

On behalf of the American Academy of CME, Inc. (Academy) and its Board of Directors and Officers, thank you for the opportunity to provide input on the proposed changes to guidance provided for Physician Payment Sunshine legislation.

The Academy is an independent, non-profit, medical education foundation. Both on our own, and in collaboration with other organizations, the Academy provides certified continuing education (CME/CE) to physicians, nurses, nurse practitioners, physician assistants, pharmacists, dietitians, and other healthcare professionals. As CME/CE professionals, we espouse the concepts of transparency and disclosure, especially as they relate to the interplay of medical practice, clinical education and industry.

I am writing regarding the Medicare Physician Fee Schedule for 2015 in which CMS has proposed removing the existing Sunshine Act exclusion for CME. We understand that the intent of the proposed change to the reporting requirement is to expand the exemption to take into account accredited education for other types of healthcare professionals including nurses, nurse practitioners, physician assistants, and others. While we support this goal, we are greatly concerned about these proposed changes.

As you are aware, accredited and certified CME/CE activities are vital components of our healthcare system. Accredited and certified CME/CE is the gold standard for education that allows our nation's healthcare professionals to remain up-to-date on the latest science impacting patient care. Our accrediting bodies for CME/CE provide strict standards which are followed to guarantee independence from commercial influence.

In CMS' February 2013 Final Rule on Sunshine Act implementation, your agency created a "CME exemption" so that physician participants knew they could present at and attend accredited CME programs without concern of being listed in the Open Payments system, which might imply that they had somehow been improperly influenced by commercial companies.

It is our understanding that the proposed revision to the rule would mean that exempt third-party transfers to CME/CE would apply only when an industry donor is unaware of physician participation (as speakers, faculty, or attendees) in a CME/CE activity either before or after the activity takes place. This raises serious concerns for us because this type of information is often available through brochures, program books, and other communication methods. As such, it would be difficult for funders to claim that they do not know this information at some point during or after a program. For example, we are required by our accrediting bodies to post information about speakers/faculty in invitation materials which we send out to potential learners or post on our websites. This information helps learners in deciding if they wish to participate in a particular CME/CE activity.

We have heard discussion of a compromise solution, which we fully endorse, that would support your intention to expand the exemption while at the same time avoiding the unintended consequence of making funders willfully ignorant of names of speakers/faculty/attendees. We recommend that you modify the language in the proposed rule to add language that clarifies that the exemption applies under section 403.904(g)(1)(i) when an applicable commercial supporter provides funding or in-kind support to a CME/CE provider but does not select or pay the covered recipient speaker/faculty/attendee directly, or provide the CME/CE provider with a list in any format of individuals to be considered as faculty/speakers/attendees for the activity. This could be addressed by the agency providing guidance that the above mentioned is achieved if the commercial supporter is unaware of the speakers/faculty/specific attendee names before signing an agreement to commit to providing the commercial support for a specific activity. Further, this guidance should clarify that if a commercial supporter becomes aware of the names of speaker/faculty/attendees after the commitment to support the activity was made, the activity would remain exempt. Otherwise, we believe the revised language would negate rather than expand the current exemption that is in place for accredited and certified CME, which we do not believe is your intent.

We strongly urge you to ensure that indirect commercial support for accredited and certified

CME/CE programs, where the accredited provider exercises complete control over the content and speakers/faculty, remains exempt from reporting under the Open Payments system, and that healthcare professionals have a clear safe harbor from Open Payments reporting when they participate in these activities. American's healthcare professionals must constantly further their education regarding the latest medical science in their field in order to achieve the best outcomes for their patients. Therefore, we must do all we can to encourage?not discourage?participation in CME/CE activities.

John Juchniewicz