



August 29, 2014

Mariyln Tavenner
Administration
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Tavenner:

The Medical College of Wisconsin thanks CMS for the opportunity to comment on the proposed rule related to PPSA. Certified CME activities, as well as the educational materials that supplement and support the activities, result in improved patient care and health outcomes. The current CME accreditation system governed by the Accreditation Council for Continuing Medical Education (ACCME) has detailed criteria focused on improve clinical quality and patient care. Further, safeguards are currently in place via the ACCME's Standards for Commercial Support™ to ensure a clear separation between promotion and education. As stated by the CME Coalition, "the proposed rule does not differentiate between accredited CME—which already is regulated by the Accreditation Council for CME, Food and Drug Administration, Office of the Inspector General, and the American Medical Association, along with industry voluntary codes, to safeguard against bias and conflict of interest—and promotional programs." CME is essential for the healthcare system as physicians must remain current in a rapidly changing field.

The Medical College of Wisconsin (MCW) was founded in 1893 as a private school and has more than 14,000 alumni. Our mission is to be a national leader in the education and development of the next generation of physicians and scientists; to discover and translate new knowledge in the biomedical sciences; to provide cutting-edge, interdisciplinary and compassionate clinical care of the highest quality; to improve the health of the communities we serve. As one of the city of Milwaukee's largest employers (5,000 employees), MCW is active in serving our community and the medical profession by not only educating future physicians, but by providing high quality certified CME to practicing physicians as well. MCW is an accredited CME provider. MCW currently employs four full time staff to manage the accreditation of approximately 200 CME activities providing approximately 70,000 AMA PRA Category one Credits™ to 4,700 physicians.

The Medical College of Wisconsin believes that CMS should not rescind §403.904(g)(1) of the Open Payments Program. CMS should retain the requirements that "the applicable manufacturer does not pay the covered recipient speaker directly" and retain the requirement that "the applicable manufacturer does not select the covered recipient speaker or provide the third party (such as the continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program." These requirements are essential elements of ACCME® Standards for Commercial Support: Standards to Ensure Independence in CME Activities ("the ACCME SCS"). 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.

We respectfully submit that the unintended consequences of the proposed rule on the CME system are significant. Accredited, independent CME activities should be exempt from reporting.

1. **Misleading the public –**

- a. The covered recipient and the applicable manufacturer are not contractually engaged. The covered recipient does not determine who the funders of CME activities are, the amount of funding, nor the allocation of said funding. The applicable manufacturer does not determine who the covered recipients are who participate in the CME activity, the nature of the participation nor the amount of participation. Given the unpremeditated nature of this circumstance, reporting CME would mislead the public in to presuming a relationship between covered recipients and applicable manufacturers where there is none.
- b. Any report generated as a result of the proposed rule, on monies received from applicable manufacturers that are not presented within a context of clinical /research performance may be detrimental to certain physicians. A physician may have a higher dollar amount attributed to her because she is renowned in her field with exceptional patient outcomes and has invented methods that not only improve patient care, but reduce healthcare costs. Another physician may also have a high dollar amount attributed to his practice, but he is not considered a leader in the field, does not keep current by attending CME activities and /or has poor patient outcomes. Yet without a proper context, patients will be misled into assuming there is no distinction between the physicians.

2. **Harming the public –**

- a. As the amount of certified CME decreases as a result of this rule, it will become more challenging for physicians to earn enough credits to maintain licensure. CME credits for licensure is a minimum standard in ensuring competent physicians are practicing within any particular state. If a state responds to the lack of CME accessible to physicians licensed in that state by decreasing the amount of certified CME required or eliminating such a requirement; the residents in that state are at greater risk of poor quality care from less competent physicians.
- b. Cover recipients, particularly those who specialize in procedural based fields of medicine may be deterred from participating in much needed training on new skills in such cases where the training is subsidized by an applicable manufacturer. The Open Payments website only states the transfer of value from the applicable manufacturer, but does not report the out of pocket dollars from the physician for the same training. This unintended deterrent would harm patients as some physicians would choose not to participate in new procedures training due to possible reporting. Moreover, the reporting could result in a perception of impropriety, risking the reputations of those who participate in CME with the intent of teaching and/or learning how to improve patient care.

3. **Increase cost of healthcare** - assigning, calculating, tracking and reporting a value to individual faculty members and/or participants of certified CME would divert precious resources from education to administration. The massive administrative burden to manage the proposed rule as it is written would require a significant increase in human resources to accommodate additional staff and documentation of compliance. This additional expense is further complicated as the proposed rule would also cause a significant decrease in revenue as the number of CME offerings would decrease. The administrative burden placed on faculty that serve as Activity Directors and their support staff would increase as the proposed rule change necessitates additional initial data collection for each meeting speaker, planner and attendee. This burden would discourage physicians from developing quality clinical content driven educational interventions. The number of CME activities will significantly decrease as current taxed resources cannot meet the needs set forth by the reporting requirements.

4. **Inaccurate data** - the risk of inaccurate reporting increases as different accredited CME providers use different accounting/costing methods and each applicable manufacturer also has their own accounting practices. As each applicable manufacturer will have different systems and requirements for collecting, recording and reporting such information, each accredited CME provider would be accountable to align their systems with each applicable manufacturer. With the number of people required to collect, aggregate, audit, and transmit data to multiple entities; the opportunities for inaccuracies in a system which could potentially jeopardize the reputation of a high quality physician with an excellent clinical track record is highly likely. Already, during this first dispute resolution period; numerous physicians submitted disputes regarding inaccurate data.

5. **Discourage education** - The proposed rule change creates an ethical obligation on the part of accredited providers to accurately calculate and proactively inform every potential CME activity attendee about the dollar amount that could be applied to their Open Payment record for attending a CME activity. The administrative burden of the calculation would be tedious at best as an accurate dollar value could not be properly calculated until after the meeting when all actual attendees can be accounted for. Further, such a disclaimer would discourage attendance at meetings that have higher dollar amounts regardless of the high quality education. Attendees have no control over how a meeting is funded or the amount of the funding. Yet, according to the proposed rule, each attendee would have a dollar value based on the support attributed to them.
The proposed rule penalizes physicians for keeping current in medicine which is not only vital to the healthcare system, but required for licensure and board certification.
6. **Unworkable Awareness Standard for CME** – Per the CME Coalition, 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.
 - a. 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.
 - b. 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)
 - c. 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.

We support the CME Coalition Proposal to define accredited or certified CME and
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.

The 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.

Therefore, in tandem with the CME Coalition proposal, we too 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. We strongly urge you to ensure that indirect commercial support for accredited and certified CME activities, where the accredited provider exercises complete control over the content and speakers/faculty, remains exempt from reporting under the Open Payments system. It is vital to the public that their healthcare providers remain well educated and informed on the latest medical science in their field, and therefore, we must encourage, rather than discourage, participation in CME.

Respectfully Submitted;

A handwritten signature in blue ink that reads "Linda Caples". The signature is written in a cursive, flowing style.

Linda Caples, MBA
Director, Office of Continuing & Professional Education