

life sciences and healthcare lawflash

from the FDA & Healthcare Practice

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Sunshine Act Update: CMS Streamlines Reporting for CME-Related Payments in 2016

CMS issues a Final Rule that removes the exclusion for reporting of continuing education payments to certain accredited organizations, while also clarifying previously existing parameters that may preclude reporting of these same payments.

On October 31, the Centers for Medicare and Medicaid Services (CMS) issued the 2015 Physician Fee Schedule, which includes changes to the Final Rule that implements the Physician Payments Sunshine Act (the Sunshine Act).¹ In an effort to create “consistent reporting requirements for all continuing education events” and to eliminate the unintended consequence of the apparent endorsement of certain organizations sponsoring such events, CMS chose to remove the language in 42 CFR § 403.904(g) in its entirety.

Under the Sunshine Act Final Rule released on February 8, 2013, special rules for continuing medical education (CME) programs at 42 CFR § 403.904(g) established that an indirect payment made to a speaker at a continuing education program was not an indirect payment or other transfer of value for purposes of the rule and, therefore, did not need to be reported when all of the following conditions were met:

- The program met the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education, the American Osteopathic Association, the American Medical Association, the American Academy of Family Physicians, or the American Dental Association Continuing Education Recognition Program.
- The applicable manufacturer did not either select the covered recipient speaker or provide the third-party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program.
- The applicable manufacturer did not directly pay the covered recipient speaker.

CMS decided to remove this language, rather than to implement other options, such as expanding the list of named accrediting organizations or incorporating standards that would allow a program to qualify for the CME program special rules, in part because this provision was redundant with the indirect payments exclusion at 42 CFR § 403.904(i)(1). The indirect payments exclusion excludes from the reporting requirements indirect payments or other transfers of value where the applicable manufacturer is unaware of the covered recipient’s identity during the reporting year or by the end of the second quarter of the following reporting year.

Because applicable manufacturers could know the identities of physician speakers at CME programs through brochures, programs, and other publications, commenters stated that it is not practical for an applicable manufacturer not to know the identity of physician speakers at a CME program. As a result, commenters asserted that the indirect payment exclusion at 42 CFR § 403.904(i)(1) was insufficient to exclude compensation provided to physicians at such events and should be modified accordingly.

1. 42 CFR Parts 402 and 403; Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule.

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In the Physician Fee Schedule Final Rule released on October 31, 2014², CMS responded by observing that payments to physician speakers at a continuing education program that do not meet the definition of an indirect payment at 42 CFR § 403.902 are not reportable. Specifically, if an applicable manufacturer provides funding to a continuing education provider, but **does not** require, instruct, direct, or otherwise cause the continuing education provider to furnish the payment to a covered recipient, the applicable manufacturer is not required to report the payment, regardless of whether the manufacturer later learns the covered recipient's identity.

Similarly, CMS noted that it does not expect tuition fees furnished to physician attendees of a continuing education program that generally have been subsidized by an applicable manufacturer to be reported. If, however, a manufacturer instructs, directs, or otherwise causes the subsidized tuition fee to go to a specific physician attendee, the payment must be reported.

CMS is working to finalize data-collection requirements that would begin January 1, 2016. Therefore, this amendment to the rule will impact 2017 reporting of payments and other transfers of value to covered recipients during the 2016 calendar year.

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² 79 FR 67547, available at <http://www.gpo.gov/fdsys/granule/FR-2014-11-13/2014-26183>.