



July 25, 2013

## **Continuing Medical Education (CME) Programs: Compliance Guide for Sunshine Rule**

This document represents our considered judgment based on our regulatory expertise in these matters. It is furnished solely to provide guidance concerning how to organize CME programs to comply with provisions of the “Transparency Reports and Reporting of Physician Ownership or Investment Interests” (Sunshine Rule)—now referred to as Open Payments. The rule is administered by the Centers for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services (HHS) and significant penalties may attach for any misreporting of data by applicable manufacturers of medical products. This summary is based on authorities existing as of the date of this document.

No guarantee can be given that CMS will agree with the analysis or recommendations provided herein, or that forthcoming legislation, regulations, or judicial or administrative opinions will not modify the validity of this compliance guide.\* Nevertheless, we believe that this Guide will provide commercial supporters, CME providers, and CME event participants with clear rules, based upon a thorough review of the most recent CMS guidance, regarding the requirements for determining which payments may be exempt from the mandated Sunshine reporting rules, and when others must be reported.

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\*These guidelines do not constitute legal advice or establish an attorney-client relationship. Compliance with these guidelines does not equate to what is permissible under federal or state law or your company’s internal policies, or exempt you from liability under such laws or policies. Please consult your in-house or outside counsel for further advice about how to comply with specific laws and regulations as they may apply to your organization.

## Acknowledgements Page

The CME Coalition ([www.cmecoalition.org](http://www.cmecoalition.org)) is a Washington-based organization comprised of CME providers, beneficiaries of CME (including both educational institutions and professional societies), and supporters of CME (such as pharmaceutical manufacturers and device makers). Additional partnerships and affiliations may be extended to health policy thought leaders and other interested parties who share an appreciation for the mission of the organization.

The mission of the CME Coalition is to:

1. educate federal policy makers on issues related to the provision of CME;
2. monitor state policy initiatives that could adversely impact CME; and
3. advocate for sensible federal and state policies to advance its practice.

The CME Coalition will fulfill this mission by developing, managing, and implementing a government affairs and public relations strategy to further the interests of CME on Capitol Hill, with the Administration and among the states.

The CME Coalition would like to acknowledge the assistance we received in preparing this guide from Alston Bird, LLC, and Rockpointe Corporation, especially Abraham Gitterman, JD.

CME Coalition members include:

- Association of Black Cardiologists
- Celgene Corporation
- Clinical and Patient Educators Association
- Clinical Care Options
- CME Incite
- Educational Concepts Group
- Forest Laboratories, Inc.
- Genentech
- Global Education Group
- Healthmatters CME
- Horizon Pharma
- Medscape Education
- National Association of Medical Education Companies
- North American Center for Continuing Medical Education
- Postgraduate Institute for Medicine
- Rockpointe Corporation
- Sanofi
- Teva Pharmaceutical Industries
- Vindico Medical Education

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# Compliance Guide

## 1 Introduction

Generally speaking, the Sunshine Rule requires medical product manufacturers to **report to CMS<sup>1</sup> any payments or other transfers of value given to physicians or teaching hospitals.** Starting August 1, 2013, any direct payment made from a manufacturer to a physician or teaching hospital is **subject to annual reporting to CMS and subsequent online publication.** The Sunshine Rule also can require reporting for “indirect” payments that may occur through CME supporter grants to a CME provider or CME department at a teaching hospital. Direct and indirect payments that may be reportable for both speakers and physician-attendees include reimbursement for costs related to CME events, such as travel, meals, speaking fees or honoraria, and educational value.

However, a significant exemption from the reporting requirements exists for certain payments or transfers of value made to speakers of certified or accredited continuing education (CE) programs, including travel and meals for speakers. Such payments are completely exempt from reporting if such payments meet three conditions: speaker compensation must: (i) relate to an event satisfying CME accreditation standards; (ii) not be paid directly by the manufacturer; and (iii) the manufacturer cannot select the speaker or provide a list of individuals to be considered as speakers. Throughout these guidelines, we will refer to CME programs that meet these three conditions as “Sunshine-exempt” CME programs.

This guidance offers suggestions concerning how to develop and organize your CME grant request and how to host your CME event to meet, eliminate, or minimize required reporting of physician participation under the Sunshine Act. This Guide also includes, as an attachment, a Flow Chart Diagram intended to facilitate understanding of the reporting requirements under the law.

## 2 Planning Your CME Event

### 2.1 When Is the Sunshine Rule Applicable?

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<sup>1</sup> CMS announced the Sunshine Act, or The National Physician Payment Transparency Program (OPEN PAYMENTS), will be hosted at the following site: <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>.

The Sunshine Rule is applicable if your CME event is (1) attended by physicians or has physician speakers/participants, and (2) is being supported by a manufacturer that makes any prescription drug/biologic or any “non-exempt” medical device or supply.

Physicians include any licensed physician, regardless of whether they are currently seeing or treating patients, and regardless of whether the physician is enrolled with Medicare, Medicaid, or CHIP.

The Sunshine Rule is also applicable if a manufacturer directly supports a teaching hospital for a CME event.

Certain exemptions or exclusions exist as discussed below.

**Example 1:** ABC Pharmaceutical Co. makes an educational grant to a CME provider to provide CE for nurses only. The written agreement outlines that only nurses will be on the faculty, no physicians. No physicians attend the event. The payments associated with this grant would not have to be reported.

## **2.2 Determining Non-reportable, or “Sunshine-exempt,” Payments to Speakers and Faculty**

To avoid classifying CME activities as reportable “indirect payments” to speakers, a CME provider should ensure:

- (1) the provider/event is accredited/certified;<sup>2</sup>
- (2) no direct payments are allowed between a CME supporter and physician<sup>3</sup> [include a provision in the written agreement, which is required by the ACCME Standards for Commercial Support (SCS) 3.4-3.6]; and

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<sup>2</sup> The following are valid accreditation/certification bodies named in the rule: the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association’s Continuing Education Recognition Program, the American Medical Association, and the American Osteopathic Association. CMS clarified in its FAQ that this list is “exhaustive.” It may consider additional bodies in the future, but only CME providers and programs accredited or certified by these five bodies are eligible for exemption.

<sup>3</sup> Which is mandated by SCS 3.8.

- (3) the CME supporter has no role in directing, suggesting, or implementing how the proceeds of the grant are used by the CME provider. [The latter two requirements are mandated by the SCS, Standard 3.2 and Standards 1.1(d); 3.1, respectively].

If the CME provider and CME program meet *all* three of these conditions, the manufacturer will *not* have to report any speaking or faculty fee-related payments (including meals, travel, and lodging) associated with the Sunshine-exempt CME program.

**Example 2:** CureAll Pharmaceutical Co. makes an educational grant to a professional neurology association, accredited by the ACCME, to support a CME program in San Francisco, CA. CureAll has no involvement in suggesting how the proceeds of the grant are used, including which faculty or speakers are selected, and there is no direct payment from CureAll to the physician faculty. The payment from the neurology association to the physician faculty for speaking would not have to be reported, including payments for meals, travel, and lodging. Payments for physician-attendees meals *may* have to be reported, as explained in Section 5.

## 2.3 How to Organize the Grant Application Process

To ensure that an event is Sunshine-exempt, CME providers should continue to follow the ACCME accreditation requirements and the ACCME Standards for Commercial Support (SCS) when writing CME grants for commercial support.

However, given the clarifications and changes provided by CMS in the final rule regarding CME programs, food and beverage, educational items and materials, incidental items (e.g. pens or notepads), and indirect payments, CME providers should take several steps in the grant-writing process to eliminate or minimize the need to report payments associated with such programs.

At all times during the CME lifecycle, CME providers must ensure close compliance with SCS 3.13, which requires providers to produce accurate documentation detailing the receipt and expenditure of *all* commercial support.

### 2.3.1 Disease Area, Class of Treatments, or Program Topic

CME providers should continue their grant writing activities in accordance with ACCME or other accredited provider standards. With respect to disease area, class of treatments, or program topic, ACCME accredited providers must closely ensure compliance with SCS 1.1, 3.1, 5.1, and 5.2.

### **2.3.2 Speakers and/or Faculty Not Employed by the CME Provider**

CME providers may prefer not to include the names of any proposed speakers or a list of faculty names in any CME grants requests for which they are seeking commercial support from an applicable manufacturer.

Likewise, CME providers *should* use discretion when including quotations or remarks from physicians the provider may have consulted with for a particular grant.

CME providers *should* include in a CME grant request a budget that includes a pre-determined and fair market value payment for all services to be rendered by all proposed faculty and speakers for the program. In creating this budget, CME providers must ensure compliance with SCS 3.9 and 3.10.

Once the grant has been awarded to the CME provider, it is acceptable for the provider to disclose speakers or faculty to the applicable manufacturer. Nevertheless, CME providers must ensure compliance with SCS 3.2 at all times regarding the selection of teachers and authors during the CME lifecycle.

### **2.3.3 Physician-Attendees**

CME providers may wish to avoid providing the names of any proposed or anticipated physician-attendees or a list of physician-attendee names already registered (in the case of a program seeking joint or additional commercial support). CME providers must also ensure compliance with SCS 3.2 regarding the selection of participants at all times during the CME lifecycle.

### **2.3.4 Geographic Location(s)**

CME providers may continue to include in their grant request target cities, regions, and various types of medical institutions (e.g. hospitals or academic medical centers). Nevertheless, CME providers must ensure the locations included in a CME grant request meet SCS 1.1(a) and other accreditation requirements for needs assessments. CME providers must also ensure compliance with SCS 3.2 regarding the selection of participants at all times during the CME lifecycle.

**Example 3:** The CME provider submits a grant application proposing an event for cardiologists around Chicago. The application provides a tentative agenda and a specific breakdown of how grant funds will be used including details of physician payments. The written grant agreement references this specific work plan. This grant would not be considered a reportable indirect payment.

### **2.3.5 Meals and Beverage**

#### **2.3.5.1 Speakers/Faculty**

Payments for meals and beverages to speakers or faculty will *not* have to be reported by manufacturers and are included in the total speaker compensation that is excluded from reporting for Sunshine-exempt CME.

Nevertheless, CME providers should include in a CME grant request a pre-determined budget for the meals and beverages of all speakers and faculty that is fair market value. CME providers should avoid itemizing food and beverage expenses for individual faculty and speakers and should instead include a total budget for all faculty and speakers.

If the CME program includes multiple educational events, and the faculty member or speaker attend a separate event as a physician-attendee (e.g. they are not speaking/serving on this program), his or her meal *may* be reportable if it is plated and \$10 and over or require tracking if under \$10.

#### **2.3.5.2 Physician-Attendees**



“Payments” to physician-attendees in the form of meals and beverages *may* have to be reported under certain circumstances as described in Section 5. However, CMS has provided a means by which to allow physician-attendees to partake in food and drink when provided in a buffet setting without a reporting requirement.

CME providers should include in a CME grant request a pre-determined budget for the meals and beverages of all physician-attendees that is fair market value. CME providers should avoid itemizing meal and beverage expenses for estimated physician-attendees.

CME providers should clearly indicate in their grant request whether they will be providing plated meals, which may subject such meals to reporting and tracking requirements, *See* Section 5.

CME providers must ensure compliance with SCS 3.11.

## **2.3.6 Travel**

### **2.3.6.1 Speakers**

For Sunshine-exempt CME programs, payments for travel and lodging to speakers will *not* have to be reported by manufacturers and are included in the total speaker compensation that is excluded from reporting for Sunshine-exempt CME.

Nevertheless, we recommend that CME providers avoid itemizing travel and lodging expenses for individual faculty and speakers and should instead include a total travel and lodging budget for all faculty and speakers. This budget should be pre-determined and fair market value.

Such payments must also be in compliance with SCS 3.7 and 3.8.

**Example 4:** Sunshine Pharma provides an accredited CME provider an educational grant. The CME provider invites Dr. Smith to serve as a faculty member at the CME event. The CME provider pays Dr. Smith directly for serving as a speaker, and for his meals and travel. Sunshine Pharma made no suggestion and had no influence in the choice of faculty. None of the payments made to Dr. Smith by the CME provider would have to be reported.

### **2.3.6.2 Physician and Non-physician Attendees**

Accredited CME providers may *never* use commercial funds to fund the travel of physician and non-physician attendees or any other non-faculty or non-author participants.

SCS 3.12 prohibits providers from paying for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity.

### **2.3.7 Educational Value; Educational Items or Materials at CME Events (Speakers and Attendees)**

CME providers are not obligated to include in a proposed budget the educational value a physician may receive by attending an accredited CME program in any format (e.g. live or online). This includes any tuition or other fees that would be associated with a physician's attendance at a Sunshine-exempt CME program. Accordingly, the Sunshine Act requires no reporting in this regard. *See* Section 3 for additional details.

At this time, it is not known how CMS would treat the reportability of educational value provided pursuant to a non-Sunshine-exempt CME event.

### **2.3.8 Date of Payment for Non-accredited CME Programs**

Applicable manufacturers and CME providers must communicate about the date for which a non-exempt CME-related payment will be reported. Some manufacturers may provide CME-related payments in several installments, as one total payment, or other variations. This is

generally the determination of the manufacturer. Potential options include:

- (1) If only one payment, the date when such payment is made.
- (2) If multiple payments, the date when the first payment is made. Alternatively, the manufacturer may list each payment date separately.
- (3) Date when the CME program occurs.
- (4) Date when the first CME program occurs (if multiple programs, e.g. grand rounds).
- (5) Date when the CME program is first made available (e.g. online).

If a CME program spans across multiple years, and multiple payments are made across reporting, manufacturers must report such payments according to the reporting year for which they occurred, they cannot move payments across years.

It is crucial for both manufacturers and CME providers to ensure that any value that may be attributed to a physician-speaker/faculty or physician-attendeo is attributed to the appropriate date to avoid potential disputes and or concerns from physicians, as well as penalties for inaccurate reporting.

### **3 CME Educational Value**

Applicable manufacturers are *not* required to report payments associated with the educational value a physician-attendeo may receive at a Sunshine-exempt CME program, including payments made to CME vendors that are used to subsidize attendees' tuition fees for CE events. The educational value exclusion for physician-attendeos applies to all CME activity types that meet the required three conditions.

#### **3.1 CME Activity Types**

The following CME activity types<sup>4</sup> and any educational value for physician-attendees associated with the specific activity are excluded from mandatory reporting:

### **1. Course**

A *course* is a live CME activity where the learner participates in person and which is planned on a one-by-one basis and designated for credit as a single activity. Examples include a conference or seminar. Likewise, a very large, week-long activity, such as an annual conference, should be reported as one course.

### **2. Regularly Scheduled Series**

A course is identified as a *regularly scheduled series (RSS)* when it is planned to have

- (1) a series with multiple sessions that
- (2) occur on an ongoing basis (offered weekly, monthly, or quarterly) and
- (3) is primarily planned by and presented to the accredited organization's professional staff. Examples of activities that are planned and presented as a Regularly Scheduled Series are Grand Rounds, Tumor Boards, and M&M Conferences.

### **3. Internet Live Course**

An *internet live course* is an online course available at a certain time on a certain date and is only available in real-time, just as if it were a course held in an auditorium. Once the event has taken place, learners may no longer participate in that activity. (Example: webcast)

### **4. Enduring Material**

An *enduring material* is a printed, recorded, or computer-presented CME activity that may be used over time at various locations and

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<sup>4</sup> As listed by the ACCME, available here: <http://www.accme.org/ask-accme/what-kind-cme-activity-types-can-be-reported-pars>.

which, in itself, constitutes a planned activity. Under this definition of “enduring material,” the content is created by the CME provider.

### **5. Internet Activity (Enduring Material)**

An *internet enduring material* activity is available when the physician participant chooses to complete it. It is “enduring,” meaning that there is not just one time on one day to participate in it. Rather, the participant determines when he/she participates. (Examples: online interactive educational module, recorded presentation, podcast).

### **6. Journal-based CME**

A journal-based CME activity includes the reading of an article (or adapted formats for special needs), a provider-stipulated/learner-directed phase [that may include reflection, discussion, or debate about the material contained in the article(s)], and a requirement for the completion by the learner of a pre-determined set of questions or tasks relating to the content of the material as part of the learning process.

### **7. Manuscript Review**

*Manuscript review* CME is based on a learner’s participation in the pre-publication review process of a manuscript.

### **8. Test Item Writing**

*Test item writing* is a CME activity based on a learner’s participation in the pre-publication development and review of any type of test-item (e.g. multiple choice questions or standardized patient cases).

### **9. Committee Learning**

*Committee learning* is a CME activity that involves a physician learner’s participation in a committee process where the subject of which, if taught/learned in another format, would be considered within the definition of CME.

### **10. Performance Improvement**

*Performance improvement* activities are based on a learner's participation in a project established and/or guided by a provider, in which a physician identifies an educational need through a measure of his/her performance in practice, engages in educational experiences to meet the need, integrates learning into patient care, and then re-evaluates his/her performance.

## **11. Internet Searching and Learning**

*Internet searching and learning* activities are based on a learner identifying a problem in practice and then accessing content in search of an answer from sources on the Internet that are facilitated by a provider. For the purpose of ACCME data collection, the ACCME includes AMA-defined point of care CME as a form of internet searching and learning.

## **12. Learning from Teaching**

*Learning from teaching* is a descriptive label for a type of CME activity. This label was developed at the ACCME as a corollary to the AMA's recognition within the PRA of direct "Credit for Teaching." "Learning from Teaching" activities are essentially personal learning projects designed and implemented by the learner with facilitation from the accredited provider.<sup>5</sup>

### **3.2 Supporting Materials or Items Distributed During a CME Program**

Supporting materials or items distributed during any of the above referenced Sunshine-exempt CME activities are also excluded from reporting because such materials or items are included in the CME tuition fees.

Such materials include slides, abstracts, and handouts, as defined by the ACCME SCS 4.3.

There may be instances, however, where a CME provider wants to provide *additional* educational items or materials that may constitute reportable payments or transfers of value. To eliminate the need for having to report

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<sup>5</sup> Examples: <http://www.accme.org/ask-accme/how-does-accme-define-learning-teaching-activity>.

any educational value associated with a Sunshine-exempt CME program, educational items or materials provided to attendees *should* meet the following conditions:

- (1) The content does not contain any commercial supporter information (e.g. logo);
- (2) The educational item or material is directly and significantly related to the CME-certified program participants attended;
- (3) The educational item or material was created by the accredited CME provider and specified faculty and staff of that provider;
- (4) The value is “de minimis”;
- (5) The funds used for the materials came from the same CME program grant; *and*
- (6) The materials meet all the requirements under ACCME SCS, Standard 4

## 4 Payments Under \$10

Unless they are considered “Sunshine-exempt,” minor payments or transfers of value from applicable manufacturers to physicians of less than \$10 do not have to be reported. However, all minor payments are subject to reporting if they exceed \$100 per individual in a reporting year, so they must be tracked.<sup>6</sup> The \$100 limit does not apply to large-scale events.

**Example 5:** Atredies Pharmaceutical and Harkonnen Drug Company equally co-support a plated meal for 200 oncologists at a CME event. The cost of the plated meal is \$18 per person. The allocated cost to each supporter is \$9 per person. This is not a reportable meal, but it does have to be accounted for in determining the \$100 aggregate annual limit for small payments.

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<sup>6</sup> The \$10/\$100 amounts represent limits for 2013. The thresholds are updated annually to reflect published increases in the consumer price index.

## 5 Attendee Meals including Food, Beverages, and Snacks

In determining whether or not physician attendee meals or beverages must be reported, CMS has essentially created different results depending upon the nature of event (accredited vs non-accredited), the manner in which the food/beverage is provided (buffet vs individually plated), and whether or not the commercial supporter is aware or subsequently (within 1¼ years) becomes aware of the recipient of a meal it has paid for.

### 5.1 Buffet-style Meals at Both Sunshine-exempt and Non-exempt CME Events – “Group Setting”

Buffet meals, snacks, soft drinks, or coffee generally available to all participants in a “group setting,” where it would be difficult to establish the identity of physicians who partook in the food and beverage, do not need to be reported *or* tracked (for purposes of the \$100 aggregated requirement) for Sunshine-exempt CME programs. In other words, “where the cost of each individual [physician-attendee’s] meal is not separately identifiable,” such as a buffet or boxed lunch, such meals are excluded from reporting and no tracking is required.

For non-“Sunshine-exempt” CME programs, however, a buffet meal *may* be reportable unless it is provided to a “large group,” where it would be “difficult to establish the identity of the physicians who partook in the meal or snack” and it is made available to all conference attendees.

A buffet meal is one in which individuals self-serve from a common table, location, or setting. Buffet meals also include: coffee/soda stations, snack tables, or pre-made bag lunches.

**Example 6:** Dr. Stevens attends a Sunshine-exempt CME event with 75 fellow cardiologists. At dinner, the CME provider has offered a large buffet of various pastas, meats, vegetables, beverages, and desserts. The value of the buffet is well \$10 and over per person. This meal does *not* need to be reported *or* tracked.

A commercial supporter may require in its Letter of Agreement that only buffet-style meals are permitted. The ACCME SCS prohibit commercial supporters from having any role or say in how commercial funds are used,



including meals. Thus, CME providers should only consider this as a request, not a requirement. If the CME provider independently determines to provide buffet-style meals, such value will be exempt from reporting.

## **5.2 Plated Meals Provided at Both “Sunshine-exempt” and Non-exempt CME Events**

### **5.2.1 Under \$10 in value**

If food and beverage are provided as a **plated meal or otherwise individually identifiable cost** to a physician-attende of any event, the manufacturer may be required to track such payments if under \$10 for purposes of determining whether the physician-attende exceeds the \$100 annual aggregate. The requirement to track the “payment” will fall upon the commercial supporter if that supporter is or becomes aware of the identity of the payment recipient by the end of the 2<sup>nd</sup> quarter in the year following the payment or transfer of value. If the cost is more than \$10 but split among several commercial supporters, each may be responsible for tracking their portion of the reportable payment.

**Example 7:** Dr. Jones attends a Sunshine-exempt CME event with 100 fellow internists. At lunch, the CME provider has provided cheese and pepperoni pizzas at a serving table along with paper plates and napkins. The value of the food and beverage is less than \$10 per person. This meal does *not* need to be reported *or* tracked.

### **5.2.2 \$10 and over in value**

If food and beverage are provided as a **plated meal or otherwise individually identifiable cost** to a physician-attende, the manufacturer may be required to report such payments if \$10 and over in value. The requirement to report the “payment” will fall upon the commercial supporter if that supporter is aware or becomes aware of the identity of the payment recipient by the end of the 2<sup>nd</sup> quarter following the reporting year of the payment. If the cost is split among several commercial supporters, each may be responsible for reporting their portion of the reportable payment.

As a practical matter, however, commercial supporters may wish to capture and report the identities of physicians who partake in plated meals at accredited or non-accredited events, in order to avoid the concern of subsequently becoming aware of their participation but inadvertently failing to report it.

**Example 8:** Dr. Rosen attends a Sunshine-exempt CME event with 100 fellow doctors. The meal provided is plated and valued at \$40. Pharmaco and Mother Goose Pharma both provided support for the event, but were unaware of the names of the physician-attendees and as a result, chose not to report any of the meal cost as “indirect payments.” Six months later, a Pharmaco sales rep met Dr. Rosen at a holiday party, where Dr. Rosen remarked, “Six months ago, I attended the most wonderful CME course that was supported, I believe, by your company. The chicken was outstanding.” Now, Pharmaco has awareness that it provided a \$20 meal to Dr. Rosen and is responsible for reporting it, or could face penalties. To avoid this, Pharmaco could have taken care of the reporting requirements at the start, and made themselves aware of the physician-participants at the time. As a practical matter, manufacturers should consider reporting all such plated meals in excess of \$10 as indirect payments. CME providers must ensure compliance with SCS 3.11.

See **2.4.3.1** on how CME providers can assist manufacturers in reporting or tracking such payments.

### **5.3 Treatment of Non-physician Attendees or Participants at Plated Meals**

Manufacturers are required to calculate the cost of a physician’s platter or plated meal by dividing the entire cost of the food and beverage by the *total* number of individuals who actually partook in the meal (ate or drank a portion of the offerings), including non-physicians, such as office staff or nurses. The *names* of such non-physicians, however, do *not* need to be reported.

**Example 9:** A CME program includes a plated lunch for six (6) physicians. Five (5) office staff members also partake in the plated lunch. The cost of the lunch is \$165. Because eleven (11) individuals partook in the meal and beverage, the cost per person is \$15. Thus, the manufacturer would have to

report the value of the meals for the six physicians that participate, but would not have to report the names of the office staff.

#### **5.4 Disclosing the Identity of Physician-Attendees for Meal Reporting**

For Sunshine-exempt CME programs that include **plated meals** (both \$10 and over, reportable, and under \$10, tracking required), the CME provider *may* disclose to the applicable manufacturer a list of the physician-attendees who actually partook in the meal to assist the manufacturer in reporting and tracking the meals associated with the CME event.

There is no legal or regulatory requirement that the CME provider disclose this list to the manufacturer. Either the commercial supporter will include this disclosure obligation in its Letter of Agreement (LOA) with a CME provider or the CME provider may voluntarily provide this list.

If the CME provider agreed to disclosure under its LOA or voluntarily chooses to disclose, the CME provider should do so only after the CME program has taken place. The list of physician-attendees should *not* be given to a commercial supporter before the grant-supported activity is entirely complete and the CME provider independently has evaluated the activity and completed all necessary post-activity or outcomes measures. For example, if a CME provider receives a grant for multiple CME sessions, the provider should not disclose the list of physician attendees at each separate session until the final session is complete and fully evaluated and measured for outcomes (if applicable).

Accordingly, a CME provider may wish to use a sign-in sheet or other tracking method to determine which physician-attendees partook in the plated meal. The sign-in sheet should include a check box for physicians intending to partake in the meal. CME providers could also remind physician-attendees before, during, or at the conclusion of the program, to notify CME provider staff if they did not partake in the meal to avoid being reported. This point underscores the benefit of providing food and beverage in a buffet-style for group settings.

There may be situations where the Open Payments reporting period is ending or near and a commercial supporter will need the list of physician-attendees before an activity is complete to meet the statutory deadline for reporting. CME providers should work with commercial supporters in

advance to address this issue, such as arranging for expedited program evaluation or outcomes measuring, or only providing buffet-style meals at programs close to a Sunshine Act reporting deadline.

## 6 Unaccredited or Non-certified CME

If the payment made to an accredited CME provider or teaching hospital does not meet any one of the required conditions for Sunshine-exemption, or is made for some other educational or educationally-related purpose, the applicable manufacturer must report the payment to CMS and select the nature of payment category that best describes the payment.

### 6.1 Speakers or Faculty

If a manufacturer supports a speaker or faculty to participate at an unaccredited or non-certified CE program or other educational program, the manufacturer could choose from the following nature of payment categories:

- (1) **Honoraria:** generally provided for services for which custom prohibits a price from being set.
- (2) **Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a CE program;** chosen primarily for promotional or marketing activities.
- (3) **Compensation for serving as faculty or as a speaker for an unaccredited and non-certified CE program;** chosen if there is no accreditation whatsoever.
- (4) **Compensation for serving as faculty or as a speaker for an accredited and certified CE program;** *could* be chosen if the program is accredited or certified by an organization *other than* the five (5) recognized by CMS.

The manufacturer must ensure that regardless of which category they choose to report the faculty or speaker compensation, the payment is for fair market value.

If the manufacturer also provides the speaker or faculty with payments for **meals, travel, or lodging**, those payments must be reported *separately* from the speaker/faculty compensation.

For meals provided at a reportable event, the manufacturer should simply include the physician-speaker/faculty in the total number of participants, if that individual partakes in the meal, for determining the per person cost of the meal. In other words, for purposes of meals, the speaker/faculty becomes a physician-attendee. *See* Section 5.

Thus, manufacturers will want to clarify what other payments besides the speaking or faculty fee the manufacturer will be providing to the speaker or faculty to ensure consistent reporting.

Manufacturers must also report the associated covered drug, biological, device, or medical supply upon which the physician is speaking if the event is educational, promotional, or marketing in nature.

## **6.2 Grant**

A manufacturer may designate this nature of payment category if the payment is made to a teaching hospital “in support of a specific cause or activity,” rather than for a specific class or program.

## **6.3 Education**

A manufacturer may designate this nature of payment category if the payment to the teaching hospital is *not* for an accredited or certified CE program, but goes towards “classes, activities, programs, or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a profession.”

If there is no specific “class, activit[y], program, or event,” or no “imparting or acquiring of particular knowledge or skills,” such payments should be reported under “Grant.”

## **6.4 Charitable Contribution**

A manufacturer may only choose this nature of payment category if the teaching hospital is tax exempt *and* the payment or transfer of value was not made in exchange for any service or benefit.

A manufacturer will choose this category only if the donation is unrestricted. Any indication between the tax-exempt hospital and manufacturer that the funds will be used for a Sunshine-Exempt CME program or other educational or non-educational purpose will render the payment unreportable and outside of this category.

**Example 10:** A manufacturer engages in a consulting contract with Dr. Johnson, the head of diabetes care at Shady Grove Memorial Hospital—a tax-exempt hospital—for services involving the launch of a new diabetes drug. Dr. Johnson instructs the manufacturer to use his consulting fee as payment to the hospital’s CME department for purposes of creating a Sunshine-exempt CME program to educate doctors about diabetes preventative care. This payment cannot be reported as a charitable contribution. The payment *must* be reported as a consulting fee for Dr. Johnson, but the entity paid would be Shady Grove Memorial Hospital.

## 6.5 Space Rental or Facility Fee

If the manufacturer solely provides payment for a teaching hospital to rent space or pay a facility fee for the purposes of hosting an unaccredited or non-certified CME or other educational program, and no other fees are paid, the manufacturer would choose this category.

## 6.6 Food and beverage for attendees

If a manufacturer supports an unaccredited or non-certified CME or other educational program by providing commercial support for food and beverage for the physician-attendees and non-physician attendees, the manufacturer must follow the guidelines in Section 5.

# 7 Payments Made Directly to Teaching Hospitals for CME

If an applicable manufacturer pays a teaching hospital *directly* for the purpose of offering or hosting a CE or CME program, certain payments associated with the event should be reported accordingly.

## **7.1 Speakers and/or Faculty for Accredited CME**

### **7.1.1 Meals, Travel, and Speaking Payments**

Payments for speaking, as well as payments for meals, travel, and lodging, would *not* be reportable if *all* three conditions for Sunshine-exempt CME programs are met. See Sections 2.2 (speaker/faculty payments) 2.3.5.1 (meals) and 2.3.6.1 (travel).

## **7.2 CE or CME Department Physician-Staff**

Payments to CE or CME departments in teaching hospitals with physicians on staff responsible for the oversight, logistics, and coordination of receiving payments from an applicable manufacturer would also *not* be reportable if *all* three conditions for Sunshine-exempt CME programs are met.

## **7.3 Physician-Attendees for Accredited CME**

### **7.3.1 Meals**

The same rules and recommendations apply for Section 5 above.

### **7.3.2 Educational Value**

The same rules and recommendations apply for Section 3 above

## **7.4 Unaccredited or Non-certified CME**

If the payment made to a teaching hospital does not meet any one of the required conditions for Sunshine-exemption, or is made for some other educational or educationally-related purpose, the applicable manufacturer must report the payment to CMS and select the nature of payment category that best describes the payment.

Teaching hospitals and manufacturers should follow Section 6 to determine reporting requirements.

## 8 Joint Sponsorship of a CME Program

CMS clarified in its recent FAQ that the list of five (5) enumerated accrediting and certification bodies is “exhaustive.” Thus, an event organized by a CME provider without accreditation or certification status from one of these bodies (an “unenumerated CME provider”) is not exempt from reporting, and would have to follow the reporting requirements as outlined in the final rule, using our guidance in Section 6.

However, under certain circumstances, if an “unenumerated CME provider” jointly sponsors a CME program with an *enumerated* CME provider (accredited/certified by one of the five bodies), that program *may* be exempt from reporting if the other two conditions are met. If the following recommendations are followed, the CME program offered jointly by an enumerated and unenumerated CME provider may be exempt from reporting:

- (1) The unenumerated CME provider cannot be a “commercial interest” as defined by the ACCME SCS.
- (2) The unenumerated CME provider engages an enumerated CME provider to offer the CME program through joint sponsorship prior to submitting a grant or proposal for commercial support.
- (3) If no prior engagement is made, the unenumerated CME provider should enter into a written agreement with an enumerated CME provider for joint sponsorship prior to (i) the creation of any educational content or materials; and (ii) the selection of any faculty or speakers for the program to ensure such faculty is properly chosen based on the enumerated CME provider’s accreditation standards.
- (4) All faculty or speaker decisions must be made in compliance with the enumerated CME provider’s accreditation standards.
- (5) All conflict of interest functions should be carried out jointly under the standards and rules of the enumerated CME provider.
- (6) All educational content creation and management, including educational materials, should be carried out jointly under the standards and rules of the enumerated CME provider, and in compliance with Section 3 in these guidelines.



- (7) All advertising or promotion for physician-attendance should be carried out jointly under the standards and rules of the enumerated CME provider.
- (8) In cases of joint sponsorship, it is the enumerated-accredited provider's responsibility to be able to demonstrate compliance to the accreditation or certification standards of its enumerated body (e.g. ACCME SCS if ACCME-accredited).

## **9 Exhibit Booths**

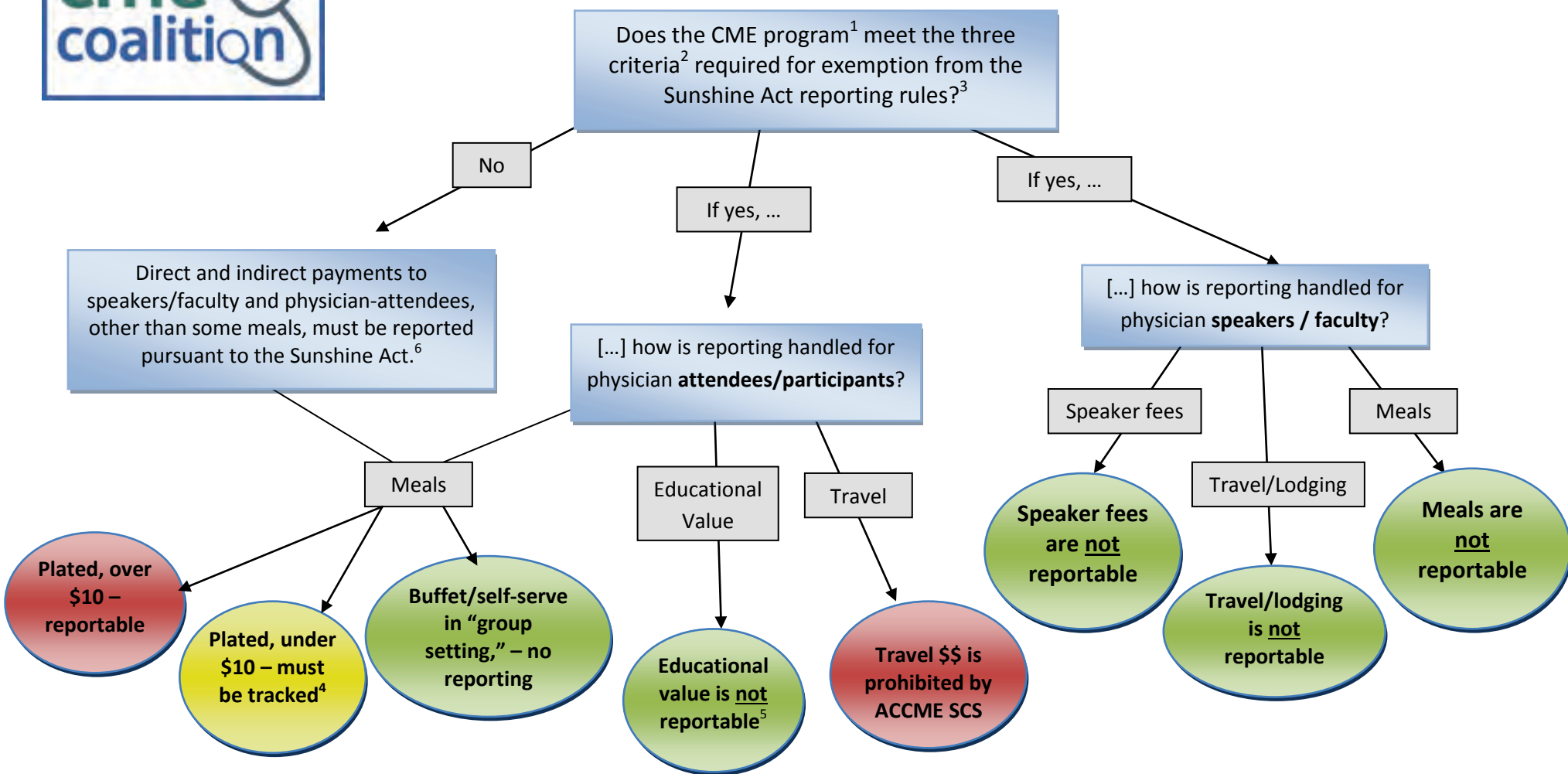
CMS has determined that manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or event.

CMS also determined that small incidental items that are under \$10 (such as pens and note pads) that are provided at exhibit booths will be exempted from the reporting requirements, including the need to track them for aggregation purposes.

CME providers and their exhibitors will not be required to report or track incidental items worth less than \$10 or snacks/soft drinks, coffee, or buffets made generally available to all participants at large-scale events.



# CME Provider Sunshine Compliance Decision Tree



<sup>1</sup> Program may include live, recorded, or online CME. Providers should be aware of which date a manufacturer reports for any CME-related payment.

<sup>2</sup> Exempted programs must (1) be accredited by one of five certified accrediting bodies designated in the Final Rule, **and only these five** (ACCME, AMA, AAFP, ADA CERP, American Osteopathic Association); (2) physician presenters or attendees may not receive direct payment from the applicable manufacturer; and (3) the manufacturer may not select the speakers nor attendees nor may influence their selection.

<sup>3</sup> The Sunshine Act only affects payments made beginning August 1, 2013.

<sup>4</sup> Payments under \$10 must be tracked, as they become reportable if the aggregate of such transfers of value exceed \$100 in any given year.

<sup>5</sup> Examples of these materials include, but are not limited to, “handouts, web downloads, or printed slides.” The following conditions should be met for any educational materials provided at a CME program: (1) the educational content should “not contain any CME sponsor [commercial supporter] information”; (2) the content must be related to the CME program; (3) value should be “de minimis”; and (4) the funds used for the materials “came from the same CME program grant.” In addition, the CME Coalition recommends that all materials meet the requirements under ACCME SCS, Standard 4.

<sup>6</sup> CMS recommends that payments to faculty or speakers at an unaccredited or non-certified CME program be reported as “compensation for services other than consulting” or “honorarium.” Depending on the circumstances, “education” or “grant” may also be appropriate. Travel and educational value and materials for speakers/faculty and physician-attendees will also need to be reported in the appropriate categories.