American Society of Anesthesiologists

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February 14, 2012

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

Re: CMS-5060-P, Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests.

Dear Ms. Tavenner:

On behalf of the over 48,000 members of the American Society of Anesthesiologists (ASA), I would like to thank you for the opportunity to comment on the Transparency Reports and Reporting of Physician Ownership or Investment Interest Proposed Rule (hereafter referred to as "Proposed Rule") that was published in the *Federal Register* on December 19, 2011. **ASA supports transparency and accountability. We believe the public should have access to accurate information about manufacturers' payments to physicians and that physicians should have a fair opportunity to dispute inaccurate reports.**

Exhibits

We appreciate and support the Centers for Medicare and Medicaid Service's (CMS) proposal to exclude certain items provided at conferences and events as "it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings." However, we seek additional clarification from CMS regarding gifts received. We give you the following example and request a response in the final rule.

Example: A physician received a total of $95 worth of meals from a manufacturer during the calendar year (with each meal being worth less than the $10 reporting threshold). That same physician attends a meeting where he/she accepts a cup of coffee valued at $6 from that manufacturer's exhibit booth. **Now that the physician has accepted over the $100 total threshold from one manufacturer in one calendar year, would the physician be subject to reporting by the manufacturer?** The proposed rule appears clear that food and beverage accepted at an event is exempt from the manufacturer reporting requirement. CMS stated "we propose that applicable manufacturers do not need to report any offerings of buffet meals, snacks or coffee at booths at conferences or other similar events where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings."

Now let's assume that same physician instead of accepting a $6 cup of coffee from that manufacturer's exhibit booth accepts $6 in gifts of nominal value (such as pens and office supplies), putting that physician over the $100 total threshold. **Would these nominal gifts be subject to reporting or are these exempt because of the difficulties the manufacturer may have in establishing the identities of the individuals who accept the offerings? In other words, are transfers of value received at a conference always exempted from the reporting requirements? We believe they should be, but we seek clarification if this is CMS's intent.**

Third Party Arbitration

We agree with CMS that manufacturers should be responsible for reporting payments to physicians and that they should be responsible for any penalties incurred as a result of not reporting this information. This is the clear intent of Congress in section 6002 of the Affordable Care Act (ACA). **We have strong concerns, however, that CMS is proposing to avoid responsibility in helping to arbitrate disputes related to public information between manufacturers and physicians.** Small physician practices have neither the time nor the resources to monitor or dispute reports submitted by large manufacturers. This proposal would place an undue personal and financial burden on physicians. **ASA strongly urges CMS to allow for a third party review of reported data in dispute if the manufacturer and physician cannot first reconcile on their own.**

Review of Reported Data

ASA appreciates that CMS will have the opportunity to correct mathematical mistakes after the reporting period. We also appreciate that CMS will flag disputes between manufacturers and physicians as "contested." Unfortunately, the proposed rule would provide an inadequate review period (45 days) of reported data. The ACA allows a review period of "not less than 45 days." Given the complexities of the system, the differing relationships and varied transfers of value that must be recorded, and the fact that this new reality will require some learning and adjustment by all parties, **we urge CMS to allow for a longer review period, especially in the first few years of implementation.** If the first few years show few disputes over publicly reported information, CMS could then modify the review period to a shorter time frame.

We appreciate that CMS is seeking comments regarding a pre-submission review between manufacturers and physicians prior to the formal review period. **In addition to extending the review period, ASA strongly urges CMS to <u>require</u>, or at the very least allow a pre-submission review.** We believe a pre-submission review can help "facilitate the early resolution of conflicts" between manufacturers and physicians. However, absent a requirement, manufacturers are not compelled to provide physicians with reported data prior to the formal review period.

CMS has proposed that manufacturers and physicians could not make changes until the calendar year following the 45 day review period. We understand CMS' concern that "allowing continual changes would be operationally difficult for CMS to handle and would reduce the utility of the data set." However, not allowing changes during the calendar year would compromise the integrity and therefore the utility of the data set. One way to remedy the operational challenges is to allow manufacturers and physicians to amend the record at least once between the end of the review period and the next calendar year. Another option is for CMS to allow changes after the review period, if CMS finds a compelling reason to do so. This will be especially important in the first few years of implementation as physicians and industry become aware of the new requirements.

ASA is also concerned with the CMS proposal to limit the review and correction of older data. For example, as proposed by CMS, in 2015, manufacturers and physicians could only change data from 2014 and 2013. CMS did not state a justification for this proposal and nothing in the statute requires CMS to limit the period in which the record can be corrected. **We urge that CMS allow for review and correction of older data. The credibility, reputation and livelihood of physicians could be compromised if strict limitations are placed on the review of inappropriate data.**

Physician Access to Reported Data

We appreciate that CMS proposed two options for physicians to review information reported about them. As CMS states, "we are considering that covered recipients and physician owners and investors would sign in to a secure website to see information reported about them." CMS continues to state "we are also considering an alternative method, in which we would require applicable manufacturers and applicable GPOs to collect and report whether a covered recipient, or physician owner or investor would like to be notified by USPS or email of the processes for review, as well as the individual's email address, if indicated." **We believe that CMS should adopt both approaches.** We believe a secure website where physicians can log-in is beneficial for physicians that may have moved recently and may not receive notifications if it is sent to an old address. However, notification via USPS, fax or email is essential as this could serve as the first notification for the physician that this data is being reported. Using both approaches would provide proper notification, while allowing physicians to remotely access information about reported manufacturer payments.

Survey Disclosure

The proposed rule requires applicable manufacturers to report third party payments to physicians. CMS states, "In addition to payments or other transfers of value to covered recipients made by applicable manufacturers themselves, applicable manufacturers (under both paragraphs (1) and (2) of the definition) are also required by statute to report payments and other transfers of value provided indirectly to covered recipients through third parties, if the applicable

manufacturer is aware of the identity of the covered recipient." Often, these third parties are survey companies acting on behalf of a manufacturer. In certain instances, they will offer a payment to a physician for participation in a survey. We are concerned that some physicians may not be aware that these payments are subject to reporting by the manufacturer. **CMS should require these survey companies to disclose the name of the manufacturer they are conducting the survey for and to make the physician aware that the manufacturer may be required to disclose these payments. We also request that the survey company provide a receipt to the physician so that he/she can keep a record of the transaction and dispute inaccurate data during the review period.**

Continuing Medical Education

We believe CMS needs to make a clear distinction between accredited continuing medical education (CME) and Food and Drug Administration (FDA)-regulated medical education. As you may know, in accredited CME, the Accreditation Council for Continuing Medical Education (ACCME) forbids commercial entities from making direct payments to speakers and participants. Any direct payment from a commercial interest to a CME speaker would constitute a violation of the ACCME Standards of Commercial Support and result in American Medical Association (AMA) actions against the accredited provider and the speaker for violation of the AMA Code of Medical Ethics. The commercial entity must submit their educational grant to the accredited provider (such as ASA) so that the commercial entity has no control of the CME content or speakers. Thus, it would be impossible for ASA to attribute the funds to a single speaker and it would be burdensome and unfair to split it across all speakers at the accredited event for reporting purposes. As this proposed rule only applies to physicians and teaching hospitals, it would be inappropriate for CMS to require commercial entities to report that they contributed to ASA's accredited CME program. Meanwhile, we believe those funds should not be assigned to those physicians speaking at CME events for reporting purposes.

For FDA regulated medical education, a speaker is paid directly by a manufacturer and this is easily identifiable. We agree with CMS that this should be included in the reports from manufacturers.

Educational Materials Exclusion

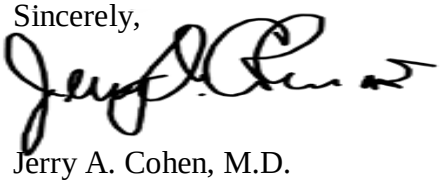
We support the reporting requirements exclusion for educational materials that directly benefit patients or are intended for patient use. CMS is also "considering whether certain materials provided by applicable manufacturers to covered recipients to educate the covered recipients themselves, but which are not actually given to patients (for example, medical textbooks), should be interpreted as educational materials that 'directly benefit patients.'" As you further define educational materials, we ask that materials intended to enhance a physician's knowledge or practice of medicine be interpreted as directly benefiting patients.

Estimated Burden on Physicians

The proposed rule would place an indirect record keeping requirement on physicians that CMS failed to account for. We disagree with CMS that physician time would be "discretionary" as physicians would need to retain their own records of items of value received from manufacturers to ensure reporting accuracy and minimize the time spent disputing the data. This is a significant burden on physicians due to the fact that inaccuracy in reporting could affect the physician's reputation and livelihood. **We ask that CMS account for or address this indirect burden in the final rule.**

We appreciate your consideration of our comments. If you have any questions regarding our comment letter, please feel free to contact Jason Byrd, J.D., ASA's Director of Practice Management, Quality and Regulatory Affairs at (202) 289-2222 or j.byrd@asawash.org.

Sincerely,



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