

A key area of interest for physicians is the impact of the Sunshine Rule on engagement in accredited and non-accredited continuing medical education (CME) events, both as a speaker and a participant. Below we discuss these issues in greater detail.

Background

On December 19, 2011, the Centers for Medicare and Medicaid Services (CMS) released the proposed rule regarding Transparency Reports and Reporting of Physician Ownership or Investment Interests (also known as the “Sunshine Rule”). Among the many provisions included, of particular concern to physicians and continuing medical education (CME) providers, was a provision that would require payments made, directly or indirectly, to physicians speaking at CME programs to be reported. Physicians were also concerned about their ability to partake in meals and accept small incidental items in conjunction with their attendance at CME events, such as their medical professional societies annual conference.

On February 1, 2013, the “Sunshine” final rule was released, which addressed each of the aforementioned issues.

Direct versus Indirect Payments

As discussed in the final rule, indirect payments or other transfers of value refer to payments or other transfers of value made by an applicable manufacturer to a covered recipient through a third party, where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s). For example, if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization's discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute "indirect payments" because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians. The physician professional association could have used the donation for another purpose at its discretion. In this situation, the applicable manufacturer would not be required to report the donation, even if a portion of the payment or other transfer of value was ultimately provided to a covered recipient as a grant (or some other type of payment or other transfer of value). However, if an applicable manufacturer gave money to a medical professional society earmarked for the purpose of funding awards or grants for physicians, the awards or grants would constitute indirect payments to covered recipients and would be subject to the reporting requirements.

Direct payments or other transfers of value are those payments or transfers of value made by an applicable manufacturer directly to a covered recipient. In general, both direct and indirect payments or transfers of value made by applicable manufacturers to covered recipients must be reported. However, in some limited circumstances, indirect payments or transfers of value may be excluded from the reporting requirements.

Speaking at CME Events

CMS finalized that applicable manufacturers will not be required to report payments to speakers at **accredited** CME events so long as the applicable manufacturers do not select the speakers or pay them directly. Specifically, the CMS states the following

“We have finalized at §403.904(g)(1) that an indirect payment made to a speaker at a continuing education program is not an indirect payment or other transfer of value for the purposes of this rule and, therefore, does not need to be reported, when all of the following conditions are met: (1) the program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP; (2) the applicable manufacturer does not select the

covered recipient speaker nor does it 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; and (3) the applicable manufacturer does not directly pay the covered recipient speaker. We believe that when applicable manufacturers suggest speakers, they are directing or targeting their funding to the speakers, so these payments will be considered indirect payments for purposes of this rule. Conversely, when they do not suggest speakers, they are allowing the continuing education provider full discretion over the CME programming, so the payment or other transfer of value will not be considered an indirect payment for purposes of these reporting requirements. We believe that this approach will greatly reduce the number of payments to speakers at accredited or certified continuing education programs that must be reported.”

CMS did not believe that all payments to physicians for serving as speakers at an accredited or certified continuing education program should be granted a blanket exclusion. Therefore, all accredited or certified continuing education payments that are not excluded by the conditions described above must be reported.

In the case of **unaccredited** and non-certified CME, the final rule states that, if the payment or other transfer of value is made indirectly, it will be subject to the same reporting requirements for all indirect payments. This is because unaccredited and non-certified CME programs do not require the same safeguards as an accredited and certified program.

Regardless of whether the CME event is accredited or unaccredited, direct payments or transfers of value must be reported.

Meals and Snacks at CME Events

As discussed in the final rule, for meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), CMS will require applicable manufacturers to report the per person cost (not the per covered recipient cost) of the food or beverage for each covered recipient who actually partakes in the meals (that is, actually ate or drank a portion of the offerings). If the per person cost exceeds the minimum threshold amount of \$10, then the applicable manufacturer must report the food or beverage as a payment or other transfer of value for each covered recipient who actually participated in the group meal by eating or drinking a food or beverage item.

CMS finalized that food and beverage provided at conferences in settings where it would be difficult to establish the identities of people partaking in the food do not need to be reported. Examples of this might be coffee and other beverages served in the “exhibit hall” to all attendees of a medical society annual conference. However, CMS does not intend this to apply to meals provided to select individual attendees at a conference where the sponsoring applicable manufacturer can establish identity of the attendees. Examples of this might be an industry-sponsored dinner where individual physician are invited to participate in the event and the applicable manufacturer is able to establish the identities of people partaking in the meal.

Physicians who do not want to receive meals should make clear to manufacturers that they do not accept them. In other words, CMS “will no longer attribute meals to physicians who do not attend the meal, so a physician who does not want to receive meals should not attend or accept them.”

Small Incidental Items Collected at CME Events

According to the final rule, small payments or other transfers of value (less than \$10) do not need to be reported, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds \$100. This applies to conferences and similar events, as well as events open to the public. For example, small incidental items (such as pens and note pads) that are provided at large-scale conferences and similar large-scale events will be

exempted from the reporting requirements, including the need to track them for aggregation purposes. However, if an applicable manufacturer hands out an item above the \$10 threshold, they should be able to track who received the payment since it is a more significant transfer.

“Date of Payment” Nuance

As discussed in final rule, applicable manufacturers must report the date that a payment or transfer of value was provided to the covered recipient. In certain circumstances, applicable manufacturers have flexibility to determine the methodology for reporting the date the transfer of value was “provided” – for example, there is flexibility for reporting travel because the purchase date (of airline tickets, for example) may be different than the date the transfer of value is actually “provided” to the covered recipient (i.e., when the physician takes the flight). As CMS discussed in the preamble, applicable manufacturers have some flexibility to choose which payment date they will use in this type of situation; however, the methodology used must be consistent within a single nature of payment category (such as travel).

In the example of an applicable manufacturer that compensates a physician for providing a consulting or other service **before** the data collection requirements become effective (e.g, consulting services are provided by the physician in May 2013 during his professional association’s annual conference), but does not actually make payment or a transfer of value to the physician until after the start of the data collection requirements (i.e., August 1, 2013), such payment would be reportable because the payment was made to the physician after the start of the data collection requirement. The date of payment would be the date the applicable manufacturer sent payment or made the transfer of value to the covered recipient to compensate him/her for the services rendered.