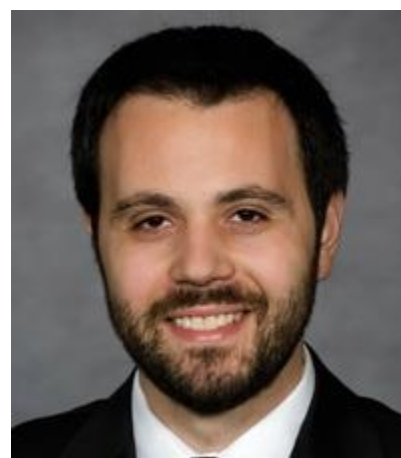


Industry Options For Continuing Education Support Remain

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In late 2014, the Centers for Medicare & Medicaid Services revised the regulation implementing the Sunshine Act, a federal law that requires reporting and public disclosure of certain payments to physicians.[1] Beginning in 2016, pharmaceutical and medical device companies will no longer be able to rely on the exclusion for reporting indirect compensation to physician speakers for accredited or certified continuing education (“CE”) events.[2] Before committing to fund a CE event after 2015, pharmaceutical and medical device companies should consider whether CMS’ change affects their Sunshine Act reporting burden and whether to adjust their CE-funding practices.



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The Sunshine Act concerns “applicable manufacturers,” which are domestically operating manufacturers of drugs, devices, biologicals or medical supplies available for reimbursement under Medicaid, Medicare or the Children’s Health Insurance Program.[3] Under that law, an applicable manufacturer must annually report to CMS the payments or other transfers of value it makes indirectly or directly to a “covered recipient,” which is a U.S.-licensed physician or teaching hospital.[4] An indirect payment or transfer-of-value is triggered when an applicable manufacturer: (1) makes a payment or transfer-of-value to a covered recipient through an intermediary or (2) “requires, instructs, directs, or otherwise causes” an intermediary to make a payment or transfer-of-value to a covered recipient.[5]

A direct payment or transfer-of-value is triggered when an applicable manufacturer makes a payment or transfer-of-value to a covered recipient without an intermediary. CMS and other federal agencies may audit an applicable manufacturer to assess its Sunshine Act compliance.[6] For failing to report data or reporting data late or inaccurately, CMS may impose upon an applicable manufacturer as much as \$1.15 million in civil monetary penalties per year.[7]

Not every payment is reportable. The Sunshine Act and its regulation provide various exclusions. For instance, until 2016, the Sunshine Act’s regulation excludes indirect payments to speakers at accredited or certified CE events if: (1) the CE event met the accreditation or certification standards for one of five organizations identified in the regulation, (2) the applicable manufacturer did not directly pay the speaker and (3) the applicable manufacturer neither selected the speaker nor gave the event organizer a slate of potential speakers to consider.[8] Relying on this exclusion, pharmaceutical and medical device

companies have supported CE by providing funding on terms consistent with the exclusion's requirements. Those same companies now must consider whether the exclusion's removal renders their funding in 2016 and beyond reportable under the Sunshine Act.

When evaluating that issue, companies may naturally turn to the exclusion for indirect payments to an unknown recipient.[9] Often, companies agree to fund a CE event before knowing who will speak; so an exclusion based on not knowing who received an indirect payment may seem like a good fit. However, that exclusion may prove difficult to use.

It is not enough for a company not to know who received the indirect payment at the time of payment. That lack of knowledge must continue until the end of the second quarter following the reporting year (the year when the covered recipient received the indirect payment).[10] Because advertising for CE is frequent, widespread and multiform, companies are likely to learn the identity of who spoke.[11]

Even if a company did not learn from CE advertising who spoke at a CE event that the company supported, a company would still need to be sure that CMS would not hold it accountable under CMS' broad definition of "knowledge." Not knowing a covered recipient's identity means not having "actual knowledge of the identity or act[ing] in deliberate ignorance or reckless disregard of the identity." [12] In other words, CMS expects applicable manufacturers to report "indirect payments where applicable manufacturers know or should know the identity of the covered recipients who receive them." [13] CMS used a broad definition so it could "prevent applicable manufacturers from directing payments to a discrete set of covered recipients whose identities the manufacturer may not actually know but could easily ascertain." [14] CMS gives the following example to illustrate its understanding:

[W]e believe that a manufacturer that directs a third party to make payments to the top billing cardiologists in a certain city or the chiefs of staff of a certain class of hospitals should be required to report these payments, even though they do not have actual knowledge of the identities of such individuals.[15]

The physicians who spoke at a CE event are a "discrete set of covered recipients" at least as identifiable as those in CMS' example because CE providers keep records showing who spoke at a CE event. Consequently, applicable manufacturers may have difficulty invoking the exclusion for indirect payments to unidentified recipients.

Given the lack-of-knowledge exclusion's difficulties, pharmaceutical and medical device companies should also evaluate whether their CE-funding terms fit within CMS' understanding of "unrestricted" payments. An unrestricted payment provides funds to a CE organization to use at the organization's discretion.[16] An applicable manufacturer provides funds for "use at the organization's own discretion [when] the organization may opt to provide a medical/educational conference or may opt to use the payment for another purpose." [17] Even if the organization chose to use the applicable manufacturer's funds to provide a CE event for physicians, the applicable manufacturer's payment would not be an indirect payment because the organization could have "opt[ed] to use the payment for another purpose." [18]

If a company's current funding terms for CE support may be characterized as "unrestricted," CMS' deletion of the indirect CE speaker payments exclusion is of no consequence. Thus, companies should consider whether their business rationale for supporting CE justifies using funding terms consistent with unrestricted payments to CE providers. Providing support that is not unrestricted may lead to greater

obligations under the Sunshine Act, with all the attendant consequences. For instance, the additional disclosure may strain relationships with physicians opposing public disclosure of Sunshine Act data. On the other hand, using unrestricted payments will reduce Sunshine Act risk while not causing additional Sunshine Act reporting burdens, all while helping educate physicians about the latest medical information.

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[1] Reports of Payments or Other Transfers of Value to Covered Recipients, 79 Fed. Reg. 67,758, 67,758-60, 68,000 (Nov. 13, 2014).

[2] *Id.*

[3] 42 U.S.C. § 1320a-7h(a)(1)(A), (e)(2); 42 C.F.R. §§ 403.900, 403.904(a).

[4] 42 U.S.C. § 1320a-7h(a)(1)(A); 42 C.F.R. § 403.904(a).

[5] 42 C.F.R. § 403.900.

[6] 42 C.F.R. § 403.912(e)(2).

[7] 42 C.F.R. § 403.912(a)-(c).

[8] 42 C.F.R. § 403.904(g)(1).

[9] 42 C.F.R. § 403.904(i)(1).

[10] *Id.*

[11] Those opposing CMS' change made this same point:

Commenters stated it is not practical for a manufacturer to not know the identity of a physician speaker receiving compensation for speaking at a continuing education event during the reporting year or by the end of the second quarter of the following reporting year because manufacturers could learn the identities of physician speakers through brochures, programs and other publications. Therefore, commenters assert that the indirect payment exclusion is not applicable to exclude compensation provided to physicians at a continuing education event and recommend the indirect payment exclusion is modified to accommodate indirect payments provided to a physician covered recipient through a continuing medical education organization.

79 Fed. Reg. at 67,759.

[12] Transparency Reports and Reports of Physician Ownership or Interests, 78 Fed. Reg. 9458, 9490 (Feb. 8, 2013).

[13] Id.

[14] Id.

[15] Id.

[16] 79 Fed. Reg. at 67,760; CMS Implements Final Rule Changes for Open Payments, Law and Policy, <http://www.cms.gov/OpenPayments/About/Law-and-Policy.html> (last visited Jan. 1, 2014) (hereinafter “CMS Implements Final Rule Changes”).

[17] FAQ 11602, <https://questions.cms.gov/faq.php?id=5005&faqId=11602> (last visited Jan. 1, 2014) (hereinafter “FAQ 11602”); CMS Implements Final Rule Changes, *supra* note 16.

[18] FAQ 11602, *supra* note 17; CMS Implements Final Rule Changes, *supra* note 16.