AMA
AMERICAN
MEDICAL
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Michael D. Maves, MD, MBA, Executive Vice President, CEO

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Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments concerning Open Door Forum on Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Administrator Berwick:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to submit comments as part of the Open Door Forum on Transparency Reports and Reporting of Physician Ownership or Investment Interests. We look forward to working with the U.S. Department of Health & Human Services (HHS) to ensure that the transparency provisions of the Affordable Care Act (ACA) are implemented and consistent with congressional intent to ensure that accurate and useful information is available to the public and safeguards are in place to prevent the publication of false, inaccurate, or misleading information.

We have two threshold comments that are outside the scope of the questions posed by the Centers for Medicare and Medicaid Services (CMS) as part of the Open Door notice, but are important to address during rule-making. First, the ACA contains a number of statutorily specified transfers of value that are identified by a host of categories and are subject to reporting. We strongly urge CMS to direct applicable manufacturers to count only once any transfers that could be categorized in more than one way. Double counting will not promote transparency and will create confusion.

Second, we urge CMS to clearly define all of the forms of value specified in statute. For example, "education" is one of the categories specified in the ACA that is subject to reporting, but there appears to be confusion already with regard to certain categories of continuing medical education (CME). CMS provided the following language in the notice concerning the Open Door:

> For CME, grants will be reported if they are requested on behalf of a specific physician and/or are given to a teaching hospital…. Many stakeholders in the CME community and healthcare industry have a large interest in ensuring that the reporting requirements under the Sunshine Act are clear, logical, and common sense.

In the broadest terms possible, the term "education" could encompass "promotional" activities, "certified CME," and noncertified CME. However, the term CME typically is used to identify "certified CME."

"Certified CME" is governed by the Standards for Commercial Support: Standards to Ensure the Independence of CME (SCS), promulgated by the Accreditation Council for Continuing Medical Education (ACCME), as well as the AMA *Code of Medical Ethics*. It includes educational activities developed and implemented in compliance with the certification requirements of the AMA's Physician Recognition Award (PRA) CME Credit System, or the accrediting policies of the American Academy of Family Physicians or American Osteopathic Association. Certified CME vis-à-vis individual physicians (even physicians attending or presenting at a certified CME program) is outside the scope of the ACA reporting requirement because any value received by an individual physician would be an indirect transfer.

In contrast, promotional activities could be categorized as educational and potentially could be subject to ACA reporting. Promotional activities are defined by the Food and Drug Administration (FDA). These are activities developed by or on behalf of a commercial entity and under the substantive influence of that entity to provide information on the therapeutic use of a product or service. These activities are governed by the labeling and advertising provisions of the Food, Drug, and Cosmetic Act. To the extent that an applicable manufacturer transfers items of value directly to a physician, this would be subject to reporting, but this would not be the case if it was an indirect transfer.

Beyond the foregoing, there are activities designed to inform and educate practicing physicians that are neither promotion nor certified CME. These other activities may or may not be commercially supported, may or may not voluntarily adhere to AMA policy or ACCME Standards for Commercial Support^{SM}, and may or may not be recognized by licensing bodies or credentialing boards as fulfilling CME requirements. These activities may be subject to reporting if the physician receives the value directly.

Additional Forms of Payment or Transfer of Value or Information

The ACA lists 14 specific natures of payment and transfers of value that applicable manufacturers are required to report. At this time, we urge CMS to require reporting on the forms of payment or transfers of value specified by statute. Reportedly, manufacturers have conducted a preliminary assessment of the data points that will require reporting based on the current statutorily identified forms of payment and transfers of value. As we anticipated, given the low threshold that triggers reporting and the breadth of reporting scenarios, the amount of data will be substantial. We believe that the current reporting requirements are exhaustive, and

going beyond the statutorily identified transfers has the potential to create significant confusion and burden. We urge CMS to develop the infrastructure and then assess whether additional expansion is warranted in a few years.

Average Consumer Information

We urge CMS to include information that clearly specifies that the transparency registry does not govern ethical conduct. There is, already, confusion about the transparency registry. There are those who believe, incorrectly, that the registry establishes ethical standards. Also, we urge CMS to include information that clarifies that there are many scenarios under which transfers of value are appropriate and helpful to patients and those that are not. Ethical codes of conduct, such as the AMA's *Code of Medical Ethics*, should be referenced generally and links provided to the various Codes of Conduct. We also urge CMS to include any comments or clarifications submitted by physicians related to transfers of value or ownership interest(s) that they received/own and which is the subject of a public report.

Reporting of Data

Electronic form

We strongly urge CMS to establish a mandatory electronic form and program that all reporting entities must use. We urge CMS to issue a template of the mandatory electronic form as part of rulemaking.

Corrections of Reported Information

The purpose of the transparency provisions of the ACA will be met only if the information subject to public disclosure is accurate and true. We strongly urge CMS to develop a process that ensures physicians (and other prescribers covered by the law) receive actual notice at least 60 days prior to public disclosure of what is contained in the reports of applicable manufacturers and group purchasing organizations.

The law provides that physicians must have an opportunity to review and submit corrections to the information submitted concerning the physician for a period of not less than 45 days prior to such information being made available to the public. This legal requirement cannot be met if physicians are not provided notice of the information contained in the report before the 45-day period begins and prior to the publication. We urge CMS to send a notice via electronic mail and U.S. Mail directly to each physician urging them to review their consolidated report from a website or phone number.

We also recommend that CMS use all existing physician communication vehicles to notify physicians of their right to review and correct their consolidated report and provide guidance on the process to challenge inaccurate, false, or misleading reported transfers of value or categorizations of form. Furthermore, we urge CMS to partner with organized medicine to

annually push out notices through state medical associations and national medical specialty societies.

We strongly recommend that CMS establish an expedited method to adjudicate disputes where physicians and reporting entities are allowed to challenge the accuracy of reports. As discussed above, we also urge CMS to provide physicians with the opportunity to include information or explanations in their public reports, including information on disputed items.

The AMA appreciates the opportunity to offer our comments. We hope that our recommendations on this issue prove helpful to CMS. We look forward to working with the agency as it continues its activities in this area. If you have questions, please contact Margaret Garikes in our Washington office at margaret.garikes@ama-assn.org.

Sincerely,

Michael D. Maves, MD, MBA