

August 22, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Administrator Tavenner:

The American Association of Colleges of Osteopathic Medicine (AACOM), which represents the 30 accredited colleges of osteopathic medicine in the United States delivering instruction at 42 teaching locations in 28 states, and the American Osteopathic Association (AOA), which represents more than 104,000 osteopathic physicians and osteopathic medical students nationwide, are writing to express our serious concerns with the Open Payments System.

AACOM and the AOA, which is a Continuing Medical Education (CME) accreditor, firmly support the concept of “life-long learning” and believe the education continuum should extend throughout a physician’s career. While AACOM and the AOA support full transparency in interactions between physicians and the healthcare industry, we believe the Centers for Medicare and Medicaid Services’ (CMS) proposal in the 2015 Medicare Physician Fee Schedule proposed rule, as well as the existing complexities of the Open Payments System, will have a chilling effect on CME. Therefore, we urge CMS to do the following:

- Retain the CME speaker exclusion as currently written and offer an alternative exemption from reporting for other organizations that also follow the ACCME Standards for Commercial Support or equivalent;
- Extend the educational materials exclusion from reporting to cover medical textbooks, scientific journal articles, and reprints that directly benefit patient care;
- Delay the publication of collected data in the Open Payments System until March 31, 2015; and
- Release written guidance before the end of August to manufacturers/Group Purchasing Organizations (GPOs), physicians and teaching hospitals, as well as their respective associations, clarifying that manufacturers/GPOs do not have the authority to unilaterally dismiss disputes.

Reports of Payments or Other Transfers of Value

AACOM and the AOA strongly oppose CMS’ proposal to remove in its entirety the Continuing Education Exclusion found in 42 CFR 403.904(g) regarding reports of payments or other transfers of value to covered recipients. The agency contends that removing this provision

would eliminate a redundancy with the exclusion identified in 42 CFR 403.904(i)(1). That exclusion would cover indirect payments or other transfers of value where the manufacturer is “unaware” or “does not know” the identity of the covered entity for up to a year and a half after the indirect payment or other transfer of value is made.

We urge CMS to retain the CME speaker exclusion as currently written in 42 CFR 403.904(g)(1), and CMS should offer an alternative exemption from reporting for other organizations that also follow the ACCME Standards for Commercial Support or equivalent. We believe the current regulation regarding CME exemptions already provides clarity. In addition, stakeholders have worked with this regulation since it went into effect and have planned their programs accordingly.

AACOM and the AOA are concerned that the proposed rule, if finalized, would erase that clarity and be subject to various interpretations by manufacturers, which would add confusion to pre-existing Open Payments System issues and create numerous unintended consequences.

Under the proposal, it would be highly improbable for a drug or device manufacturer to remain unaware of a covered recipient’s identity “during the reporting year or by the end of the second quarter of the following reporting year” after the manufacturer makes the indirect payment or other transfer of value. As soon as the advertisements and agenda are made public, the manufacturer, who sponsored the CME conference, would know the doctors and other medical professionals making presentations. The manufacturer would then need to contact the CME entity hosting the conference to get an accurate accounting of indirect payments made to each doctor for travel, food, and speaking fees.

If this proposal is finalized, it would deter physicians from presenting at conferences because of the perceived impropriety, and increase costs to state affiliates and national organizations that could not receive sponsorships for presenters. This cost would have to be passed on to the physician attendees. We suggest CMS consider modifying section 403.904(i)(1) so that the exemption would apply when the applicable manufacturer is unaware of the speakers/faculty and other participants **before** committing to fund the activity.

We realize that CMS does not want to appear to be endorsing or favoring any particular organization, however it is equally if not more important that the distinction between certified/ accredited CME and other educational programs be preserved. Overall, AACOM and the AOA believe that current standards of professional self-regulation should be maintained.

In the “Transparency Reports and Reporting of Physician Ownership or Investment Interests” final rule (February 8, 2013 Federal Register), CMS finalized at 403.904(g)(1) that “payments or other transfers of value provided as compensation for speaking at a Continuing Education program are not required to be reported” if the following conditions are met:

1. The event must meet the accreditation or certification requirements and standards for continuing education for one of the following organizations:
 - American Osteopathic Association
 - Accreditation Council for Continuing Medical Education

- American Academy of Family Physicians
 - American Medical Association, and
 - American Dental Association’s Continuing Education Recognition Program;
2. the applicable manufacturer does not pay the covered recipient speaker directly; and
 3. the applicable manufacturer does not select the covered recipient speaker or provide the third party with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

Accredited/certified CME providers have rules and regulations in place to ensure that the payment is for objective, evidence-based, scientific activities that will benefit patients and health care professionals. The AOA adopted, with minor additions, the Uniform Guidelines for Accrediting Agencies of Continuing Medical Education. In addition, the AOA Standards for Commercial Support are adapted from the policy set forth in the Accreditation Council on Continuing Medical Education (ACCME) standards for commercial support. These rules create strict firewalls to prevent any conflict of interest.

It is important to note that there is a clear distinction between accredited/certified CME and promotional education. Faculty in commercially-supported CME programs/activities has a relationship with the accredited CME provider, *not* with any company supporting the activity/program. For example, the Standards for Commercial Support (SCS) require that faculty relationships be with accredited providers of CME, and *not* be directly paid by companies which might be supporting the program/activity.

In addition, attendees at commercially-supported CME programs have a relationship with the sponsoring organizations (*i.e.*, the specialty society) and *not* with any company supporting the activity/program. In contrast, speakers at promotional events have a direct relationship with a company. Direct compensation for serving as a speaker in a **promotional** educational program offered by an applicable manufacturer should be reported in the Open Payments System.

Educational Materials

Under the Sunshine Act, Congress outlined 12 specific exclusions from the reporting requirement, including “educational materials that directly benefit patients or are intended for patient use.” AACOM and the AOA believe CMS misinterpreted the statute when it determined that the exclusion did not cover medical textbooks, scientific journal article supplements, and reprints used to educate physicians. These publications are peer-reviewed and include the latest information on evidence-based medicine which certainly benefit patients directly with better care by their physicians. **Therefore, we call on CMS to extend the educational materials exclusion to cover medical textbooks, scientific journal article supplements, and reprints.**

Physician Registration

Given the agency’s current timeframe for registration and releasing information about the review and dispute process, there is little time for outreach to the physician community about the processes and procedures. Although significant efforts have been made to educate physicians about the registration and review processes, we are concerned that many physicians

still do not know about the requirements. Therefore, they will have little time, if any, to review the data being reported about them and to dispute any possible errors.

In addition, we have found the two-phase registration process to be extremely complex. Physicians and teaching hospitals first must register in Medicare's Enterprise Identity Management (EIDM) System. To complete the process, they must then register into the actual Open Payments System. While registration is voluntary, physicians and teaching hospitals must register in order to review and possibly dispute their data, which is an additional process. It also has been reported that CMS is having difficulties with ensuring the proper attribution of information to the right physician in the Open Payments System. This resulted in the Agency being compelled to take the Open Payments web site temporarily offline in an effort to resolve the issue.

AACOM and the AOA urge CMS to delay the publication of data collected in the Open Payments System for six months until March 31, 2015. We note that during 2013, CMS had communicated that registration would begin January 1, 2014; however, it actually did not begin until June 2014. Therefore, our recommended postponement would compensate for the Agency's own delay as well as the most recent setback with the web site.

Considering the difficulties, we believe the postponement would benefit stakeholders and CMS. The postponement would allow the agency more time to correct any technical and administrative challenges related to the web site and the Open Payments System. In addition, the Agency would have more time to work closely with professional societies on developing and providing educational materials concerning the Open Payments System's processes and procedures.

Unilateral Dismissal

AACOM and the AOA are particularly concerned about a supplemental document that was included in the May 5 Federal Register notice. According to the 508-CMS-10495 Review and Dispute Email Notifications document, manufacturers/GPOs may dismiss a dispute if they determine that no change is required to the data, or request the physician or teaching hospital who initiated the dispute to withdraw it. It appears from the document that a manufacturer/GPO could make a unilateral decision that no change is required to the data and dismiss the dispute. If a physician or teaching hospital disagrees with the dismissal, the transaction may be disputed again.

The February 8, 2013 final rule does not include a unilateral dismissal of a dispute. According to the final rule, manufacturers, GPOs, covered recipients, and physician owners or investors will have an opportunity to review the Open Payments reports. Covered recipients and physician owners or investors have 45 days to review and submit corrections, and an additional 15-day resolution period before CMS publishes the report publicly on its web site. Parties involved in a dispute are authorized to resolve it. If the dispute is not resolved within the 60-day review, correction, and resolution time period, CMS will publicly report the data, but mark the information as disputed.

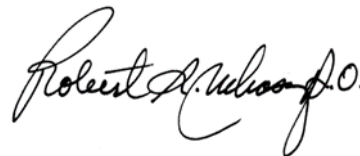
AACOM and the AOA believe a unilateral dismissal of disputes, as outlined in the notifications document, contradicts the final rule and violates the right to due process of the physician or teaching hospital. It is our understanding that CMS intends to release clarifying guidance that manufacturers and GPOs do not have the authority to unilaterally dismiss disputes. To date, we have seen no such guidance. Before the end of August, **CMS should release written guidance to manufacturers/GPOs, physicians and teaching hospitals as well as to their respective associations, clarifying that unilateral dismissals are not permissible.**

We hope CMS takes our concerns into consideration as it moves forward with the Open Payments System. We look forward to working with CMS on this issue and other issues of importance to the osteopathic medical education community and osteopathic profession.

Sincerely,

A handwritten signature in black ink, appearing to read 'SC Shannon'.

Stephen C. Shannon, DO, MPH
AACOM President and CEO

A handwritten signature in black ink, appearing to read 'Robert S. Juhasz, DO'.

Robert S. Juhasz, DO
AOA President