suppliers underscores the need for accompanying comprehensive and appropriate context information with respect to publicly available data. That release elicited stake-holder complaints regarding a lack of context with respect to the data.²

The possibility of misinterpretations, misunderstandings, and false assumptions if proper context is not provided is particularly high with respect to the public posting of aggregate data submitted by manufacturers as part of Phase I, Step 2 of the data registration and submission process. Unlike the detailed data reporting required by the statute and the final regulations, the Phase I aggregate data submission required manufacturers to identify only the following for general and research payments: (i) Total aggregate amount of payments or other transfers of value provided to covered recipients or physician owners/investors during the reporting period; (ii) Total number of payments or other transfers of value made; and (iii) Total number of covered recipients or physician owners/investors that were recipients of the payments or other transfers of value during the reporting period. The aggregate data submission did not include, for example, covered recipient names nor nature of payments categories. Also, although the aggregate data submission required manufacturers to submit aggregate information regarding research payments, the submission did not allow manufacturers to indicate what, if any, portion of the

aggregate data was eligible for delayed publication. For these reasons, publicly posting the aggregate data is particularly at risk of misinterpretation without appropriate context and background. We therefore renew and resubmit our earlier stated positions and recommendations regarding Open Payments context and background.

Stakeholder Input on Background Text

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

In the final rule implementing Section 6002 of the ACA, CMS agreed that stakeholder input is essential to the success of the public website and indicated that it planned to engage stakeholders regarding the content of the website. We appreciate CMS' willingness to engage in an open dialogue regarding this important issue, and we share again additional information and context related to medical device company-physician interactions.

Examples of Industry and Physician/Teaching Hospital Arrangements

There are numerous ways in which medical innovation companies compensate physicians, academics, and health care professionals for their time, expertise, and intellectual property in connection with the development of new medical technologies, the improvement of existing technologies, and training and education of other health care professionals in the safe and effective use of medical technology, among other beneficial services. These arrangements fuel advances in medical technology, and improve medical care and the quality of health care available to American patients and consumers. We recommend that the background text include specific information regarding the various common arrangements between industry and physicians and teaching hospitals. Included as Appendix A is proposed background text related to specific examples of common arrangements between industry and physicians and teaching hospitals.

Codes of Conduct

In addition to the above information, it is important to note that industry-physician relationships are also driven by manufacturers' voluntary compliance with and adoption of codes of conduct, such as AdvaMed’s Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code” or “Code”). AdvaMed’s Code distinguishes interactions that result in bona fide contributions to the advancement of medical technology, and has long guided companies on...
structuring many of the relationships pursuant to which reportable transfers of value are paid (e.g., consulting; royalties). Pursuant to the AdvaMed Code, medical technology companies, both AdvaMed members and non-members, may certify that they have agreed to abide by the Code, and further that they have implemented policies and procedures to implement the Code as part of an effective compliance program. In addition to the Code, AdvaMed takes aggressive steps on an ongoing basis to educate the industry and health care professionals about the Code, ethical interactions, and compliance. The AdvaMed Board Committee on Ethics and Health Care Compliance has approved a series of Code of Ethics Best Practices guidance documents to assist companies in ensuring that their interactions with health care professionals, including physicians, are ethical and compliant. The AdvaMed Code and the specific Code of Ethics Best Practices guidance documents are available on AdvaMed’s website at http://advamed.org/issues/1/code-of-ethics.

In developing website content related to the nature of relationships between physicians and teaching hospitals and the industry, including an explanation of beneficial interactions, we recommend that CMS incorporate existing industry codes of conduct and guidance, including the information referenced above. Such codes and guidance are widely accepted within the industry and have been developed with the intent to differentiate beneficial financial relationships from those that may create improper conflicts of interest.

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We thank you for considering these comments, and AdvaMed looks forward to continuing to engage in active dialogue with CMS regarding the implementation of Open Payments.

Sincerely,

Christopher White, Esq.
Senior Executive Vice President, General Counsel
APPENDIX A

Examples of Industry and Physician/Teaching Hospital Arrangements

• Consulting Fees are both common and essential in the physician-industry innovation-focused relationship. Physician expertise is critical in the development of new medical technologies as well as the refinement and improvement of existing medical devices. Physician input into the device development process assures that an innovation will be of practical use to medical practitioners and will improve patient outcomes. For example, implanted medical devices can sometimes be reshaped to make it easier for physicians to implant. Such an adjustment can save time and prevent potential complications. An improvement such as this cannot be done without the input of physicians who have real world experience with the device. Consulting fees are also paid for a variety of other activities, including training sales staff and other physicians on safe and effective use of an applicable manufacturer's products.

• Honoraria may be paid when physicians provide their time, preparation, and expertise to conferences or medical congresses to share research, provide input on new innovations, and highlight clinical challenges with existing technologies. These discussions are critical to educating physicians, advancing the science of medicine, and ensuring the efficacy of new products. Additionally, honoraria may be paid for instructing company personnel, such as medical science liaisons and research development professionals, about the clinical challenges faced in a particular practice area. Physicians deserve compensation for the time taken away from their practice to help with these efforts for the common good. Honoraria therefore may be paid for the same types of activities as consulting fees, although honoraria are typically used when the physician is expected to provide a limited number of services during a year, and an honorarium agreement may be entered into for each service.

• Education is an essential component of the innovative process. When a new device is developed, or an existing technology improved, physicians and other health care professionals often require training on the correct technique, application and usage of the technology. In fact, in many cases, the FDA requires product-specific training and education for new devices.

• Research is the bedrock of advancing medical progress. To bring a new, beneficial health care innovation from concept to the patient may require years of research and development, at substantial expense. Manufacturer's research payments compensate physicians, health care professionals, research institutions, and members of the academic community who bring their unique expertise and perspectives to the research and development process. Research payments and grants offset a variety of other expenses related to research and development, such as institutional review board preparation and approval, patient informed consents, patient follow-up visits for designated periods of time, reimbursement of certain patient expenses, submission of
required data, adverse event reporting, investigator meetings, monitoring visits to confirm compliance, and publication of clinical results.

• **Royalty or license.** In many cases, a new product or an improvement of an existing technology springs from the mind of the health care professional. As practitioners in the field, physicians regularly generate new ideas, designs or prototype technologies. In exchange for the physician's intellectual property rights and know-how, companies and physician-innovators may enter into agreements that grant the physician innovators royalties or other payments based on sales of products that use the physicians' intellectual property.

• **Direct compensation for serving as a faculty or a speaker.** Physician-to-physician sharing of medical and scientific knowledge is vital to disseminating information on the most effective uses and applications of new medical innovations, and in training other practitioners on the safe and effective use of technology. Manufacturers typically do not compensate faculty for accredited programs; instead, they compensate physicians serving as faculty for manufacturer programs through consulting or honoraria agreements.