



Open Payments and Continuing Medical Education

A subset of drug, biological, and device manufacturers have raised questions concerning the Physician Payments Sunshine Act (dubbed the Open Payments Program) reporting requirements and participation in commercially-supported accredited and certified continuing medical education (accredited/certified CME) programs in 2016. The following outlines the relevant statutory, regulatory and sub-regulatory guidance issued by the Centers for Medicare and Medicaid Services (CMS) through February 1, 2016.

Under the American Medical Association (AMA) CME Credit system standards and Code of Ethics and ACCME accreditation standards, commercial supporters are prohibited from having any direct or indirect influence or control with respect to the content, faculty, speakers, or attendees of an educational program or activity. Therefore, educational grants given to AMA certified and ACCME accredited programs, including online or enduring educational programs, which comply with those standards, do not meet the definition of an "indirect payment" and, as such, are exempt from reporting by commercial supporters under the Physician Payments Sunshine Act ("Sunshine Act" or "Open Payments"). This conclusion is consistent with the October 2014 final regulations and recent guidance issued by CMS.

Specifically, CMS concluded in October 2014 that "payments or other transfers of value, including payments made to physician covered recipients for purposes of attending or speaking at continuing education events, which do not meet the definition of an indirect payment as defined at § 403.902 are not reportable." Further, CMS emphasized that CME-related payments that comply with independence standards such as the AMA's certified and ACCME's accredited CME programs are "not reportable regardless" of whether the manufacturer "learns the identity of the covered recipient" in any future timeframe "because the payment or transfer of value did not meet the definition of an indirect payment."

With respect to physician speakers or faculty for CME programs or activities, CMS clarified that when a manufacturer "provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under § 403.904(i)(1)."

With respect to physician attendees at CME programs or activities, CMS further clarified that "tuition fees provided to physician attendees that have been generally subsidized at continuing education events by manufacturers are not expected to be reported," unless the manufacturer requires, instructs, or directs the subsidized tuition fee "to go to a specific physician attendee."

In both cases, CMS clarified and reiterated that when an "applicable manufacturer conveys 'full discretion' to the continuing education provider, those payments are outside the scope of the rule" and thus, not subject to reporting. As noted above, the AMA and ACCME mandate that commercial supporters convey full discretion to CME providers to ensure that all decisions regarding the content, faculty, speakers, and attendees are made free from the control of a commercial supporter. Consistent with these standards, the rules of accreditation strictly prohibit any commercial supporter from having any direct or indirect influence or control with respect to the content, faculty, speakers, or attendees of an AMA certified or ACCME accredited educational program or activity. Under no circumstances may a commercial supporter require, instruct, direct or otherwise cause a CME provider organization to use particular physician speakers or faculty or invite specific physician attendees for a CME program or activity.

Therefore, while every commercial supporter must make its own determination as to the reportability of specific payments, compliant AMA certified and ACCME accredited programs or activities should not

meet the definition of a reportable payment under the Physician Payments Sunshine Act (“Sunshine Act” or “Open Payments”).

Finally, the AMA strongly encourages its members to actively participate, both as faculty and attendees, in independent, certified and accredited continuing medical education. Graduation from medical school and completion of residency training are only the first steps in a career-long educational process for physicians. To take advantage of the growing array of diagnostic and treatment options, physicians must continually update their medical knowledge and practice skills. CME is a mainstay for such learning, and the preservation of its independence, integrity, and reputation is of paramount importance to the AMA.