



COUNCIL OF MEDICAL SPECIALTY SOCIETIES

COMMITTED TO EXCELLENCE IN PROFESSIONALISM, EDUCATION AND QUALITY OF CARE

35 East Wacker Dr., Suite 850, Chicago, IL 60601-2106
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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

February 16, 2011

Dear Acting Administrator Tavenner,

The Council of Medical Specialty Societies (CMSS), with 38 member organizations representing 700,000 physicians in the US, is 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. CMSS 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.

CMSS operates under a Strategic Priority of Professionalism, which we define to include:

- Altruism (putting the needs of patients first),
- Self-regulation (a responsibility of a Profession), and
- Transparency (to peers [disclosure], patients and the public)

A mechanism, among others, for transparency to the public includes the description in the Dec. 19, 2011 Federal Register on page 78743, I. Background, 2. Transparency Overview, column 1, paragraph 2:

“We recognize that disclosure alone is not sufficient to differentiate beneficial, legitimate financial relationships from those that create conflicts of interests or are otherwise improper. Moreover, financial ties alone do not signify an inappropriate relationship. However, transparency can shed light on the nature and extent of relationships....”

History of CMSS with the Physician Payments Sunshine Act (PPSA):

The Council of Medical Specialty Societies (CMSS) enjoyed a productive relationship with legislative staff during the crafting the PPSA in 2008 and 2009. During that process, we were able to provide government representatives with information on definitions and nuances of relationships, such as the distinction between grants to providers of Accredited and Certified CME who independently select faculty, in contrast to direct payments to physicians by companies for purposes related to drug development, marketing and promotion, including promotional educational speaking engagements.

Among the points previously contributed by CMSS, which we were gratified to see included in the Act and which we reiterate here, are:

- Independent Accredited and Certified CME offered by CME Providers is *separate* and distinguished from promotional education offered by applicable manufacturers;
- Faculty in Accredited and Certified CME activities have a relationship with the CME Provider, *not* with any applicable manufacturer which may make an educational grant to the CME Provider to support the CME activity; and



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- Participants in Accredited and Certified CME activities *do not have* a relationship established with any applicable manufacturer by virtue of that manufacturer making an educational grant to the CME Provider to support the CME activity.

In addition, CMSS successfully communicated with CMS during the rule making in 2011, resulting in exclusion in the proposed rule of two elements:

- Food items of minimal value in exhibit halls at meetings, available to all attendees (not just physicians), should not be reportable under the Act
 - (Federal Register page 78748, bottom of column 3, II. Provisions of the Proposed Regulations, (2) Food and Beverage)
- Gifts to physicians which are primarily for use with or for the benefit of patients should not be reportable under the Act
 - (Federal Register page 78750, column 2, II. Provisions of the Proposed Regulations, h. Exclusions, bullet 3; also page 78751, column 1, (2) Educational Materials That Directly Benefit Patients or Are Intended for Patient Use)

Comments on the Proposed Rule:

We will focus our comments on two critical elements of the proposed rule, including first:

- Federal Register page 78748, Column 1, bullet 13, 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:

- Federal register 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.”



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Definition of 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 American 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. In addition, the ACCME SCS are supported by the “**Code on Interactions with Health Professionals**” of the Pharmaceutical Research and Manufacturers of America (PhRMA Code). 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.

Accredited and Certified CME is produced, developed and delivered, including the selection of faculty, independently, with no influence of any applicable manufacturer which may choose to make an educational grant to the CME Provider for the CME activity.

Absence of Relationships of Faculty of Accredited and Certified CME Activities with Manufacturers:

Faculty relationships in Accredited and Certified CME are with the CME Provider, and not with any applicable manufacturer which may make an educational grant to a CME Provider to support the CME activity, and which may subsequently ascertain the identities of the 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 manufacturers which may make an educational grant to the CME Provider to support the Accredited and Certified CME activity.

Faculty would not be pleased to be put 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 which is supported by an educational grant to the CME Provider by an applicable manufacturer. 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 applicable manufacturers are prohibited, cannot occur, and therefore would be irrelevant when it comes to disclosure under the PPSA. Furthermore, applicable manufacturers will not be in a position to report, as they have no relationships with CME faculty, either directly or indirectly, even if they subsequently become aware of the identities of the faculty members.



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Pre-existing Relationships of CME Faculty with Manufacturers:

A unique situation arises when a faculty member at an Accredited and Certified CME activity has a pre-existing relationship with a manufacturer, outside of the CME program, such as serving on a corporate speakers' bureau, stock ownership, or other relationship. In such cases, those relationships must be disclosed, and are covered under the reporting requirements on page 78748, column 1, as such payments fall under "consulting fees, compensation for services other than consulting, honoraria", or another category.

However, those relationships do not qualify in this section of the Act, as the 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."

Relationships of Promotional Educational Speakers with Manufacturers:

If the intent of the proposed rule is to disclose relationships between manufacturers and speakers at a promotional educational program offered by applicable manufacturers, we would agree that those relationships should be transparent and should be appropriately included in reporting (and we believe are included already under "honoraria" on page 78748). However, these speakers should not be described as faculty or speakers in an Accredited and Certified CME activity, since promotional educational programs, offered by manufacturers, are not Accredited or Certified CME programs.

We believe that all would agree that there is no sense in including language in the final rule which betrays a misunderstanding of regulations governing relationships between faculty of Accredited and Certified CME programs offered by CME Providers, as distinguished from speakers at promotional educational programs offered by applicable manufacturers.

Absence of Relationships of Participants in Accredited and Certified CME Activities with Manufacturers:

We are concerned that there may be a misguided attempt in the proposed rule (pp. 78750-1) to establish a relationship between applicable manufacturers who may make an educational grant to a CME Provider and participants in the Accredited and Certified CME activity, when the manufacturer becomes aware of the identity of the participants. There would be unintended consequences inherent in the communication of the identities of physician participants in Accredited and Certified CME activities to companies. Reporting the names of participants who attend independent Accredited and Certified CME activities supported by educational grants from applicable manufacturers, thereby mistakenly identifying those participants as having a relationship with the funding company will discourage physicians from attending Accredited and Certified CME activities. 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 the PPSA to control expenditures in government sponsored health care programs.

In 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



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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 independently 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. Neither faculty nor participants in Accredited and Certified CME activities have relationships established with applicable manufacturers by virtue of the manufacturer making an educational grant to the CME Provider under the ACCME Standards for Commercial Support of continuing medical education.

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.

Sincerely,

Norman B. Kahn, MD
Executive Vice President and CEO



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American Academy of Family Physicians (AAFP)
American Academy of Hospice and Palliative Medicine (AAHPM)
American Academy of Neurology (AAN)
American Academy of Ophthalmology (AAO)
American Academy of Otolaryngology-Head and Neck Surgery (AAOHNS)
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