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Regulations Development Group
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

RE: Public Comment on Proposed Information Collection: *Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments*
Document Identifier: CMS-10493 and CMS-10495

Dear Ms. Jones:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Proposed Information Collection: *Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments* [also referred to as the Physician Payments Sunshine Act]. The proposed data collection exceeds the necessity and utility of the proposed data elements needed to implement the Open Payments Program (hereinafter referred to as the Sunshine Act Program). We strongly urge the Centers for Medicare & Medicaid Services (CMS) to adopt the recommendations outlined below in order to comply with the Paperwork Reduction Act (PRA).

CMS Enterprise Portal and User Identity Management Systems

CMS specifies that, in addition to registering for the Sunshine Act Program physician portal, physicians must first register with the CMS Enterprise Portal and User Identity Management Systems (EPIM). The discussion document does not contain a justification under the PRA for this requirement. As a result, we cannot evaluate whether or not there is a rational basis for this requirement. CMS is urged to provide a discussion and justification for this requirement and solicit comments before imposing this administrative burden.

Physician Emails and Phone Numbers

Physicians are not required by the Sunshine Act to provide CMS with their emails or phone numbers. The data templates appear to mandate the submission of information in order for physicians to utilize the Sunshine Act Program physician portal to review, dispute, and seek correction of reports, including

emails (business and personal) and phone numbers (business and personal). Requiring physicians to submit a broad scope of information not mandated by law, or creating the impression that such information is required as opposed to voluntary, violates the Sunshine Act statutory provisions. It also runs afoul of the congressional intent to limit the scope of personally identifiable physician information that would be disclosed to the public through the public Sunshine Act Program website or pursuant to Freedom of Information Act (FOIA) requests. To the extent that CMS concludes such information is essential for the implementation of elements of the program, such as electronic notification, we urge CMS to unambiguously communicate that the information solicited is not required and is protected by the Privacy Act and exempt from disclosure to third parties under FOIA.

Specifically, we urge CMS to clarify that the submission of phone numbers (business or personal) or emails (business or personal), is voluntary, and is not required to review Sunshine Act consolidated reports, dispute the contents of such reports, or secure corrections. Furthermore, to the extent that physicians (or their representatives) elect to receive notifications, they should not be compelled to provide more than one email or phone number for such notifications. Further, CMS must notify physicians in advance if the agency takes the position that voluntarily submitted information, such as emails and phone numbers, will be disclosed to the public based on a FOIA request or used for other agency or government activities. The agency is also required to notify physicians if it intends to use such contact information for any purpose other than the Sunshine Act Program.

The Sunshine Act limits the information that CMS may compel parties subject to the Sunshine Act to submit and further restricts what information may be provided to the public. For example, manufacturers are required to submit a physician's national provider identifier number (NPI), but the agency is prohibited from publishing this information in the Sunshine Act Program public database. The Sunshine Act Program provision of the Affordable Care Act modified the Social Security Act by adding a new section. This new section requires reporting entities to provide CMS with: (1) the name of the covered recipient; and (2) the business address of the covered recipient, and in the case of a covered recipient who is a physician, the specialty and NPI of the covered recipient. In a subsequent section, CMS is prohibited from including the NPIs in the public website. The data elements for identifying physicians were limited by Congress to ensure that the minimum amount of information was collected to protect the privacy interests of physicians and, equally important, to minimize the risk of identity theft.

To the extent physicians want to have CMS notify or communicate with the physician or the physician's representative, CMS should specify that physicians (and/or their representatives) have the option of: (1) logging into the online portal to obtain information without notification (via email, phone, or mail); or (2) selecting a method or method(s) of notification. Further, CMS should urge physicians to carefully select the method of communication or contact with the agency.

Estimated Impact and Burden of Review and Dispute Resolution

A number of erroneous assumptions were made when estimating the number of physicians who will be impacted by the reporting requirement and the burden of this program on physician practices. CMS' projections of anticipated burden on physicians and their designated representatives of reviewing Sunshine Act reports and achieving dispute resolution is based on an inadequate assessment of the number of physicians subject to reporting and extrapolated from state-based Sunshine reporting requirements that are not as broad in scope or nearly as complicated. Further, it does not appear that

physician organizations were systematically asked to provide comments on these projections though it appears other stakeholders were.

State-based reporting requirements are not reasonably comparable to the national Sunshine Act reporting requirement in terms of scope of items that are reportable, the number of physicians subject to reporting given the broad scope of indirect transfers included by CMS, as well as the inclusion of reprints and medical textbooks. Extrapolating the resource impact based on state transparency reporting requirements seriously underestimates the impact of the federal Sunshine Act. The Sunshine Act regulations include a broad number of indirect transfers, unrivaled in most state reporting requirements and well in excess of what is reasonably authorized by the federal statutory language. Furthermore, in recently issued sub-regulatory guidance, CMS expanded the reporting requirements to include reprints of articles from peer reviewed medical journals that are already readily available to physicians for free. Not only is this last minute decision estimated to triple the expected reporting requirement, but it is highly unlikely that the majority of physicians and patients would consider clinical resources, such as journal articles, reportable gifts. To the extent that physicians continue to accept such reprints, we anticipate widespread disputes over the correct fair market value since the reprint articles would be free in many cases to physicians and any other valuation would be contrary to the statute and congressional intent as the Sunshine Act was designed to capture the transfer of value to physicians—not convenience costs to manufacturers. At a time of austerity, these disputes are likely to consume significant physician resources and agency resources well in excess of projections based on indirect transfers and reprints alone.

Physician interest in reviewing such reports will be far more robust compared to state reporting registries given the ease of access to the national public registry and what is reasonably expected to be in-depth media coverage. CMS should anticipate that the majority of licensed physicians will seek to review and secure corrections to such reports in 2014. Currently, many physicians are unaware that they are receiving reportable indirect transfers. After the information is made public, there may be significant disputes related to valuations or characterizations of such transfers. Given the unworkable standard governing indirect transfers that undermines the limits established in the statute, we expect that there will be litigation that was not factored into the resource assessment of this document. Because false and inaccurate reporting could cause reputational harm and damages, including loss of patients, termination from employment or sanctions, increased governmental scrutiny, and deterioration in professional standing, CMS has underestimated the resources physicians will need to expend to ensure reports are accurate and fair and the costs in these other areas due to false and inaccurate reports. We expect the costs are easily double the current per physician time and cost estimate and should include most physicians.

Finally, in light of the foregoing concerns, physicians are entitled as a matter of law, based on the Sunshine Act provisions and fundamental due process rights afforded to individuals who would be harmed by government action, to include public comments in the public registry on all transfers without regard to whether there is a dispute. Government actions that facilitate the publication of false, inaccurate, and/or misleading information about individuals without affording the individuals, in this case physicians, the opportunity to present their perspective is a denial of a fundamental due process. The AMA strongly urges the agency to give physicians the opportunity, through the public registry, to provide commentary about all reported transfers of value and ownership interests. CMS must provide physicians with the option to provide comments on their public reports similarly to reporting manufacturers and group purchasing organizations. Any other outcome denies physicians their fundamental due process rights and undermines the congressional intent that is at the core of the Sunshine Act that the public will

receive fair and accurate information with appropriate context. Furthermore, CMS has the authority to provide this option through sub-regulatory guidance since this was not prohibited in the final regulation.

The above is all the more pressing in light of reports that the majority of inaccurate reports will not be corrected prior to publication. Congress reasonably expected that the agency would provide an adequate amount of time for disputes to be resolved prior to publication. However, the AMA has received reports from individual manufacturers as well as major stakeholders, that there will be widespread errors and little to no likelihood that the disputes will be resolved prior to publication. Congress intended that disputes would, for the most part, be resolved prior to publication otherwise the pre-publication review period is without any meaningful value.

We appreciate the opportunity to comment and urge CMS to adopt the recommendations outlined above.

Sincerely,

James L. Madara, MD