



August 27, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Tavenner:

The American Medical Informatics Association (AMIA) is a medical specialty society with an interdisciplinary membership of 5,000 professionals and students committed to the science and practice of biomedical and health informatics.

AMIA is writing you today to express our general support for the Open Payments program and its goal of creating “transparency around the nature and extent of relationships that exist between drug, device, biologicals and medical supply manufacturers, and physicians and teaching hospitals (covered recipients and physician owner or investors).”

However, we are registering our profound concern regarding the proposed changes to the existing Sunshine Act reporting exclusion for continuing medical education (CME) activities.

AMIA does not currently accept commercial support for its certified CE activities. However, with the economic stresses impacting the practice of medicine today—such as implementation of electronic health record systems, already burdensome reporting requirements such as Meaningful Use, hiring of additional staff to manage the health insurance process, and ever-greater educational requirements to maintain competency—commercial support of our educational activities is certainly something we consider. We are sensitive to the fact that our members are paying significant sums to implement so many of the other changes that health reform demands and at a certain point will simply not be able to keep paying on their own for all of their continuing education and maintenance of certification materials.

The process of creating certified CME involves the incorporation of the Accreditation Council for Continuing Medical Education’s (ACCME) Areas and Essentials, a minimum of 15 out of 22 Criteria, and the Updated Standards for Commercial Support (SCS). The SCS in particular address—through six well-defined standards—the importance of keeping the source of commercial support for educational activities from influencing the content of those activities. You may find the SCS here: <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

In order for an ACCME-accredited organization, like AMIA, to maintain its accreditation, it is essential to adhere to the SCS, as well as the Areas and Essentials and at least 15 Criteria, for the creation of all of its certified activities for physicians. As part of the reaccreditation process, which occurs in four- or six- year

cycles, CME providers must produce documentation of 15 activities to demonstrate compliance with all of the ACCME's guidance.

We are describing this process to you so as to illustrate that there are processes already in place that ensure that certified educational activities are designed for education and not promotion, whether there is commercial support or not. CME providers are in jeopardy of losing their ACCME accreditation if they do not adhere strictly to these guidances. If the ACCME ascertains that an education provider is not in compliance, there is already a process in place to remove accreditation from that violator.

Therefore, the proposed CMS expansion of the reporting requirement to include commercially supported CME activities does not recognize an already well-established divide between education and promotion. This level of reporting would jeopardize the commercial support funding of education that is essential to ensuring that today's physicians remain competent.

Note, too, that today's CME emphasizes the measurement of educational effectiveness in terms of outcomes in improved physician competence, performance, or patient results. Equating commercial support of CME with promotional activities would result in greatly reduced funding, and have a severe negative effect on the implementation of this new, quality-improvement type of educational activity.

AMIA strongly supports CMS's maintaining the CME exemption of the Open Payments act. This exemption should apply to CME activities that bear credit from a national credit system and/or are offered by an organization that strictly adheres to the SCS standards. AMIA also urges exclusion of CME activities where the industry donor is unaware of the speakers and participants before committing to fund the activity. The commercial support landscape has changed greatly over the last decade. In fact, many commercial supporters do not want to know the name of faculty before awarding a grant for educational support lest this be interpreted as influence. Once CME providers have issued activity announcements, a commercial supporter's knowledge of the faculty is inevitable. Commercial supporters' knowledge of faculty after a grant has been awarded does not demonstrate influence any more than physician learners' knowledge of faculty does.

Regarding the distribution by drug and device companies of medical textbooks, reprints of peer reviewed scientific clinical journal articles, and other services used to educate physicians: **AMIA believes that this interaction has the potential for industry to influence practitioners' behavior.** The direct benefit to patients and their medical care is not the clear result of this interaction in the same way that impartial, SCS-compliant CME is.

In conclusion, please note that **AMIA strongly urges CMS to retain the CME exemption to the Sunshine Act.** We believe the unintended consequences of considering commercial support of CME a reportable relationship would have a severe impact on the development of continuing education that keeps our physician workforce and residents and fellows in teaching hospitals competent to treat the US patient population.

Sincerely,



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AMIA Board of Directors Chair