February 17, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-5060-P  Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 FR 78742 (December 19, 2011)

Dear Ms. Tavenner:

The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule, entitled “Medicare, Medicaid, Children’s Health Insurance Programs; Transparency reports and Reporting of Physician Ownership or Investment Interests,” published in the December 19, 2011 Federal Register. The AAOS, which represents over 18,000 board-certified orthopaedic surgeons, has been a committed partner to CMS in patient safety, cultural competency, and the provision of high-quality, affordable healthcare. We commend CMS on its efforts to enhance transparency, and offer the following remarks regarding the proposed manufacturer reporting of payments or transfers of value provided to physicians and teaching hospitals.

Our comment letter focuses on proposed provisions that we believe will impact physicians:
Due process issues for those adversely impacted by inaccurate reporting;
Challenges in reporting of indirect transfers of value/payment;
Negative impact on continuing medical education (CME); and
Administrative burden for physicians.

Due Process Concerns
The AAOS is concerned that, as outlined in the proposed rule, the process may compromise the accuracy of information provided, and also preclude those adversely affected by inaccurate information from disputing the report. The Affordable Care Act (ACA) mandated that drug and device manufacturers participating in U.S. federal health care programs begin tracking any transfers of value or payments of $10 or more to physicians and teaching hospitals (covered recipients). Information from these annual reports will be made available on a public website.

Individuals and entities that are the subject of public reporting are entitled to receive notice of any report that implicates them as well as an opportunity to correct misleading or inaccurate reports. Where a payment or transfer of value is made at the request of a physician or designated as being made on behalf of the physician, the physician as well as the recipient of the payment, should receive notice. The AAOS believes the proposed process does not provide an adequate means for physicians to challenge reports. Misleading or inaccurate information could be publicly posted on a government website for a significant amount of time while denying physicians basic due process rights to challenge such information.
CMS stated in the proposed rule that it does not believe that the federal government should be actively involved in arbitrating disputes between physicians and manufacturers, and proposes a voluntary pre-submission review/dispute process for physicians and a post-CMS submission process where physicians are provided aggregate reports by the agency but must contact manufacturers to resolve disputes. Under the process delineated in the proposed rule, however, the government, as a conduit of reporting provided by manufacturers, would bear no responsibility for ensuring the accuracy of publicly posted transparency reports. Moreover, there would be no consequence for a manufacturer that inaccurately reports on transfers of value, whereas the consequences to an individual physician are significant. Physicians may suffer considerable damages, including investigation by government and private entities, potential disciplinary actions, public censure, ridicule, and destruction of professional reputation and livelihood.

Also, under the proposed rule, manufacturers have incentive to over-report payments to avoid penalties for failure to timely report, but there is no consequence for manufacturers who make a mistake in reporting. In addition, the AAOS is concerned with CMS’ proposal to limit a physician’s ability to challenge the accuracy of reports to the “current” and prior reporting year within a compressed 45-day window each year. This short timeframe denies physicians significant substantive and procedural due process rights.

The AAOS is supportive of providing physicians with opportunity to access manufacturer’s information as it is being gathered and to correct inaccuracies on an ongoing basis. The AAOS further suggests that CMS consider tasking a third-party arbiter with resolving disputes about reports between manufacturers and physicians.

In summary, the AAOS recommends that the proposed rule be modified to:
• Provide for adequate notice to physicians as well as recipients of payment, where a payment or transfer of value is made at the request of a physician or is designated as being made on behalf of the physician;
• Provide for a meaningful, adequate process for physicians to challenge reports;
• Ensure the government, as a conduit of reporting provided by manufacturers, bears responsibility for the accuracy of publicly posted transparency reports;
• Ensure there are consequences for a manufacturer that inaccurately reports on transfers of value;
• Provide physicians with opportunity to access manufacturer’s information as it is being gathered and to correct inaccuracies on an ongoing basis; and
• Consider tasking a third-party arbiter with resolving disputes about reports between manufacturers and physicians.

CME Concerns
The AAOS is concerned provisions in the proposed rule on transfer of value to a covered recipient through a third party could negatively affect CME providers, including physician organizations. The Physician Payment Sunshine Act as originally written in the ACA excluded faculty and other third parties participating in CME programs from having to disclose indirect payments to covered recipients, including physicians. As drafted, the Act protected CME by excluding coverage of indirect payments to covered recipients by applicable manufacturers such as industry contributions to continuing education programs or presentations. Under the proposed rule, these organizations would become responsible for reporting all payments to covered recipients.
Organizations involved in accredited and certified CME have adopted and operate under the strict protocols of the “Standards for Commercial Support (SCS): Standards to Ensure the Independence of CME Activities” promulgated by the Accreditation Council for Continuing Medical Education (ACCME). Under ACCME standards, accredited and certified CME must be developed independently, without influence of any manufacturer that may choose to make an educational grant to the CME provider.

“Accredited CME” refers to CME activities that meet the requirements and standards of a CME accrediting body such as the ACCME. “Certified CME” refers to CME activities that carry CME credit offered by the American Academy of Family Physicians, the American Medical Association, and the American Osteopathic Association.

CME providers initiate and maintain relationships with their faculty. The faculty of accredited and certified CME activities are selected, directed, reviewed, evaluated and paid by the CME provider and have no relationship with the manufacturers that may make an educational grant to the CME provider to support accredited and certified CME activity.

Therefore, it is unreasonable to place CME faculty in a position of being assumed and reported to have a relationship with a manufacturer, by virtue of having accepted a CME provider’s invitation to speak at an accredited and certified CME program. Speakers who do not have relationships with manufacturers will be reluctant to serve as faculty to avoid being characterized as having such relationships.

The proposed rules create significant responsibilities for CME providers to track payments based on applicable manufacturer reporting, rather than in accordance with ACCME or other
accrediting organization requirements. CME providers currently track payments and keep records on myriad transactions, but the proposed rules would add an additional layer of administrative burden. It will be challenging for CME providers to track every dollar provided by a CME supporting entity that helps underwrite a given CME program, and provide accurate attribution of those funds to every faculty speaker or CME activity participant.

Moreover, CMS proposes that direct compensation for serving as faculty or as a speaker for a medical education program is interpreted broadly to encompass all instances in which applicable manufacturers pay physicians to serve as speakers and not just those situations involving medical education programs. In addition, the proposed rule does not differentiate between accredited CME and other speaking engagements.

Under the proposed rule, CMS interprets “payment or other transfer of value” to include instances where the manufacturer learns of the identity of a physician before, during, or after the manufacturer makes a payment or transfers value to a third party or when made through an “agent.” CMS would require reporting where a manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of a physician. This interpretation could undermine the independence of CME and other activities where manufacturers make grants, but are barred from any control over how funds are used because third parties would have to report in detail back to all manufacturers the value attributed to each physician in their organization after the indirect transfer is made.

Under the proposal, CME faculty would have to be listed as receiving a payment from industry despite the fact that under ACCME guidelines, manufacturers are explicitly prohibited from having any control over the content, speakers, or attendees to ensure the independence of the programming. The manufacturer, however,
would not be able to make proper attribution of value unless the CME provider or conference host provides a detailed attribution for all faculty and CME/conference attendees. Accordingly, the unintended consequence would be the transfer of an exhaustive amount of information to manufacturers about individual physicians participating in CME. The AAOS believes CMS has exceeded its statutory authority to the extent it requires reporting on certified CME because Congress excluded CME from transparency reporting requirements.

The ACA mandates that manufacturers are required to specify and report the portion of the transfer of value/payment made directly to a physician or an indirect transfer made at their request or designated on the physician’s behalf. CMS’ proposal to estimate or impute attribution even where there is no direct transfer or a qualifying indirect transfer is beyond its statutory authority. Under the proposed rule, CMS proposes that payments received by an organization will be apportioned among the physicians in the organization or institution. This methodology, however, could result in misleading reporting. A physician employed by a large organization or institution could have funding and transfers imputed to their report that they cannot reject, they do not receive directly, and for which they have no knowledge.

The AAOS believes that direct compensation by an applicable manufacturer to a physician serving as a speaker in a promotional educational program should be reportable, but payments made by a CME provider to faculty of accredited and certified CME activities should not be not reportable (as specified under Sec. 6002 of the ACA). Grants from applicable manufacturers to CME providers are governed by the ACCME Standards for Commercial Support, which prohibit direct payments from manufacturers to faculty, and prohibit manufacturers from having any influence on the CME program including selection of faculty.
Accordingly, the AAOS recommends that the proposed rule be clarified in the following ways to avoid unintended consequences:

- The final rule must distinguish between direct compensation for serving as a speaker in a promotional educational program offered by a manufacturer, which should be reportable, and compensation paid by a CME provider to faculty in CME programs, who are independently selected and have no relationship with a manufacturer, which should not be reportable;

- The final rule must specify that grants from manufacturers to CME providers for CME activities do not constitute an indirect transfer of value either to faculty independently selected and paid by the CME provider, or to participants in the CME activity; and

- The final rule must specify that neither faculty nor participants in CME activities have relationships established with manufacturers by virtue of the manufacturer making an educational grant to the CME provider under applicable ACCME standards.

Conclusion
The AAOS believes the collective information collection requirements under the proposed rule would impose significant burden on physicians. All physicians would have to document their professional activities because they cannot know in advance when an indirect transfer or payment will become a reportable event. All activities would have to be tracked because most physicians will not know until they receive notice from a manufacturer or CMS whether they received anything of value from a manufacturer indirectly.
While the AAOS is supportive of CMS’ underlying goal of enhancing transparency, we believe the proposed rule, if implemented without significant modifications, will result in the publication of misleading information and impose unduly burdensome administrative requirements on physicians, without enhancing transparency of physician-industry interactions. We appreciate this opportunity to provide input on the proposed rule for Transparency Reports and Reporting of Physician Ownership or Investment Interests and look forward to continuing to work with CMS to ensure that transparency reports contain meaningful and accurate information. If you have any questions on the AAOS comments, please do not hesitate to contact our Medical Director, William R. Martin, III, MD, at (202) 546-4430 or martin@aaos.org

Sincerely,

John R. Tongue, MD
President
American Association of Orthopaedic Surgeons