

Published by *Healio.com* on August 7, 2014.

The Sunshine Act and CME-related payments

--By Marilyn May and Abraham Gitterman, Arnold & Porter LLP

As many know, in late September of this year, the Centers for Medicare and Medicaid Services is planning to make public information about payments that drug and device manufacturers have made to physicians in 2013, as required by the Physician Payments Sunshine Act (Sunshine Act or Open Payments).

For 2013, drug and device manufacturers were not required to report payments to physicians for speaking or serving as faculty at certain accredited or certified continuing medical education (CME) or continuing education (CE) programs. Additionally, for the 2013 reporting year, drug and device manufacturers were not required to report the tuition fees or associated educational materials for physicians who attended such programs.

Although stakeholders have been focused largely on ensuring that the 2013 information is accurate before it becomes public and provided in a manner that includes appropriate context, CMS decided to try to change the rules going forward. In July 2014, CMS issued its proposed rule for policy and payment changes to the Medicare Physician Fee Schedule for calendar year 2015. Buried deep within the proposed rule, CMS included several revisions to the Sunshine Act that will change the way payments made in connection with CME/CE would have to be reported for physician speakers, faculty and attendees.

Under the current regulations, payments to physician speakers or faculty at accredited/certified CME/CE programs do not have to be reported by the manufacturer if:

1. The CME/CE program is accredited or certified by the Accreditation Council for Continuing Medical Education, American Medical Association, American Academy of Family Physicians, American Dental Association Continuing Education Recognition Program or American Osteopathic Association.
2. The manufacturer does not directly pay the physician speaker.
3. The manufacturer does not select the speaker or provide the third-party vendor with a distinct, identifiable set of individuals to be considered as speakers.

In addition, manufacturers do not have to report certain indirect payments to physician attendees at accredited/certified CME/CE programs. According to CMS, the reporting regulations are not intended “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).”

CMS explained in a presentation and additional guidance which CME/CE payments must be reported for both physician speakers and attendees at accredited/certified CME/CE programs, as well as non-accredited/non-certified programs:

CONTINUING MEDICAL EDUCATION Physician-Attendees and Physician Faculty/speakers

Indirect payments associated with CME activities:	Physician-Attendees	Physician-Faculty/Speakers	Physician-Attendees	Physician-Faculty/Speakers
	Accredited or certified *		Non-accredited or non-certified	
Meals**	✓	X	✓	✓
Travel and Lodging	✓	X	✓	✓
Tuition Fees	X	X	✓	✓
Educational Materials included in CME Tuition Fees	X	X	✓	✓
Educational Materials not included in CME Tuition Fees	✓	X	✓	✓

* Must meet all of the conditions in accordance with § 403.904(g)(1)

** Special rules apply in accordance with § 403.904(h)

CMS's plan to remove the so called "CME Exemption" by eliminating that section of the regulation entirely has caused concerns among stakeholders.

One reason CMS gave for the proposed change was that it did not want to be perceived as playing favorites among CME/CE organizations. According to CMS, since the existing regulation went into effect implementing the CME Exemption, other accrediting organizations "have requested that payments made to speakers at their events also be exempted from reporting," and that such organizations "have stated that they follow the same accreditation standards" as the five currently enumerated organizations.

Rather than focusing specifically on CME/CE accrediting or certifying bodies or organizations such as the AMA or AAFP, CMS now says that the CME exclusion is "redundant" with the existing exclusion for indirect payments or other transfer of value by manufacturers. In CMS's analysis, when a manufacturer provides funding to a CME/CE provider or another third-party organization (regardless of its accreditation status), but does not either select or pay the speaker directly, or provide the CME/CE provider or third party with a distinct, identifiable set of covered recipients to be considered as speakers for the CME/CE program, CMS will consider those payments to be excluded.

According to CMS, the emphasis on the manufacturers' control over the selection and payment of speakers — rather than the status of the entity providing the educational program — is "consistent" with the

preamble of the final rule, which states “if an applicable manufacturer conveys ‘full discretion’ to the continuing education provider, those payments are outside the scope of the rule.”

If finalized, the proposed modification to the CME/CE exemption may be helpful for speakers or faculty at unaccredited or noncertified programs. For example, if an applicable manufacturer gave full discretion to a CME/CE provider (eg, the manufacturer did not select or directly pay the physician speaker or faculty), payments to speakers or faculty made indirectly by that provider to the physician may not be reportable, regardless of what organization accredited the program.

However, because the proposed change to the reporting regulation is only in the preamble, not in the regulation itself, many stakeholders are concerned that speaker or faculty payments at CME/CE programs will be subject to the indirect payment reporting requirements, which condition reportability on whether the manufacturer is aware of the identity of the recipient of an indirect payment. Because the names of CME/CE speakers and faculty are often listed on programs, brochures or websites, if the indirect payment rules apply, manufacturers may be required to report such payments.

For attendees, the question of whether payments to CME/CE vendors to subsidize tuition and educational materials will be reportable is even murkier — causing even greater concern regarding the effect CMS’s proposed change could have on physician-attendees. Because current CMS guidance and FAQs excluding such transfers of value are tied to the accredited/certified status of the CME/CE provider, eliminating the CME/CE exclusion means that the transfers of value may be reportable under the current indirect payment provisions. Although physician attendance at CME/CE programs is not generally made public, manufacturers could learn of a physician’s attendance at a CME/CE program with which the manufacturer sponsored through other interactions in the reporting period or subsequent two quarters.

For CMS to truly exempt from reporting indirect payments at CME/CE programs, the Agency would need to explicitly include language in the final regulations — rather than the preamble — to clarify that the awareness standard would not apply to CME/CE-related indirect payments or transfers of value made to physician speakers, faculty and attendees.

The proposed revisions would take effect on Jan. 1, 2015. Comments are due to CMS by Sept. 2, 2014. Stakeholders, such as the [CME Coalition](#) have been actively lobbying CMS and Congress to reconsider the proposed rule and have released materials explaining the potential effects of CMS’s proposal. In the meantime, physicians should continue inquiries into whether their attendance at CME/CE is reportable under the Sunshine Act.

Check with the CME/CE provider, meeting organizer or staff at any conferences or CE/CME programs to determine whether a physician’s attendance will be reportable under the Sunshine Act, including tuition, meals and educational materials associated with the program.

Check with the CME/CE provider or meeting organizer whether speaker, faculty or consulting fees associated with the conference or CME/CE program will be reportable.

Follow any instructions regarding sign-in sheets or contact information so that if the CME/CE program is reportable, the meeting organizer or manufacturer can contact the physician regarding any disputes or discrepancies.

Marilyn May, JD, can be reached at Arnold & Porter LLP, 555 12th St. NW, Washington, DC 20004-1206; 202-942-6830; email: Marilyn.May@aporter.com.

Abraham Gitterman* can be reached at Abraham.Gitterman@aporter.com.

**Admitted only in Pennsylvania and New Jersey; practicing law in the District of Columbia during the pendency of his application for admission to the D.C. Bar and under the supervision of lawyers of the firm who are members in good standing of the D.C. Bar.*