

January 15, 2015

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Tavenner:

On behalf of the 41 medical specialty society members of the Council of Medical Specialty Societies, we write to express our confusion and disappointment with the recently posted [Law and Policy website guidance](#) (“Website Guidance”) on the reportability of payments to speakers at Continuing Medical Education (“CME”) events under the Open Payments program.

In September this year, CMSS and many others urged CMS not to remove the Open Payments exemption for reporting of payments to certain accredited CME providers that are used for speaker payments and tuition subsidies (“the CME Exemption” or “the CME Exception”). CMS disregarded these pleas and announced that it was removing the CME Exception as part of the Final Medicare Physician Fee Schedule Rule, 79 Fed. Reg. 57547, 67758 (Nov. 13, 2014) (“Final Rule”). As we feared, CMS’s decision to abandon the CME exemption in favor of the less clear, indirect transfer rule has already led to confusion among stakeholders. The Website Guidance adds significantly to this confusion by contradicting CMS’s rationale for removing the CME Exemption.

As continuing education providers to our collective membership of over 750,000 healthcare professionals, CMSS member societies believe that accredited continuing education improves patient care by enhancing the knowledge and skill of health care professionals. Our national standards (ACCME Standards for Commercial Support of CME) protect against commercial influence by ensuring that companies offering financial support of accredited educational programming have no control over the content or choice of speakers. The language in the preamble to the Final Rule that CMS used to justify removal of the CME exception clearly stated that industry payments to support accredited CME would not be indirect transfers and thus would not be reportable if the applicable manufacturer was not involved in designating the physician speaker, even if the applicable manufacturer later learned the identity of the physician speaker within the allotted timeframe. By contrast, the Website Guidance disregards the preamble language of the Final Rule and would require reporting any time where a supporting manufacturer provides a contribution for an accredited CME event and learns the identity of physician speaker within the required time frame, even where the manufacturer had nothing to do with the selection of the CME speaker(s). This complete reversal is disingenuous and will lead to unnecessary reporting that inevitably will chill physicians’ participation in continuing education, as both faculty and attendees.

The website guidance contradicts the Final Rule

CMS’s stated intention in removing the CME exemption was to create a consistent reporting requirement for continuing education and to actually broaden the set of continuing education related payments that would be free from reporting. The Final Rule justified this removal by explaining that industry financial support of CME would not be reportable in cases where the manufacturer is not involved in picking the specific physician speakers, even if the manufacturer later learns the identify of such speakers. Specifically, the preamble to the Final Rule stated:

For example, if an applicable manufacturer or applicable GPO provides funding to support a continuing education event but does not require, instruct, direct, or otherwise cause the continuing education event provider to provide the payment or other transfer or value in whole or in part to **a covered recipient**, the applicable manufacturer or applicable GPO is not required to report the payment or other transfer of value. The payment is not reportable regardless if the applicable manufacturer or applicable GPO learns the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year because the payment or other transfer of value did not meet the definition of an indirect payment.

79 Fed. Reg. at 67760 (emphasis added). Thus, as long as the applicable manufacturer does not identify specific physician *speakers*, there is no reportable indirect transfer, even if the manufacturer later learns the identity of the speaker within the allotted time frame. CMS included language in the preamble that suggested the same rule would apply to physician *attendees* at CME events—i.e., that the manufacturer would have to identify specific physician attendees for tuition subsidies to be reportable.

The Website Guidance disregards and contradicts the Final Rule preamble rationale for removing the CME Exemption. After restating the indirect transfer of value rule and exclusion, the Website Guidance states that the following scenario will be reportable in 2017:

An applicable manufacturer provides a payment to an accredited continuing education organization for a continuing education event for physicians. The applicable manufacturer does not pay the physician speaker directly, nor does the manufacturer select the speaker or provide the continuing education organization with a distinct, identifiable set of individuals to be considered as speakers for the continuing education. The applicable manufacturer is able to determine who the physician speaker was by the end of the reporting year or by the second quarter of the following reporting year.

This is precisely the type of scenario that CMS said would not be reportable in the Final Rule preamble because it would not meet the requirements for an indirect transfer of value, since the applicable manufacturer would not have required, instructed, directed, or otherwise caused the continuing education provider to provide the payment or transfer of value, in whole or in part, to a specific covered recipient.

By disregarding and contradicting the agency's rationale for removing the CME Exemption, the Website Guidance will greatly expand the number of payments that will be reported. This will inevitably discourage physicians who have no other financial relationship with an applicable manufacturer from speaking at CME events. To avoid confusion, uncertainty, and disputes over reporting requirements, we strongly urge CMS to immediately revise the Website Guidance to conform to the language of the Final Rule preamble.

CMS should issue promised guidance exempting subsidies unless designated for specific physician attendees

CMS should affirm that subsidies to attendees at CME events are not reportable unless the applicable manufacturer designates the payment for specific physician attendees. As with physician speakers, tuition subsidies meet the definition of indirect transfers of value only if the applicable manufacturer requires, instructs, directs, or otherwise causes the continuing education provider to provide the payment or transfer of value, in whole or in part, to a specific covered recipient. Without this clarification on the reporting of tuition subsidies to attendees, the Website Guidance will lead to confusion and over reporting of payments by manufacturers. The appearance of a relationship with a manufacturer where no relationship actually exists could deter physicians from attending CME events. To prevent a potentially devastating impact on educational programming, we urge CMS to promptly issue the guidance that was promised in the Final Rule preamble: "We will provide sub-regulatory guidance specifying tuition fees provided to physician attendees that have been generally subsidized at continuing education events by manufacturers **are not expected to be reported.**" 79 Fed. Reg. 67760 (emphasis added).

CMS has muddied the waters in an already tense compliance environment by publishing inconsistent guidance and undermining the basic premise of the indirect transfers rule. Indirect transfers of value should not be reportable if the manufacturer does not require, instruct, direct or otherwise cause the payments to be made to a specific covered recipient, regardless of whether the manufacturer eventually becomes aware of the identity of covered recipients. Please promptly issue revised guidance that confirms the agency's interpretation of continuing education payments as published in the preamble to the Final Rule.

Thank you for your consideration.

Sincerely,



Norman Kahn, MD
Executive Vice-president & CEO
Council of Medical Specialty Societies