

February 16, 2012

Marilyn Tavenner, Acting Administrator  
Center for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5060-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Dear Acting Administrator Tavenner,

The undersigned represent the national organizations involved in Continuing Medical Education (CME) in the United States, including Accreditation of CME Providers, granting of CME Credit for CME activities, and fulfillment of the responsibility of the Profession of Medicine to self-regulate in the arena of Continuing Medical Education. We are pleased to comment on the proposed rule "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests", 42 CFR Parts 402 and 403 [CMS-5060-P] RIN 0938-AR33.

The CME community in the United States is supportive of the Physician Payments Sunshine Act (PPSA), as adopted by Congress as Section 6002 of the Patient Protection and Affordable Care Act of 2010. Indeed, during the crafting of the PPSA we had the opportunity to describe to legislative staff the complexities of relationships in Accredited and Certified CME offered by CME Providers in the US, in contrast to promotional educational programs offered to physicians directly by pharmaceutical and device manufacturers. For example, we were able to provide information on definitions and nuances of relationships, such as the distinction between grants to providers of certified CME, who in turn select faculty, in contrast to direct payments to physicians by companies for purposes related to drug development, marketing and promotion.

Language of the PPSA as adopted appropriately addressed a few specific issues, which appear in the proposed rule to need clarification and modification, to avoid unintended consequences. These issues include:

1. Distinguishing between Accredited and Certified CME offered by CME providers, and promotional education offered by pharmaceutical and medical device manufacturers;
2. Recognizing the roles and relationships that faculty in Accredited and Certified CME programs have with CME Providers and not with companies which may provide grants to CME Providers; and
3. Recognizing that attendees at or participants in Accredited and Certified CME programs have no relationships with companies which may provide grants to CME Providers.

We will address our comments to the two sections of the proposed rule, including first:

- Page 78748, Column 1, bullet 13, Direct compensation for serving as faculty or as a speaker for a medical education program, and  
Page 78750, column 1, (4) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program;
  - In the federal register, it states "We propose that this category be interpreted broadly to encompass all instances where applicable manufacturers pay physicians to serve as speakers, not just those situations involving 'medical education programs.'" It goes on to state "We realize that this interpretation does not allow for differentiation between continuing medical education (CME) accredited speaking engagements, and all other speaking engagements. We are considering, and welcome comments on, whether to limit this category to CME-accredited speaking engagements and report other speaking engagements in another category, such as compensation for services other than consulting, or additional category."

And second:

- Page 78750, Column 2, h. Exclusions, bullet 13, Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient, and  
Page 78751, Column 2, (5) Indirect Payments Through a Third Party;
  - In the federal register it states "However, any payment or other transfer of value provided to a covered recipient through a third party, whether or not the third party is under common ownership with an

applicable manufacturer or operating in the US, must be reported, if the applicable manufacturer is aware of the covered recipient's identity."

First, let us provide some applicable background. For example, the Federal Register references accredited CME, but does not reference extant firewalls in place in the Professional Self-regulation of relationships between CME Providers and industry.

Accredited and Certified CME:

**"Accredited CME"** refers to those activities in Continuing Medical Education that have been deemed to meet the requirements and standards of a CME accrediting body (ex., the Accreditation Council for Continuing Medical Education (ACCME); the America Osteopathic Association, the American Academy of Family Physicians). **"Certified CME"** refers to those activities in Continuing Medical Education that carry CME credit offered by one of the three grantors of CME credit in the US: the American Academy of Family Physicians (since 1948), the American Medical Association (since 1968), and the American Osteopathic Association (since 1972).

Professional Self-regulatory Firewalls in Accredited and Certified CME:

All organizations involved in Accredited and Certified CME in the US have adopted and operate under the strict firewalls which are promulgated, monitored and enforced through the "Standards for Commercial Support (SCS): Standards to Ensure the independence of CME Activities" of the Accreditation Council for Continuing Medical Education (ACCME), to which the entire profession of medicine adheres. The SCS (most recently revised in 2004) set standards for relationships between Accredited and Certified CME Providers and the companies which may provide grants to CME Providers. Faculty of certified Continuing Medical Education (CME) programs are selected, directed, reviewed, evaluated and paid by the Accredited CME providers, and have no relationship with the manufacturers. Indeed, not only is this a requirement of SCS, but also of the "Code on Interactions with Health Professionals" of the Pharmaceutical Research and Manufacturers of America (PhRMA Code).

Faculty who have no relationships with companies supporting certified CME programs will not be pleased to be put in a position of being assumed and reported to have a relationship with a manufacturer, by virtue of their accepting an invitation to present at the CME program. Indeed, many if not most speakers who have no relationships with manufacturers will refuse to serve as faculty, in order to avoid being assumed and reported to have such relationships.

*In the context of Accredited and Certified CME, direct payments to physicians (either in the role of faculty or attendees) by companies are prohibited, cannot occur, and therefore would be irrelevant when it comes to disclosure under the PPSA. Manufacturers will not be in a position to comply with this provision of the Act, as they have no relationships with CME faculty, either directly or indirectly.*

Required Disclosure of Relationships Between Physicians and Industry:

When a faculty member at a CME program has a relationship with a manufacturer, pre-dating and outside of the CME program, such as serving on a corporate speakers' bureau, stock ownership, or other relationship, those relationships must be disclosed as part of the CME activity. Such relationships are reportable under PPACA Section 6002 and must be disclosed under transparency reports. However, in the context of Accredited and Certified CME, a speaker's participation in the CME activity does not qualify as a reportable activity under Sec. 6002, as the manufacturers cannot have any role in speaker selection for the Accredited and certified CME activity. Furthermore, manufacturers cannot, and do not, under all rules governing faculty of CME programs, provide "*direct compensation for serving as faculty or as a speaker for a continuing medical education program.*"

Company Relationships with Speakers in Promotional Education:

In the proposed rule, there may be confusion of the roles and relationships of faculty in Accredited and Certified CME programs as contrasted with the roles of speakers in promotional education offered directly by pharmaceutical and medical device companies, as reflected on page 78748 of the proposed rule, column one, bullet thirteen, where one of the categories listed for reporting is "Direct compensation for serving as faculty or as a speaker for a medical education

program”, and which are instead overseen by the Food and Drug Administration (FDA). This is the critical distinction we successfully made with congressional staff during the period of crafting the PPSA.

We agree with disclosure of relationships between manufacturers and speakers at a promotional educational program sponsored by the manufacturers, as these relationships should be transparent and are appropriately included under other categories, such as consulting fees, compensation for services other than consulting, or honoraria. However, these speakers should not be described as “faculty or speakers in a CME program” since promotional educational programs, offered directly by manufacturers, are not Accredited and Certified CME programs.

Absence of Relationships of Participants in Accredited and Certified CME Programs:

There could be unintended consequences inherent in the communication of the names of physician participants to funding companies. CMSS Member Organizations are concerned that publishing the names of participants who attend independent CME events funded by commercial support, and identifying those participants as having a relationship with the funding company, may discourage physicians from attending. Moreover, communication of such a list of names could be used by funding companies for marketing purposes, which would seem to defeat the ultimate intent of these bills, to control expenditures in the Medicare and Medicaid programs.

Summary:

Direct compensation by an applicable manufacturer to a physician serving as a speaker in a promotional educational program should be reportable. Payments made by a CME Provider to faculty of Accredited and Certified CME activities are not reportable under Sec. 6002 of the PPACA. 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.

The proposed rule needs to be clarified and modified to avoid unintended consequences in two areas that relate to Accredited and Certified CME:

1. Page 78750, column 1, (4) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program

*The final rule needs to distinguish between direct compensation for serving as a speaker in a promotional educational program offered by an applicable manufacturer, which should be reportable under the Act; in contrast to faculty serving as speakers in Accredited and Certified CME programs, in which the faculty are selected and paid by the CME Provider and have no relationship with any applicable manufacturer which might be supporting the CME activity through an educational grant to the CME Provider.*

2. Page 78751, Column 2, (5) Indirect Payments Through a Third Party

*The final rule needs to clarify that grants from applicable manufacturers to CME Providers for Accredited and Certified 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 Accredited and Certified CME activity, nor are there in such cases payments made at the request of or on behalf of the faculty.*

Thank you for the opportunity to comment on the proposed rule to implement the Physician Payments Sunshine Act, of which we are supportive. Should you have any questions, or should our comments require clarification, please do not hesitate to contact us.

Signers:



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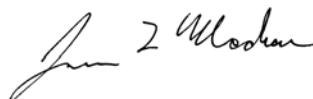
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