



Questions presented to CMS from the CME Coalition on April 25, 2013 regarding Clarifications on The Finalized Rule Implementing the Physician Payment Sunshine Act – Section 6002 of the Patient Protection and Affordable Care Act.

The CME Coalition both appreciates and endorses the manifest goals of the Physician Sunshine Act and the finalized regulations issued by CMS on February 1, 2013. For a host of reasons, we recognize the public interest in knowing whether physicians are financially benefiting from the same companies that produce the medicines they prescribe and the devices that they use. We greatly appreciate CMS’ willingness to provide certain protections for some payments related to accredited or certified continuing medical education (CME). We also strongly agree with CMS’ assertion that accrediting and certifying bodies and “the industry standards for commercial support create important and *necessary* safeguards, prohibiting the involvement of the sponsor in the educational content.”¹

The final rule states that “payments” to speakers are completely exempt from reporting if such payments meet three conditions: speaker compensation must: (i) relate to an event satisfying CME accreditation standards; (ii) not be paid directly by the manufacturer; and (iii) the manufacturer cannot select the speaker or provide a list of individuals to be considered as speakers.

In light of the finalized rules and discussion of accredited CME, the Coalition has several questions we are hoping CMS can provide additional clarification and guidance.

1. Accreditation and Certification Bodies for Continuing Medical Education

Question:	Are there additional accreditation or certification bodies other than those enumerated in the final rule that may qualify for the exclusion related to compensation for serving as faculty or as a speaker for an accredited or certified continuing education event?
Suggested Answer:	Yes. While the list of accreditation or certification bodies set forth in 42 C.F.R. § 403.904(g)(1)(i) is extensive, it is not intended to be an exclusive list. Other entities provide accreditation or certification as to the legitimacy of educational content beyond the Accreditation Council for

¹ 78 Fed. Reg. at 9492.

	<p>Continuing Medical Education (“ACCME”), the American Academy of Family Physicians (“AAFP”), the American Dental Association’s Continuing Education Recognition Program (“ADA CERP”), the American Medical Association (“AMA”), or the American Osteopathic Association (“AOA”). Other independent third party accrediting bodies meeting the same, or substantially similar requirements or standards, particularly in the areas of</p> <ol style="list-style-type: none"> (1) independence from commercial support; (2) programs and activities designed to meet provider identified educational needs (e.g. medical/scientific); (3) other elements that are intended to promote learning in an environment that supports professionalism and avoids undermining objectivity; and (4) limitations on interactions with commercial sponsors, <p>may also qualify for the exclusion (e.g., the European Accreditation Council for Continuing Medical Education (“EACCME”)).</p>
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The final rule indicates as a condition for excluding the reporting of payments to speakers and faculty, that a CME program must be accredited by one of five enumerated accrediting bodies.² *We recommend that CMS clarify that the list of accreditation or certification bodies included in the Final Rule is not exclusive and that other organizations meeting the same or similar requirements or standards may also qualify for the exclusion related to compensation for speaking at a continuing education program.* For example, if a physician speaks at a CE program accredited by the American Nurses Credentialing Center (ANCC), Accreditation Council for Pharmacy Education (ACPE)—both of which have adopted the ACCME standards for commercial support as their guidelines—the physician’s compensation should not be reportable if the other two conditions are met. Even if the accrediting body or organization has not adopted ACCME or other standards, as long as the organization meets the same or similar requirements or standard, speaker or faculty compensation should be excluded from reporting if it meets the other two conditions.

Likewise, Canada³ and Europe⁴ have agreements with the ACCME for recognizing certain AMA credits. Accordingly, if a U.S. licensed physician served as a speaker or faculty at a program recognized under the agreements in one of these countries, the physician’s compensation should not be reportable if the other two conditions are met. This clarification is consistent with the intent of exclusion – to protect the unique relationship of industry support for accredited or certified CE as long as certain safeguards are met – and ensures that the Sunshine Provisions do not inappropriately “regulate the business of the drug and device industries.”⁵

² 78 Fed. Reg. at 9479. Listing the ACCME, AOA, AAFP, AMA, and the ADA CERP.

³ <http://www.accme.org/accreditors/partners-accreditation>

⁴ <http://www.ama-assn.org/ama/pub/education-careers/continuing-medical-education/physicians-recognition-award-credit-system/other-ways-earn-ama-pra-category/international-programs/uemseaccme-credit-conversion.page>

⁵ Statements on Introduced Bills and Joint Resolutions, Senator Charles Grassley, S. 2028, page S11218 (Sept. 6, 2007).

2. Meals for Physician-Attendees and non-covered recipients at Accredited or Certified CME Programs

Question:	Are meals for physician-attendees and non-covered recipients, provided at accredited or certified CME programs that meet all three conditions, included in the “industry support of CME programs ... that will not be considered [reportable] indirect payments”?
Suggested Answer:	Yes. When an accredited or certified CME program meets all three requirements, the industry support of the CME program, including meals provided to all attendees including physician-attendees and non-covered recipients, is not a reportable indirect payment. Thus, as long as the CME program meets all three requirements, and the applicable manufacturer does not specify or select individual attendees to receive meals, meals to physician-attendees and non-covered recipients at accredited or certified CME program are exempt from reporting.

Requiring a manufacturer to report meals for a physician-attendee at an accredited or certified CME program would be a direct violation of ACCME SCS 3.1, 3.7, 3.9, 3.12, or the second condition (paying a physician directly). Importantly, SCS 3.1 clearly asserts that the “[CME] provider must make *all* decisions regarding the disposition and disbursement of commercial support,”⁶ including *meals*, and SCS 3.9 states that “*No other payment shall be given to ... any others involved in the activity.*”⁷ Further, SCS 3.12 states that “The [CME] provider may not use commercial support to pay for travel, lodging, honoraria, or *personal expenses* for non-teacher or non-author participants of a CME activity.”⁸

The final rule maintains that applicable manufacturers are “not responsible for reporting payments made to CME vendors that are used to subsidize attendees’ tuition fees for Sunshine-exempt continuing education events.”⁹ CMS did state that “payments or other transfers of value associated with attendance of [a CME] event (such as travel and meals) must be reported *as required.*”¹⁰ In making this assertion, however, CMS referred stakeholders to its explanation of the “Education” nature of payment category, which stated that only payments for meals and travel associated with CME events, must be reported if the applicable manufacturer “*specified [the] covered recipients associated with*” CME events.¹¹ Such internal reference strongly suggests that travel and meals for attendees would only have to be reported if the applicable manufacturer *specified* identifiable attendees to receive meals. This conclusion is also supported by the fact that the final rule explains elsewhere that its exclusion for reporting food and beverage provided at conferences in settings where it would be difficult to establish the identities

⁶ ACCME SCS 3.1 (emphasis added).

⁷ ACCME SCS 3.9 (emphasis added).

⁸ ACCME SCS 3.12 (emphasis added).

⁹ 78 Fed. Reg. 9492.

¹⁰ 78 Fed. Reg. 9492 (emphasis added).

¹¹ 78 Fed. Reg. 9481 (emphasis added).

of people partaking in the food does “*not* ... apply to meals provided to *select* individual attendees.”¹²

Furthermore, the “Education” section explicitly states that CMS does “not intend to capture the *attendees* at accredited or certified continuing education events whose fees have been subsidized through the CME organization by an applicable manufacturer (as opposed to payments for speakers at such events).”¹³ By emphasizing attendees, and distinguishing them from speakers, the final rule appears to demonstrate CMS’ intent to exclude from reporting any “fees” for such attendees that have been subsidized through the CME provider. Thus, the final rule appears to suggest that subsidized *fees* for *attendees*, such as educational value or materials and meals associated with a Sunshine-exempt CME programs are excluded from reporting. Moreover, the final rule’s decision to use “fees” instead of “tuition,” as used in the CME section, further indicates that CMS did not intend to capture fees (such as meals and educational value) for attendees subsidized through the CME organization by an applicable manufacturer.

The final rule requires that CME programs meet the accreditation standards of the ACCME, which includes Standard for Commercial Support 3.2, which prohibits applicable manufacturers from providing advice concerning CME participants. Thus, manufacturers cannot *specify* or *select* individual attendees, or “require, instruct, direct, or otherwise cause” a payment or transfer of value in the form of a meal or beverage to be made to such attendees.

For these reasons, we ask that CMS clarify that meals provided to physician-attendees at Sunshine-exempt CME programs in all circumstances, plated or buffet, be excluded from reporting and tracking because such fees are included in the subsidized fees and tuition for attendees through the CME provider.

3. CMS Example of an Unrestricted Grant

Question:	Is the CMS example of an “unrestricted” donation applicable to accredited or certified CME that meets all three conditions?
Suggested Answer:	No. Because CMS will not consider industry support of CME that meets all three conditions as a reportable indirect payment, the unrestricted example is inapplicable.

In the final rule, CMS said that the Sunshine-exempt CME programs “will not be considered indirect payments... for the purposes of reporting.”¹⁴ Later, CMS used an example to help explain indirect payments. Specifically, CMS stated that a manufacturer that provides an “unrestricted” donation to a physician organization which uses some of the donated funds to provide grants to physicians would not be reportable because the manufacturer “did not require, instruct, or direct” the use of the funds.¹⁵ On the other hand, if a manufacturer had earmarked

¹² 78 Fed. Reg. 9479 (emphasis added).

¹³ 78 Fed. Reg. 9481 (emphasis in the original).

¹⁴ 78 Fed. Reg. 9458, 9492 (February 8, 2013).

¹⁵ *Id.* at 9,490.

the donation for physician grants, then that would be considered an indirect payment, and thus reportable because the manufacturer was directing a certain use of the funds.¹⁶

We believe that the example of an earmarked grant being reportable is inapplicable to Sunshine-exempt CME programs because the final rule explicitly recognizes that Sunshine-exempt CME programs “will not be considered indirect payments... for the purposes of reporting.”¹⁷

Furthermore, the grant process associated with Sunshine-exempt CME programs, even if the nature of those programs is specified by the grantor, can fairly be described as an unrestricted grant for purposes of applying the Sunshine Act rule. Under ACCME standards, the disposition of funds is left to the complete discretion of the CME provider thus, in effect, making these CME grants unrestricted.¹⁸

While the CME grant, or proposal itself, may be “restricted” because it targets a particular disease or class of treatments, Congress’ intent and the final rule focus on *how* the payment is being made through a third party to a physician, not *what* topic (e.g., diabetes, cancer) to which the payment is directed. The proposal is unrestricted in terms of *whom* the CME provider will choose for speakers, or invite to attend, because the ACCME SCS prohibit applicable manufacturers from choosing, recommending or providing a list of speakers or attendees. In fact, the CME provider’s involvement is “specifically to maintain the anonymity”¹⁹ of the speakers and the sponsor until the CME provider has been awarded commercial support.²⁰

4. Travel, Lodging, and Meals Provided to Speakers and Faculty of Accredited-CME Programs

Question:	Are payments for travel, lodging and meals to speakers and faculty of accredited or certified CME events that meet all three conditions, included in the total compensation that is exempt from reporting?
Suggested Answer:	Yes, because attributing such payments to speakers or faculty at accredited or certified CME events violates accreditation standards.

Requiring applicable manufacturers to report payments to speakers or faculty at accredited or certified CME events that meet all three conditions would cause a direct violation of ACCME SCS 3.1, 3.7, 3.8, 3.9, or the second condition (paying a physician directly). Importantly, SCS 3.1 clearly asserts that the CME “provider *must* make *all* decisions regarding the disposition and disbursement of commercial support”²¹ and SCS 3.8 explicitly states that “The [CME] *provider*, the joint sponsor, or designated educational partner *must pay any teacher or author* honoraria or *reimbursement of out-of-pocket expenses ...*”²² SCS 3.9 states that “*No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved in the activity.*”²³

¹⁶ *Id.*

¹⁷ 78 Fed. Reg. 9458, 9492 (February 8, 2013).

¹⁸ See ACCME SCS 3.1.

¹⁹ *Id.*

²⁰ This is consistent with ACCME SCS 3.2.

²¹ ACCME SCS 3.1 (emphasis added).

²² ACCME SCS 3.8 (emphasis added).

²³ ACCME SCS 3.9 (emphasis added).

It is commonplace in the CME industry that speakers and faculty of accredited or certified CME programs receive *total compensation* for their services, which include reasonable out-of-pocket expenses for travel, lodging and meals commensurate with the time they serve as a speaker or faculty for the CME event. This total compensation is paid for by the CME provider through the larger CME grant provided by the applicable manufacturer, similar to research grants.²⁴ Applicable manufacturers cannot attribute out-of-pocket expenses or payments to faculty or speakers for meals, travel or lodging with an accredited or certified CME program without violating the ACCME Standards for Commercial Support.

Accordingly, we request that CMS clarify that reasonable payments for travel, lodging and meals that are paid directly by the CME provider to the speaker or faculty, and are part of the larger CME grant, be *included* in the *total speaker compensation* that is excluded from reporting for Sunshine-exempt CME programs. We believe this clarification is clearly consistent with CMS' intent to "greatly reduce the number of payments to *speakers*."²⁵

5. Educational Value and Educational Materials Associated with Accredited or Certified CME Programs

Question:	Are educational materials or items associated with an accredited or certified CME program that meets all three conditions, such as slides or handouts, included in the tuition fees for continuing education events that are excluded from reporting?
Suggested Answer:	Yes.

CMS excluded from reporting any educational value for physician-attendees associated with a CME event that meets all three conditions for exemption. Specifically, CMS maintained that applicable manufacturers are "not responsible for reporting payments made to CME vendors that are used to subsidize attendees' tuition fees for continuing education events."²⁶ In distinguishing "Education" from payments related to Sunshine-exempt CME, CMS also stated its intent "not ... to capture the *attendees*²⁷ at accredited or certified CE events whose *fees* have been subsidized through the CME organization."²⁸

We thank CMS for this exclusion, but seek additional clarification. CME providers frequently provide physician-attendees with educational materials, such as slides or handouts. To ensure that CME providers are not providing any payment or transfer of value outside the "tuition" CMS excluded, we ask that CMS clarify what educational materials associated with a Sunshine-exempt CME program are part of the exclusion. To assist CMS with this decision, we propose that CMS adopt the following factors to determine if the educational materials provided at an accredited or certified CME program fall within the exclusion of "tuition fees" or CE "fees." Therefore, if:

²⁴ 78 Fed. Reg. at 9484.

²⁵ 78 Fed. Reg. 9458, 9492 (February 8, 2013).

²⁶ *Id.* at 9492.

²⁷ *Id.* at 9481 (emphasis in original).

²⁸ *Id.* at 9481 (emphasis added).

(a) The educational item or material is directly and significantly related to the accredited CME program for which they attended;

(b) The educational item or material was created by the accredited CME provider and specified faculty and staff of that provider;

(c) The funds used to create the educational item or material came from the *same* supporter and larger grant for the CME program; *and*

(d) The educational item or material meets all the requirements under ACCME SCS, Standard 4,

The materials or items are *included* within the subsidized attendee tuition fee and are therefore *exempt* from reporting and tracking requirements.

We also ask that CMS recognize that due to the various educational formats and venues, CME providers may disseminate educational materials or items in various forms, such as in print, online, or on a thumb drive. We ask that CMS include in the tuition fee the time it takes to create such materials or items and the value of printing or electronically accessing such materials,²⁹ as long “as they are directly related to the development” of the CME program and meet the conditions enumerated above.

6. Buffet Meals at an Unaccredited Program That Take Place at a Large Conference Where There is General Sponsorship or an Exhibit Booth

Question:	If an applicable manufacturer supports an unaccredited educational program at a large annual conference and serves buffet meals, but also provides payment for general sponsorship or has an exhibit booth, will the awareness standards be applicable to the buffet meals provided at the unaccredited program?
Suggested Answer:	No. CMS will not apply the awareness standards to such meals in the event that the same manufacturer also provides general sponsorship or has an exhibit booth. CMS’ intent was to reduce the reporting of payments at such large events and it would be difficult for an agent of the manufacturer serving in a booth to determine whether a physician partook such meal.

Large annual meetings or conferences typically involve multiple supporters and multiple accredited and non-accredited activities. At such events, an applicable manufacturer may have provided payment to host an unaccredited educational program, which includes buffet meals that would not be reportable under the final rule because it would be difficult to identify which

²⁹ For example, an online CME program may require downloading materials or a CME provider may provide a thumb drive with CME slides and handouts.

physicians actually partook in the meal. In addition, the same supporter may have provided general sponsorship, which includes an exhibit booth or a promotional program.

During these large annual meetings or conferences, a physician-attendee may attend both the unaccredited educational program, and the exhibit booth, or the promotional program. A manufacturer’s employee or agent that staffs the exhibit booth or attends the promotional program may become aware of a physician’s identity, either through conversation or through a list of attendees obtained prior to the conference. Although this employee or agent may become aware of the physician’s identity, he/she is *not* aware of whether the physician *actually partook* in the meal at the unaccredited educational program supported by the applicable manufacturer. Thus, the buffet meal is not a reportable indirect payment and should remain exempt from reporting.

Moreover, imposing a knowledge requirement on such individuals would be burdensome and beyond CMS’ intent in the final rule to reduce the reporting of interactions at large-scale events, many of which CMS recognized “will not be reportable.”³⁰ Payments or transfers of value associated with the exhibit booth and/or promotional program would still be reportable as required. Accordingly, we ask that CMS clarify that under these circumstances, the buffet meals provided at a large conference would not be reportable or become reportable when an applicable manufacturer also has provided general sponsorship or has an exhibit booth because the manufacturer would still be unaware of the physician’s who *actually partook* in the meal.

7. Excluding “residents” and “fellows” from reporting and the definition of covered recipient

Question:	Are “fellows” within the definition of “resident,” which would exempt them from reporting?
Suggested Answer:	Yes, fellows should be considered interchangeably with resident.

In the final rule, CMS excludes from the definition of covered recipient “residents.”³¹ Historically, the terms “resident” and “residency” referred to a period during which physicians-in-training lived on the hospital campus and provided uninterrupted patient care.³² Currently, the term “residency” describes the phase of medical training following completion of medical school, and a “resident” is a physician acquiring specialized training under the direct supervision of attending physicians.³³ Likewise, “fellows” are in a phase of medical training in which they sub-specialize and focus on a specific area within the larger scope of the field in which residents are training.

³⁰ 78 Fed. Reg. at 9486.

³¹ 78 Fed. Reg. at 9467.

³² AMA Resident and Fellow Section Legislative Advocacy Committee: Defining the Role of the Resident Physician (citing Shepherd GR. History of continuing medical education in the United States since 1930. *J Med Edu* 1960; 35(8):740-758).

³³ Long DM. Competency-based residency training: the next advance in graduate medical education. *Acad Med* 2000; 75(12):1178-83.

The American Medical Association defines “resident” as: (1) members serving in residencies approved by the ACGME or AOA; (2) members serving in fellowships approved by the ACGME or AOA; (3) members serving fellowships in subspecialty training when such program is affiliated with and under the supervision of an approved residency training program; (4) members serving fellowships in structured clinical training programs for periods of at least one year, to broaden competency in a specialized field; (5) members serving, as their primary occupation, in a structured educational program to broaden competency in a specialized field, provided it is begun upon completion of medical school, residency, or fellowship training; and (6) members serving as active military and public health service residents who are required to provide service after their internship as general medical officers, including dive medical officers, or flight surgeons before their return to complete a residency program and are within the first five years of service after internship.³⁴

Because fellows are continuing their medical training like residents, and like residents, may not have a NPI and/or State professional license number, CMS should not require applicable manufacturers to report payments or other transfers of value to fellows.

Respectfully submitted,

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³⁴ AMA 2013 Bylaws