AMA
AMERICAN MEDICAL ASSOCIATION

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October 10, 2012

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Acting Administrator Tavenner:

The American Medical Association (AMA) appreciated the opportunity to participate, along with the Centers for Medicare & Medicaid Services (CMS), in the September 12, 2012 Roundtable on the Physician Payments Sunshine Act (Sunshine Act) hosted by the U.S. Senate's Special Committee on Aging. In light of the issues raised, we are submitting follow-up comments to you on Sunshine Act implementation. Although the Roundtable participants represented disparate stakeholder interests, there appeared to be consensus on a number of key issues, including the need to ensure an adequate period of time for implementation prior to triggering the reporting requirement, limiting the scope of the reporting requirement to transfers explicitly specified by statute, and ensuring that legitimate, legal, and ethical transfers of value and other interactions between industry and physicians are not framed as suspect, inappropriate, or fraudulent. **All stakeholders agreed, including the U.S. Senators who introduced the Sunshine Act, that the purpose of the law is to promote transparency, not to chill, or curb, otherwise appropriate interactions that advance the art and science of medicine.**

As we have stated previously in discussions with CMS and in our formal written comments on the proposed rule, we support the underlying goal of enhancing transparency. However, we believe the proposed rule, if implemented without significant modifications, will result in the publication of misleading information and impose costly and burdensome paperwork requirements on physicians while shedding very little light on actual physician-industry interactions. Below we have amplified on areas of concern in the proposed rule as well as recommended modifications to ensure that the final rule comports with the statute as well as congressional intent. **We look forward to working with CMS and other stakeholders in**

order to streamline the regulatory burden, ensure accurate and fair reporting, and allow adequate time to conduct outreach and education on the final rule to physicians.

Implementation of the Final Regulation

The AMA supports transparency and to that end, we have worked with Congress on the Sunshine Act. As we noted during the Senate Roundtable, there were modifications made to the Sunshine Act that reflected a considered decision to avoid a "boil the ocean" approach to transparency reporting as this would create more questions than answers, increase disputes, and impose a substantial administrative burden.

Several key points that we made during the congressional debate and at the Senate Roundtable bear repeating here as CMS makes important decisions with regard to implementation of the Sunshine Act. It is critically important that the final rule and resulting mode of implementation do not create the impression that the transparency reporting requirements establish ethical standards or reflect program integrity or fraud and abuse laws.

The AMA was founded with the purpose of establishing ethical standards for all physicians. First developed in 1847, the *AMA Code of Medical Ethics* (AMA Code) undergoes continual revision, guided by the AMA Council on Ethical and Judicial Affairs (CEJA). The opinions contained in the AMA Code establish core standards of conduct for the medical profession that address relevant issues in medical practice. The AMA Code constitutes the most comprehensive source of ethical guidance for physicians and serves as the primary compendium of medical professional ethical statements in the United States. **While not all transfers are subject to reporting under the Sunshine Act, the AMA provides ethical guidance that covers all transfers—including indirect ones.**

The AMA has clear ethical guidelines that govern physician interaction with industry. In brief, based on the AMA Principles of Medical Ethics (Principles) and the AMA Code, physicians' responsibility to their patients is paramount. **This means that physicians must not place their own financial interests above the welfare of their patients and their medical recommendations must not be inappropriately influenced by financial considerations**.[1] The AMA, along with other stakeholders in the medical profession, continues to take appropriate measures to reduce the actual or perceived conflicts-of-interest that might arise from industry transfers of value to physicians, in order to safeguard the delivery of quality health care based on the best available science, thus earning and maintaining the trust of patients.

[1] In 2011, the AMA's House of Delegates, a deliberative body comprised of representatives from state medical associations and medical specialty societies, adopted an ethics policy on Financial Relationships with Industry in Continuing Medical Education proposed by CEJA. CEJA's report on this matter identified the core ethical principles of transparency, independence, and accountability. The report's recommendations provide practical ethical guidance to maintain the independence and integrity of continuing professional education and promote public trust.

The AMA believes that physician relationships with industry should be transparent, meaningfully independent, and focused on benefits to patients. The AMA supports providing information that physicians and the public need to make informed, critical judgments about physician-industry relationships. In addition, the AMA supports practices that ensure that a physician's clinical judgments are objective and evidence based and that a physician's interactions with industry are transparent.

The Sunshine Act does not set ethical standards for the medical profession nor does it codify fraud and abuse or program integrity laws. We urge CMS to take steps to make the foregoing clear. **While the transparency reporting undoubtedly could provide information in some cases on transfers that violate professional ethical codes or even federal and state fraud and abuse laws, the purpose of the Sunshine Act registry is not to supplant the role of the profession in regulating ethical conduct or to create new fraud and abuse laws.**

There is a danger in conflating these issues since it could lead to a public perception that most, if not all, transparency reports are prima facie evidence of unethical or illegal behavior. This perception has the potential to chill beneficial collaboration and information exchange between physicians and industry. For example, we would not want a stigma associated with industry-physician collaborations that facilitate the clinical application of knowledge we are rapidly gleaning about the human genome. New technologies and discoveries such as molecular pathology diagnostics have the potential to revolutionize the practice of medicine as we know it. Physician decisions are heavily dependent on the quality of the scientific information available, provided to them, in part, by industry and federal regulators. There remains a need for interactions between physicians and industry to ensure the free flow of valid scientific information. When the information is accurate and complete, physicians have the necessary tools to make the right treatment decisions. If information is not properly provided by industry, or if physicians never receive such information, necessary and appropriate medical care can be jeopardized.

For the above reasons, we urge you to reconsider tasking the Center for Program Integrity with implementation of the final Sunshine Act regulation because it will cause significant confusion about the purpose of the transparency reports and create a strong perception that anything contained in a transparency report presumptively raises ethical, fraud, abuse, and program integrity concerns. The sponsors of the Sunshine Act made clear during the Senate Roundtable that this was not their intent since the majority of the interactions are appropriate. Yet, CPI's implementation could create the perception that the reports raise program integrity concerns. Combating this perception could be exceedingly difficult and will unduly chill appropriate, legal, and ethical physician-industry interactions that promote innovation and advances in clinical knowledge. While we appreciate that CPI has experience with the imposition of civil money penalties (which manufacturers potentially would be subject to if they fail to comply), **we recommend bifurcation of the responsibility whereby another component of the agency is responsible for the data collection, reporting, and appeals while CPI is referred**

compliance matters including enforcement. Further, we have additional concerns that some transparency reports—we anticipate a small number—could be used as evidence by CPI in its program integrity role and, yet, CPI would control the corrections and other elements of what would become evidence. This creates a strong perception of, if not an actual, conflict of interest where a component of an agency molds and generates the evidence that then is used by the very same component of the agency to establish violations of agency policies or fraud and abuse/program integrity laws. The foregoing is mitigated through checks and balances and is not an uncommon practice and policy within the U.S. Department of Health and Human Services.

Areas of Concern with the Proposed Rule

The following areas provide a summary of the AMA's additional concerns and recommended changes to the proposed rule.

CMS is Required to Publish Accurate Transparency Reports

CMS has proposed a process that would deny physicians substantive and procedural due process rights. The proposed process is unlikely to ensure accurate reporting or a reasonable opportunity to correct false, misleading, or inaccurate reports by severely limiting the ability of physicians to review and challenge incorrect reports. The proposed rule does not require manufacturers to provide physicians with the option of an ongoing opportunity to check reports nor does it indicate that the agency or some other independent third party will arbitrate disputes between physicians and manufacturers. In addition, the agency proposes to severely restrict the ability of physicians to challenge reports with a compressed 45 day window.

Limiting physician response to a 45-day window is inconsistent with Congress' intent to ensure such reports are accurate and is inconsistent with the fact that there is no similar constraint on requesting correction once a report has been made public. In light of the current state of technology, industry has the capability to allow for real-time updates and modification of reports. All of the foregoing was born out during the Senate Roundtable by the comments offered by the Sunshine Act sponsors as well as the industry participants that included representatives of pharmaceutical and medical device companies.

We strongly urge CMS to restructure the process that the agency has outlined and require industry to provide physicians with ongoing access to reports, provide physicians an opportunity to include commentary to any public disclosures of transfers, and establish a neutral arbiter to resolve disputes. The proposed rule opens the door to the real possibility that a large number of physicians could become the victims of false, inaccurate, or misleading reporting and suffer significant damages including investigation by government and private entities, potential disciplinary actions, public censure, ridicule, and destruction of professional reputation and livelihood.

CMS is Not Authorized by Statute to Expand Reporting to Indirect Transfers (Not Otherwise Specified in Statute) Such as Certified CME

Although the statute limits reporting to direct payments/transfers of value to physicians (with certain carefully specified exceptions), CMS has proposed expanding the category of transfers subject to reporting to a broad class of indirect transfers. The statute requires that manufacturers report indirect payments and transfers of value made to third parties at the request of the physician or as designated by the physicians, thereby closing a potential loophole to avoid reporting that had characterized original Senate and House bills (S. 2029, "Physician Payments Sunshine Act of 2007" and H.R. 5605, "Physician Payments Sunshine Act of 2008"). By opening the door to a far broader number of indirect transfers that are of questionable relevance, the proposed regulation would obscure significant interactions between industry and physicians and impose a significant paperwork burden.

Equally concerning, CMS has proposed reporting standards that will include indirect transfers that occur through certified CME[2]—this interpretation is not supported by statutory language. The AMA agrees that other educational activities, including those that are characterized as CME (but which are not certified), could be subject to reporting as there could be direct transfers of value to individual physicians and industry could control and/or influence the content of the educational materials. Certified CME is independent and manufacturers have no control or input into the content, the speakers, or the attendees. In light of the foregoing, certified CME is not covered by the Sunshine Act and CMS should make this clear. Furthermore, there was broad agreement among the Senate Roundtable participants that requiring reporting on indirect transfers including certified CME would pose a significant administrative challenge and were not the type of transfers that most concern patients.

CMS is Required to Ensure Accurate Attribution and Is Not Allowed to Use Estimates

Whereas the Affordable Care Act (ACA) provides for reporting of actual payments/transfers of value to a covered physician, CMS has proposed attributing a payment/transfer on the basis of a physician's employment, affiliation, or association with an entity or person that received a direct payment/transfer even if the physician him or herself did not receive any payment/transfer, direct or indirect. Attribution even where there is no direct transfer or qualifying indirect transfer is beyond CMS' statutory authority, violates basic principles of due process, and is inconsistent with congressional intent.

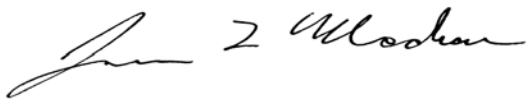
Congress did not intend that transfers of value made by manufacturers to an organization or entity that employ physicians be apportioned among physicians affiliated with the organization without regard to whether individual physicians received the transfer, requested

[2] Certified CME is defined as: 1. nonpromotional learning activities certified for credit prior to the activity by an organization authorized by the credit system owner, or, 2. nonpromotional learning activities for which the credit system owner directly awards credit.

the transfer, or designated a third party to receive it on their behalf. To do so could result in grossly misleading reporting. Physicians employed by a large organization or institution could have payments/transfers imputed to them that they had no knowledge of, no opportunity to decline, did not receive directly (or even indirectly), and are unable to challenge effectively. CMS is required to direct manufacturers to document and report only those payments and transfers made directly to physicians or those specified indirect transfers/payments requested by the physician or designated on their behalf. We strongly oppose CMS' proposal for reporting of payments/transfers attributed to individual physicians solely on the basis of their affiliation with organizations or institutions that received payments/transfers of value.

We appreciate the opportunity to provide our views to CMS staff, and we look forward to working with you and other stakeholders to promote the goal of transparency in a meaningful manner. If you have any questions, please contact Carol Vargo, Assistant Director, Federal Affairs at 202-789-7492 or carol.vargo@ama-assn.org.

Sincerely,



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