

Dear CMS:

I am pleased to submit comments on behalf of the CME Coalition (www.cmecoalition.org) – an advocacy organization comprised of, and representing, continuing over thirty medical education (CME) providers, supporters, and beneficiaries. We appreciate this opportunity to respond to an Open Payments Program Feedback Request posted recently on CMS' [website](#).

The following responses are provided to the questions you posed:

- 1. What has been the impact, if any, of these reporting requirements on the distribution of educational materials and provision of CME to physicians by industry?*

According to many of our member organizations, upon publication of the rule in 2016 there was a significant pause in funding for accredited CME as commercial supporters tried to assess the interaction of the rule and its sub-regulatory guidance. Our members also experienced (and reported to us) numerous telling examples of the chilling effect of uncertainty for leading medical experts who had traditionally served as faculty at CME programs. Indeed, even though funders had no influence over the content of their presentation, we saw that some very highly respected CME faculty were withdrawing from teaching out of concern that their participation would somehow be construed as a reported “payment” in the Open Payments database, and that the risk to their professional reputation was too great.

Fortunately, as the great majority of stakeholders have interpreted the FAQs to exclude most independent, accredited CME activities from the definition of “payment,” support for CME has resumed and faculty are returning to their programs. We remain concerned, however, that if CMS were to ever make changes to the rule or FAQs to require reporting for independent CME, that we would see significant reductions in both funding of and participation in accredited CME programs.

We should also add that we have seen that journal reprints and text book resales have declined significantly since reporting for their provision to doctors was instituted in 2013.

- 2. What is the nature of the financial relationships between CME providers, applicable manufacturers and Group Purchasing Organizations (GPOs), and physician covered recipients, including how CME providers select and compensate physician and other speakers using funds received from industry?*

There are extensive barriers preventing the slightest industry influence from entering the accredited educational content that our members support, provide and rely upon. Many accrediting organizations have directly adopted Standards for Commercial Support (SCS) as promulgated by the Accreditation Council for Continuing Medical Education (ACCME). In addition to the ACCME SCS, the American Medical Association (AMA) has several ethical rules

relevant to CME, manufacturers are bound by OIG guidelines and the AdvaMed and PhRMA Codes, and manufacturers have incorporated FDA's Final Guidance on Industry-Supported Scientific and Educational Activities into their commercial support policies.

In preparation for submitting this comment, the CME Coalition analyzed the standards of more than a dozen accrediting bodies. Many accreditors have directly adopted the ACCME SCS and have monitoring activities and disciplinary procedures in place, including the ability to revoke a program's accreditation status if that program fails to live up to their rigorous standards.

The ACCME SCS, and other similar standards of commercial support, create a principled firewall that prevents undue industry influence. As an overview, under the SCS, CME providers must ensure that the following decisions are made free of any control of a commercial supporter: (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.¹

Providers must also show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider.² An individual who refuses to disclose relevant financial relationships must be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the CME activity.³ CME providers must implement a mechanism to identify and resolve all conflicts of interest prior to the education activity being developed and delivered to learners.⁴

Providers must make all decisions regarding the disposition and disbursement of commercial support⁵ and cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as a condition of contributing funds or services.⁶ CME providers must have a written agreement that documents the terms, conditions, and purposes of the commercial support that binds the provider and its educational partner(s).

CME providers must also have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers, and authors.⁷ Moreover, CME providers, the joint providers, or designated educational partners must pay directly any teacher

¹ Accreditation Council of Continuing Medical Education (ACCME) Standards for Commercial Support (SCS) Standard 1

² Standard 2.1

³ Standard 2.2

⁴ Standard 2.3

⁵ Standard 3.1

⁶ Standard 3.2

⁷ Standard 3.7

or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.⁸ This means that an applicable manufacturer may never pay a faculty member directly nor can they make any other payment to the director of the activity, planning committee members, teachers, or authors, joint provider, or any others involved with the supported activity.⁹ In addition, CME providers are prohibited from using commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity.¹⁰ The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint provider, or educational partner. CME providers must produce accurate documentation detailing the receipt and expenditure of the commercial support.¹¹

The ACCME SCS also extends into arrangements for commercial exhibits or advertisements. Exhibits and ads cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.¹² Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.¹³ Educational materials that are part of a CME activity, such as slides, abstracts, and handouts, cannot contain any advertising, trade names, or product-group messages.¹⁴

Individual faculty or CME presenters must disclose to learners any relevant financial relationships. This disclosure must include (1) the name of the individual; (2) the name of the commercial interest(s); (3) the nature of the relationship the person has with each commercial interest.¹⁵ For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.¹⁶ Moreover, the source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind," the nature of the support must be disclosed to learners.¹⁷ The financial information must be disclosed to learners prior to the start of the educational activity.¹⁸

3. What was the impact of the removal of the CME exclusion in the 2015 Physician Fee Schedule Final Rule on how industry reports CME payments?

⁸ Standard 3.8

⁹ Standard 3.9

¹⁰ Standard 3.12

¹¹ Standard 3.13

¹² Standard 4.1

¹³ Standard 4.2

¹⁴ Standard 4.3

¹⁵ Standard 6.1

¹⁶ Standard 6.2

¹⁷ Standard 6.3

¹⁸ Standard 6.5

Although the 2015 Physician Fee Schedule Final Rules ostensibly eliminated the blanket reporting exclusion previously given to all CME, as a practical matter, the overwhelming majority of CME related support is still not reported to Open Payments because by definition, accredited CME must be independent of the influence of any commercial supporter. As a result, because current CMS sub-regulatory guidance (FAQ #8165) states that support for CME is not a reportable payment so long as the payor does not “instruct, direct, or otherwise influence the...” accredited CME (as a general rule) is never reportable.

So, in sum, although there was initially considerable confusion among stakeholders around the implication of the 2015 rule on CME, in addition to the continued confusion caused by CMS when it states that the CME “exemption” has been “removed” or “eliminated”, FAQ #8165 has been widely interpreted to exclude the reporting of CME that doesn’t meet the definition of reportable payment.

4. How do educational materials, such as journals and textbooks, directly and indirectly benefit patients?

The importance of up-to-date, peer-reviewed scientific medical information as the foundation for good medical care is well documented. Scientific peer-reviewed journal reprints, supplements, and medical text books have long been considered essential tools for physicians to remain informed about the latest in medical practice and patient care. Independent, peer-reviewed medical textbooks and journal article supplements and reprints represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients.

The Food and Drug Administration’s (FDA) 2009 industry guidance, titled “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices,” underscores the importance of this scientific peer-reviewed information. The FDA noted the “important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications.”

We believe that the Physician Payment Sunshine Act was designed to support the dissemination of precisely this type of independent educational material, and not to create barriers or stigma to its use and adoption by doctors for the betterment of their patients.

5. How might it be possible to reduce unnecessary reporting burden while ensuring transparency of the financial relationships between providers and industry?

We believe that, in general, the Open Payments program provides for reasonable disclosure of pertinent relationships between providers and industry while excluding commercial support for the truly independent continuing medical education of doctors and other providers. Indeed, we generally applaud this approach.

In three regards, however, we recommend that CMS revisit its regulations and guidance in order to eliminate unnecessary, and potentially misleading, reporting burdens while maintain strong transparency.

First, we recommend that CMS reverse its current requirement that medical texts and journal reprints be reported as though they were gifts or inducements to physicians. Instead, we should be encouraging the availability of peer reviewed material to our health care providers in order to support their ability to provide standard of care treatment to patients.

Second, we believe that the current reporting exemption for “buffet-style” meals and refreshments provided during the course of CME activities is arbitrary and should be replaced with a “reasonable meals” standard. Although most of today’s accredited CME activities have moved to a buffet-style approach to feeding participants, we believe that the format of the meal service is an imprecise way of determining its appropriateness. As a general rule, meals provided at accredited events are modest, but we fail to see how the differentiation between seated and buffet-style meals serves as a proxy.

Third, while the overwhelming majority of accredited CME stakeholders understand the sub-regulatory guidance provided in FAQ #8165 to effectively define independent, yet commercially supported, accredited CME activities as outside the scope of the rule, we believe that it would be beneficial to all involved should CMS decide to bring greater certainty to all involved by promulgating a rule to essentially adopt the formulation of the FAQ, namely, to directly exclude independent accredited CME activities whereby the commercial support does not “instruct, direct, or otherwise cause” the payment to be made to a given doctor or provider.

To accomplish this, we would suggest that the current regulation be amended in the following way (proposed changes in bold):

42 C.F.R. § 403.904(h)(1)(a) Indirect payments or other transfers of value (as defined in § 403.902), where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

(b) For purposes of this exclusion, no reporting shall be required for a transfer of anything of value to a covered recipient if the payment or other transfer of value is provided in connection with an accredited and/or certified continuing education program. This includes payments or transfers of value to physician speakers or faculty, the value of the tuition or attendance fees, as well as any educational materials or items associated with the program.

Thank you for your consideration of these comments.

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