



*Proposal in Response to CMS Call for
Comments on CME Exemption
August 7, 2014*

I. Background

On July 3, the Centers for Medicare and Medicaid Services (CMS) proposed eliminating the “CME exemption” of the Sunshine Act, which explicitly exempts speaker compensation at certain accredited events from reporting requirements. Without an exemption, a manufacturer who contributes a grant to a CME provider would make what is defined as an “indirect payment” whenever the provider uses the manufacturer’s funds to cover physician speaker fees. These payments become reportable should the manufacturer learn of the identity of the recipient of the value transfer up to 18 months after the grant is executed.

As currently written, the Sunshine Act Final Rule requires three items for a payment related to a CME program to be “Sunshine exempt.” First, the program must meet the accreditation or certification requirements of one of five explicitly mentioned bodies: ACCME, AOA, AMA, AAFP or ADA CERP. Second, the manufacturer must not select the speaker nor provide the CME provider with a distinct, identifiable set of individuals to be considered as speakers. Third, the manufacturer must not directly pay the speaker.

In an effort that it claims is intended to expand the list of educational events where speaker expenses would be exempt from reporting, on July 3rd, CMS proposed to remove the CME exemption in its entirety. According to CMS, speaker payments would now simply fall into the “indirect payment” exemption of the Sunshine Act, which excludes from reporting any payments where the manufacturer remains "unaware" of the identity of the physician during the next 18-month period.

In part, CMS suggests that its intent in removing the CME exemption is to avoid picking favorites among accrediting bodies. To bolster this stated intent, the proposed preamble states that payments to a continuing education provider where the manufacturer does not either (1) give the provider a distinct, identifiable set of physicians to be considered as speakers, or (2) directly pay the physician speaker, would fall under the indirect payment exemption. At face value, this preamble simply has CMS removing the accrediting body requirement from the current CME exemption: whenever a manufacturer gives any education provider funds, but (1) avoids sending a list of speakers and (2) doesn’t pay physicians directly, the manufacturer would be exempt from reporting speaker pay.

Despite CMS' stated intentions, however, we believe that removing the explicit CME exemption that exists in the current Final Rule could have the disastrous effect of expanding the reporting requirements for accredited CME for at least three reasons:

- (1) **Unworkable Awareness Standard for CME:** The “indirect payment” exemption that CMS relies on disappears if, within 18 months, the applicable manufacturer finds out, or becomes “aware” of the identity of the physician recipient. Because CME presenters are always publicly listed, as a practical matter, speaker payments will have to be reported as a general rule.

Because of the current “CME Exemption” language, CMS does not apply the “awareness” standard to CME programs that meet all three requirements. Thus, today, manufacturers are not on notice that they may be responsible for tracking indirect payments to physician speakers or attendees that they later find out spoke at, or attended, exempt CME events.

An additional concern with the proposal is that CMS' new policy is slated to take effect starting in 2015, and thus the awareness standard would presumably apply retroactively to all indirect CME payments.

- (2) **Attendees:** As noted in the current preamble language in the Final Rule discussed in (1), above, CMS exempts the reporting of attendees' educational value or the value of tuition-related materials at CME events, but only if the CME event meets the “three requirements” that it outlines in the subsection it now proposes to eliminate. While manufacturers are disallowed from choosing or even influencing who attends accredited CME programs, the “awareness” standard could potentially implicate a whole host of attendees in the 18-months following an educational event.

[FAQ 8386](#) reveals just how much emphasis CMS places on the three prongs in the current rule: “Lodging, travel and meals for speakers of an accredited or certified CME event meeting all three requirements in 42 CFR 403.904(g)(1) will be deemed to be included in the total speaker compensation and, therefore, exempt from reporting under Open Payments. However, travel, lodging and meals and all other natures of payments provided in conjunction with the accredited or certified CME event (*with the exception of educational materials included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions, such as handouts, web downloads or printed slides*) will need to be reported for physician attendees (who are not speakers).” (emphasis added)

- (3) **Preamble v. Final Rule:** Whereas the revised rule being proposed would be silent on any special treatment for CME related payments, CMS only suggests that indirect payments to speakers at CE events would be exempt from reporting in its proposed *preamble* to the Rule. This is worrisome because preamble language standing alone is considered very unreliable from a legal standpoint. A definition or even acknowledgement of “accredited or certified continuing medical education” would thus be absent from the Final Rule making the status of CME-related payments very uncertain.

II. CME Coalition Proposal

With these concerns in mind, we have drafted specific language for CMS to adopt in place of their proposal. The summary of our comments is as follows:

1.) First, we are proposing that CMS maintain an explicit definition in the Final Rule of "accredited or certified CME" in the definition section of the Final Rule itself

We believe that, given the structure of the Rule, we must have a definition for what a “Sunshine Exempt event” looks like. We believe that CMS is never going to exempt all “indirect payments” from reporting, so there is a need to create a category of events where speaker and attendee value is exempt from reporting. Our proposal expands the current CME exemption beyond the currently enumerated five accrediting bodies to include all *bona fide* accreditors.

Our proposed definition is:

Revise §403.902 (Definitions) to add “accredited or certified continuing education program”:

- A. An educational activity designed, sponsored or hosted by a third party organization that is accredited or certified by an accrediting body or organization that is recognized by a state or federal government. The accrediting body or organization must:*
- a. Have standards regarding the acceptance and use of payments or other transfers of value from applicable manufacturers;*
 - b. Enforce compliance with these standards through audit, inspection, complaints, or otherwise;*
 - c. Have the authority to impose penalties for non-compliance with such standards, including loss of status or ability to offer credits to physicians;*
 - d. Require the third party organization to certify compliance with such standards on a regularly scheduled basis (e.g., bi-annually); and*
 - e. Not be owned or controlled, in whole or in part, by an applicable manufacturer*
- B. The educational activity can be in-person, online, or through other educational platforms.*
- C. The educational activity includes the value of the tuition or attendance fees, as well as any educational materials or items associated with the program (e.g., slides or handouts) as long as (i) the content is related to the educational activity; and (ii) the funds used for the materials came from the same financial support.*

2.) Second, on top of this revised definition, we would propose the following response to the CMS request for comment

- We recommend incorporating the definition of “accredited or certified continuing education” in section (g) to specifically exempt payments to speakers, faculty, and attendees at events that meet the previously described exemption definition. Additionally, our revision to (g) includes three more safeguards (which all accredited and certified CME providers already have in place) to provide addition assurance to CMS.
- Thus, our proposal not only provides continuity from the current Final Rule, in (a) and (b), but also adds (c), an additional firewall, which states that a manufacturer may not influence attendees. So, in total, there are four explicit firewalls in our proposed revision to be spelled out

in the Final Rule, namely, the CME program: (1) must meet the definition of “accredited or certified”, (2) manufacturers must not pay physicians directly, (3) manufacturers must not send speaker lists or suggest speakers, and (4) manufacturers must not influence, invite, or select physician attendees.

- Our proposal also specifies that the “awareness” standard for indirect payments does not apply to accredited or certified CME.

Thus, instead of deleting section (g), we would revise it to state:

- (A) *Payments or other transfers of value provided indirectly to physician speakers, faculty, or attendees at an **accredited or certified continuing education program** (as defined above) are not required to be reported if all of the following conditions are met. The applicable manufacturer must not:*
- a. Select or pay the covered recipient speaker directly;*
 - b. Provide the CE/CME provider with a distinct, identifiable set of covered recipients to be considered as speakers; and*
 - c. Influence, invite or select the covered recipient-attendees or otherwise condition its financial sponsorship on the participation of particular covered recipients.*
- (B) *The awareness standard (as defined in § 403.902) shall not apply to physician speakers, faculty, or attendees at an accredited or certified continuing education program.*

III. Conclusion

In tandem with our proposal, we would also stress that CMS continues to have the power to audit manufacturers and that manufacturers must continue to attest to their reports’ accuracy. Companies may also include in their assumptions document that they only give grants to accredited or certified CME providers.

We recognize that this is very complicated and expect that CMS will receive a broad range of recommendations. Therefore, we recommend that CMS propose to expand the exemption to all *bona fide* accredited CME.