



The Continuing Medical Education Coalition's Frequently Asked Questions (FAQs) supplement to its Sunshine Act Compliance Guide

**September 25, 2013
Andrew M. Rosenberg, JD
Senior Advisor
CME Coalition**



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September 25, 2013

Frequently Asked Questions (FAQ) about Sunshine Act and CME

Note: The following FAQ document is provided in response to numerous questions we have received from CME stakeholders, and represents the CME Coalition’s best effort to respond with accuracy. We are very confident in the advice we are providing herein, but please note that this does not represent legal advice and we suggest that you may wish to retain your own legal counsel to ensure your compliance with the Act.

Please note also that applicable manufacturers and commercial supporters are used interchangeably in this document. However, there is a chance that a CME provider may receive commercial support from an entity that does *not* fall within the definition of “applicable manufacturer” under the final Sunshine Rule. Prior to accepting a grant or any commercial support, CME providers are encouraged to clarify with all commercial supporters, particularly jointly supported events, whether the supporter(s) is an “applicable manufacturer.” This will help CME providers plan their programs accordingly.

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I. ACCREDITATION

1. Does a certified COPE (Council on Optometric Practitioner Education) for optometry activity fall under approved accredited list (ACCME, AOA, etc)?

No. CMS recently clarified in its FAQ that the original list of five (5) accrediting or certifying bodies “is exhaustive.” Thus, payments provided as compensation to speakers at CME events run by CME providers that are *not* accredited or certified by one of the enumerated bodies are reportable. CMS explained that “CME events must be run by CME providers that are accredited or certified by one of the accreditation or certification entities ... and, accordingly, meet the accreditation or certification requirements and standards of any of those specific entities.” Payments for speakers, faculty, and physician attendees would all have to be reported as required (e.g., meals, travel, honorarium, educational materials, etc.). CMS did indicate that it will consider modifications to this provision in “future rulemaking.”

Thus, if a program is accredited by the ANCC and receives funding from an applicable manufacturer, and a physician speaker or faculty member is used to compensate the physician speaker or faculty member, the manufacturer will have to report separate payments for any category which they are applicable, including but not limited to: 1) speaking; 2) consulting; 3) services other than consulting; 4) meals; 5) travel/lodging; 6) educational materials/items.

CME providers should reference the CME Guidelines for recommendations about addressing this issue further, such as joint-sponsorship with a CME provider recognized by one of the five accrediting bodies.

- 2. If a CE program is certified for nurses only (by the ANCC), is supported by an applicable manufacturer, and a physician decides to attend or participate as a faculty or speaker, are payments or transfers of value to that physician reportable?**

Yes, because the ANCC is not within the five enumerated accrediting bodies, and thus the CE program is not exempt from reporting. The manufacturer would have to report all applicable payments, including meals (over \$10, tracking under \$10); educational value; any travel or lodging, and any other fees if the physician spoke or consulted on the program.

- 3. Is reporting required for faculty, speakers, or physician-attendees, licensed in the U.S., who attend a CME program accredited by an international entity that has a recognition agreement with one of the five recognized accrediting bodies in the U.S.?**

We anticipate further guidance on this issue.

Until CMS finalizes this issue, we recommend that applicable manufacturers track and report any direct or indirect payments made to physician faculty or attendees who are U.S. licensed physicians and participate in international meetings, either as speakers/faculty or attendees out of an abundance of caution.

CME providers should reference the CME Guidelines for recommendations about addressing this issue further, such as joint-sponsorship with a CME provider recognized by one of the five accrediting bodies.

- 4. If an educational grant has both non-accredited and accredited components, i.e., steering committee, patient education tool, etc., how is this activity considered vis-à-vis the reporting requirements?**

Although the Final Rule does not specify, we recommend that such joint components be separated in grant proposals in order to reduce any chance that including both programs may eliminate Sunshine exemption for the accredited CME portion.

If the grant application is submitted with both accredited *and* non-accredited components, the CME provider must still ensure that all three (3) conditions are met to exempt the accredited aspect of the program from reporting. As previously noted, however, such a scenario with multiple events will likely require a case-by-case analysis to determine what aspects of each program are reportable and for whom (speakers/faculty and/or physician-attendees).

- 5. If an annual meeting or large conference has both accredited CME and non-accredited educational programs, is the entire meeting or conference exempt?**

No. As CMS clarified in an FAQ, this situation will likely require a case-by-case analysis. Most likely, any CME program at the annual meeting or large conference that meets the three CMS requirements will be exempt, and thus only certain non-exempt meals to physician-attendees will be reportable. All other aspects of the annual meeting (e.g., meals, educational value, travel, etc.) that are not Sunshine-exempt or part of the Sunshine-exempt CME program will be reportable as required.

6. How should grants to patient advocacy organizations for non-accredited patient education be treated? What about patient-caregiver (non-physician) education?

Grants to third parties may be reportable as indirect payments if the applicable manufacturer requires, instructs, directs or otherwise causes payment to be made to a physician. In this case, if a patient advocacy group receives a grant from an applicable manufacturer “earmarked” for the purpose of funding awards or grants for physicians to participate in non-accredited patient education or patient-caregiver (non-physician) education, the awards or grants would constitute reportable indirect payments. Thus, any compensation to the physician, including speaking or consulting, as well as travel/lodging and meals, would all be separately reportable. Payments to physicians for such programs, depending on the circumstances, could be reported as:

- Honorarium (must separate travel/lodging and meals);
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a CE program (must separate travel/lodging and meals);
- Compensation for speaking or serving as faculty at an unaccredited or non-certified CE event (must separate travel/lodging and meals);
- Grant;
- Education;
- Charitable donation (if tax-exempt)

The educational value to the patients or caregivers (non-physicians) and any meals, travel, etc., would *not* be reportable since patients and non-physicians (e.g., nurses) are not covered recipients. However, to the extent an applicable manufacturer makes payments or other transfers of value to patients or non-physician caregivers to be “passed through to a physician,” such payments would be indirect payments to the physician and would have to be reported under the physician’s name. *See* Final Rule 78 Fed. Reg. at 9467.

However, if the patient advocacy organization receives a completely unrestricted grant from an applicable manufacturer, in which the organization has complete discretion on how to use the funds, and later decides to award compensation to a physician for a non-accredited patient education or patient-caregiver education (non-physicians), such payments would not be reportable—in other words non-reportable indirect payments. *See* Final Rule 78 Fed. Reg. 9490.

II. COVERED RECIPIENTS

7. How are payments for CME made directly from an applicable manufacturer to a teaching hospital to be reported?

An applicable manufacturer must report a CME grant or funds for CME paid directly to a teaching hospital in the appropriate nature of payment category as a direct payment to a covered recipient. Thus, an applicable manufacturer could report a CME grant or funds as:

- a. Education;
- b. Grant;
- c. Charitable donation (if tax-exempt); or
- d. Space rental or facility fees (if only for this purpose)

In addition, the grant or CME funds may also be reportable as indirect payments to physicians. Accordingly, the applicable manufacturer must determine if the CME program being funded will meet the three CMS requirements for exemption. If the teaching hospital's CME department is accredited by one of the five enumerated bodies, and the program meets the other two requirements, the special rules governing CME will apply and the teaching hospital will only be required to report or track certain non-exempt meals to physician-attendees.

If the teaching hospital will provide non-exempt meals, we recommend that the applicable manufacturer exclude any value of meals provided to physician-attendees from the total award or grant given to the teaching hospital to avoid "double counting." For example, if the teaching hospital receives a \$1,000 grant for CME, and \$100 is used to provide plated meals to ten (10) physicians. The applicable manufacturer should attribute \$900 as a grant to the teaching hospital, and \$10 to each physician that partook in the meal (indirect payments). Otherwise, the \$100 used for meals would be attributed to both the teaching hospital and the ten (10) physicians, resulting in double counting. *Note:* as discussed in an FAQ below, the applicable manufacturer would not have to report a related covered product for the meal because CME is not "education" for the purposes of the final rule.

If, however, an enumerated body does not accredit the teaching hospital's CME department or the CME program itself, or the program fails to meet one or both of the other two requirements, the applicable manufacturer will be required to report the direct payment to the teaching hospital *and* all reportable indirect payments the teaching hospital makes to physicians. The payments would be indirect because the teaching hospital's CME department would be paying or transferring value to the physician-speakers/faculty and physician-attendees. In this case as well, the teaching hospital and applicable manufacturer will want to avoid double counting.

For example, a teaching hospital receives a \$1,000 grant for an unaccredited educational program. \$100 is given to a physician for speaking and all associated fees (travel, etc.). \$100 is used to provide plated meals to ten (10) physicians. \$100 is used to provide educational to all ten physicians. The applicable manufacturer should report a \$700 grant to the teaching hospital; \$10 meals to each physician; \$10 education to each physician; and \$100 to the physician-speaker (fees for meals, travel/lodging, and compensation each separately reportable).

Under either circumstance, we recommend that teaching hospital and applicable manufacturer communicate to avoid the double counting of any reportable indirect payments.

8. If a teaching hospital's CME office receives an educational grant directly from an applicable manufacturer, is this grant reportable if the office only accredits the educational program (e.g., a satellite symposium), but no CME program actually takes place at the teaching hospital?

A direct educational grant from an applicable manufacturer to a teaching hospital must be reported regardless of whether the CME activity takes place at the teaching hospital. Teaching hospitals are covered recipients and an educational grant to a teaching hospital over \$10 would be a reportable payment. As noted above, however, teaching hospitals should work with the applicable manufacturer to ensure that only the value the teaching hospital receives is attributed to them.

If the entity receiving the grant is a non-teaching hospital, no direct payment for the educational grant would be attributed to the hospital because it is not a covered recipient. Thus, the applicable manufacturer and non-teaching hospital would report only reportable indirect payments, if any, that are made by the non-teaching hospital to physicians.

9. How should an applicable manufacturer report a CME program co-sponsored by a CME provider and teaching hospital?

The answer to this question likely depends on who receives the payment. If the applicable manufacturer pays the teaching hospital directly (e.g., the CME Department), see the question #9, directly above. If a portion of the funds is given to both the teaching hospital and the CME provider, the applicable manufacturer will have to report the payment to the teaching hospital as a direct payment, as noted above. In this case, the applicable manufacturer should report only the actual value given to the teaching hospital. For example, if the CME grant is for \$5,000 and the teaching hospital receives \$2,500, the manufacturer should report the \$2,500 as a "grant" to the teaching hospital. No value would be reportable to the CME provider because it is not a covered recipient, however, reporting or tracking of certain non-exempt meals given by the CME provider would be required.

If the funds are paid solely to the CME provider, no payments would be attributed to the teaching hospital; however, certain non-exempt meals would be reported to any physician (including teaching hospital faculty) who attends the CME program and partakes in the meal.

Accordingly, we recommend that teaching hospitals and CME providers conducting co-sponsored activities separate payments attributed to each entity in the grant application or RFP, to assist the applicable manufacturer in reporting. If a CME provider or teaching hospital is added as a co-sponsor after the application or RFP, both entities should determine their separate payments and communicate this directly to the applicable manufacturer before any payment for the program is made.

10. Do we expect that nurse prescribers, PAs will become covered recipients in the future?

It is highly unlikely. Congress would specifically have to amend the act to add nurses, NPs, PAs, etc., which CMS explicitly acknowledged in the final rule. Of the few states that require such reporting, there are very minimal payments, so the cost of putting together the reporting of such payments makes the investment by other states unlikely as well. However, with the push for more NP/pharmacist care, it could be on the horizon in years to come.

11. What happens if a CME speaker or faculty member asks for their compensation or honorarium associated with a Sunshine-Exempt CME program to be transferred to a charity or other individual or entity?

For purposes of ensuring compliance with the Sunshine Act regulations, we recommend that all compensation to speakers or faculty associated with a Sunshine-exempt CME program be given directly from the CME provider to the faculty member or speaker because such compensation (including meals, travel and lodging) is excluded from reporting. Therefore, there should be no concern by the faculty member or speaker about reporting.

12. If a speaker or faculty member for a Sunshine-exempt CME program attends another Sunshine-exempt CME program for which they are *not* serving as a speaker or faculty, (e.g., annual meeting or large conference), are any payments or transfers of value reportable for those *other* CME programs?

Yes. If the other CME programs the physician attends meet all three requirements, then any non-exempt meals at such other programs would be attributed to the physician, as well as any educational materials the physician receives that are not part of the other Sunshine-exempt CME program.

Additionally, if the speaker or faculty member attends, participates or partakes in any other reportable activity at the annual meeting or large conference (e.g., exhibit hall), associated payments or transfers of value must also be attributed to that physician.

13. What happens if a physician sends a non-physician to a conference and that person comes back to train the doctor. Is this reportable?

If an applicable manufacturer supports nurses to attend any kind of educational event with the purpose of educating the physician upon their return, this would be considered a reportable “indirect payment” to that physician. In other words, the company is considered to be using the nurse as an “intermediary” to pass through the payment or transfer of value (education, travel, meal) to the physician. If the company supports nurses to attend the event without a pre-conceived agenda towards the doctor, then it would not be a reportable indirect payment.

III. APPLICABLE MANUFACTURERS

14. Are manufacturers of diagnostic services (e. home testing sleep) or lab services defined as applicable manufacturers?

If they make a product or products that are reimbursed by Medicare, then yes. Certain exceptions may apply if the amount of products they make that are covered by Medicare is less than 5%.

IV. EDUCATIONAL MATERIALS

15. How should you determine the educational value of a CME program?

If the CME program meets all three (3) conditions for Sunshine exemption, there is no need to determine educational value. The cost of tuition and other CME fees (e.g., educational materials associated with the event) is not reportable. As CMS clarified, “Educational materials that are included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions, such as handouts, web downloads or printed slides, are excluded from reporting under Open Payments provided that (1) the content does not contain any CME sponsor information, (2) the content is related to the CME program, (3) the value is de minimis, and (4) the funds used for the materials came from the same CME program grant.” CME providers should also closely follow ACCME SCS 4 when dealing with educational materials.

If the CME program does not meet all three conditions for Sunshine-exemption, the applicable manufacturer will need to come up with its own methodology to calculate the educational value of the program physician-attendees receive, including any educational materials or transfers of value. Meals and travel/lodging for any physician-attendees must be reported separately from the educational value. In this case, the CME provider will want to communicate with the applicable manufacturer about what value the manufacturer will attribute to physician-attendees so that the CME provider can notify physician-attendees that their attendance and participation in the program is reportable.

16. What constitutes the sort of “sponsor information” that should be prohibited from inclusion in CME educational materials?

CME providers should ensure that all educational materials are in compliance with ACCME Standards for Commercial Support. The ACCME recently proposed to amend SCS 4.3, which would prohibit any educational materials that are part of a CME activity, such as slides, abstracts and handouts from containing any “corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.” The ACCME has also proposed to amend SCS 6.4, which would prohibit the use of a “corporate logo, name or a product-group message of an ACCME-defined commercial interest” when the disclosure of commercial support is being made (e.g., disclosure slide).¹ This process is pending.

The CME Coalition, in the meantime, is currently developing a voluntary industry Code of Conduct for the Responsible Use of Corporate Logos that is intended to promote transparency and appropriateness in the use of logos. We encourage stakeholders to reference this voluntary Code at the CME Coalition website, and to adopt its standards voluntarily.

¹ <http://www.policymed.com/2013/05/accme-proposal-for-simplifying-and-evolving-the-accreditation-requirements-and-process-for-cme.html>

17. Are enduring CME materials mailed to physicians for CME credit exempt from reporting?

Yes, if the CME program meets all three CMS requirements for exemption and the conditions for excluding educational materials are met. When the CMS requirements and conditions are met, any format of CME educational materials and value are exempt from reporting, including enduring materials mailed to physicians. CME providers should reference the CME Coalition Guidebook for further details.

18. How should we treat handouts that are given out on flash drives?

If educational materials for the CME program are provided to physicians on a flash drive, the value of the flash drive likely would not need to be reported, so long as the flash drive itself is of incidental value, and it would reasonably be included in the tuition or CME fees associated with the cost of the program (which CMS explicitly recognized would not be reportable).

“Educational materials that are included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions, such as handouts, web downloads or printed slides, are excluded from reporting under Open Payments provided that (1) the content does not contain any CME sponsor information, (2) the content is related to the CME program, (3) the value is de minimis, and (4) the funds used for the materials came from the same CME program grant.” CME providers must ensure that *only* materials relevant to the CME program are contained on the flash drive, and all SCS 4 requirements are met. The flash drive should not contain any logos or marketing of any commercial supporter.

19. How should an applicable manufacturer report journal reprints provided at a CME program?

This is a difficult question to answer and will require a case-by-case analysis by CME providers and commercial supporters. If a CME provider uses a portion or portions (e.g., table, abstracts, graph, chart) of a journal reprint in their CME materials (that meet the CMS requirements), this portion would not be reportable.

However, if the CME provider is distributing an entire journal reprint and the value of the reprint is not “de minimis,” the reprint *may* be reportable or tracked for the purposes of the \$100 annual limit. If all the other factors CMS has outlined are met, the manufacturer may want to consider explaining its approach in their voluntary assumption document. The CME provider may also want to track or include a sign-in sheet of physicians who actually received the entire journal reprint to assist the manufacturer if it decides to report such reprints. Further, the CME provider should communicate with the manufacturer prior to the CME program to determine what approach each party should take.

20. What is the definition of “textbook” in the context of CME?

CMS did not finalize a definition of “textbook” within the final rule. Merriam Webster’s defines “textbook” as “a book about a particular subject that is used in the study of that subject.” Merriam Webster’s defines “book” as “a set of written, printed, or blank sheets bound together

into a volume.” Thus, the CME Coalition recommends that applicable manufacturers and CME providers use the following definition of “textbook” for the purposes of Sunshine Act reporting:

“A bound book, written or printed by a publisher, about a particular subject that is used in the study of that subject, and is generally available for sale in bookstores or other similar distribution channels where similar books are normally available”

CME educational materials are tailored to the specific CME program and therefore are not generally available for sale in bookstores or other similar distribution channels. Further, CME educational materials are focused more narrowly on the specific topic of a CME program and are not broadly about a particular subject. Moreover, CME materials are not used in the study of a subject in the same manner as textbooks; physicians use such materials to assist them in learning about new treatments and clinical information.

Thus, a CME provider that gives physicians handouts or syllabi that have reprinted educational tools, patient handouts, consult guides, charts or graphs, journal abstracts or other similar materials would not be considered “textbooks” for the purposes of reporting.

V. STIPENDS FOR POST-ACTIVITY OUTCOMES REPORTING

21. Are stipends or transfers of value given to physician-attendees for post-activity outcomes reporting (e.g., surveys), which are funded through the commercial supporter’s CME grant, reportable under the Sunshine Act?

This question will likely require a case-by-case analysis. Measuring the outcomes of CME programs and activities is a crucial part of CME and is vital to ensuring that CME providers continue to provide high quality education while improving the efficiency and effectiveness of physicians receiving such education. Many CME providers measure outcomes by collecting data from physicians and their patients through follow-up surveys 60 to 120 days after they have participated in a Sunshine-exempt CME program. In some cases, CME providers may provide physicians payments or transfers of value to complete the surveys, such as \$10-\$20 gift cards. Under these circumstances, the post-activity transfers of value to the physicians might be considered a reportable indirect payment under the Sunshine Act.

To avoid having to report such transfers of value, CME providers and commercial supporters may have two options: **1) Market Research Exemption; or 2) CME Educational Value Exemption.** Under either option, both CME providers and commercial supporters should abide by the following recommendations:

- A. The CME program must meet all three CMS Sunshine-exempt requirements;
- B. The outcomes survey or measures must be clearly described in the grant proposal or educational design, including the financial incentives to be offered (e.g., \$10 gift card);
- C. All outcomes surveys or measures should be solely related to the educational purposes of the CME provider and in compliance with the ACCME accreditation standards;
 - i. Measuring the learning achieved in or by the activity; and/or

- ii. Gathering formative assessment data to refine learning objectives and better define educational gaps
- D. The outcomes survey or measures must be sent directly from the CME provider to only physicians who actually participated in the applicable CME program or activity;
- E. Payments or transfers of value associated with the outcomes survey or measures must be made directly by the CME provider and only to physicians who actually participated in the applicable CME program or activity; and
 - i. Must be made from the grant funds supporting the CME program;
 - ii. Should be “de minimis”;
 - iii. Should state that payment is being made for the purposes of measuring outcomes associated with the physician’s attendance at the applicable activity; and
 - iv. Should contain no information or logos regarding the commercial supporter
- F. Never disclose to the commercial supporter the identity of physicians who:²
 - i. Attended the CME program; and
 - ii. Completed the outcomes survey or measures

Market Research Exemption

First, CMS recognized in the final rule that indirect payments would not be reportable in situations when “the reason a payment or other transfer of value is being made through a third party is that the identity of the covered recipient remains anonymous.” 78 Fed. Reg. 9490. For example, CMS noted that it does “not intend” payments from an applicable manufacturer to a third party “to conduct a double-blinded market research study, which includes paying physicians \$50 for responding to a set of questions” to be a reportable indirect payment because the “third party’s involvement is specifically to maintain the anonymity of the respondents and sponsor.” *Id.*

Accordingly, if a CME provider maintains the anonymity of both physicians who attend the CME program and who respond to the outcomes survey, and if the recommendations above are met, such payments should not be considered reportable indirect payments and are excluded from tracking and reporting. However, such payments are likely reportable if plated meals are provided at the CME program because plated meals make the identity of physician-attendees known to the manufacturer.

CME Educational Value Exemption

Alternatively, the value of the outcome survey may be exempt from reporting as part of the educational materials included in “tuition and fees” if the CME provider specifically includes the nature and amount of payment to be given to physician-attendees for the post-activity survey. Under the final rule, CMS explained that manufacturers are “not responsible for reporting

² If the CME program includes plated meals that the manufacturer must report, post-activity payments for outcomes surveys may also become reportable. For example, if a CME program includes plated meals, the manufacturer will know the identity of physician-attendees, and any post-activity payments for outcomes surveys will not be considered made for the purpose of maintaining the anonymity of the respondents. Accordingly, post-activity payments for outcomes surveys for plated CME programs are likely reportable, unless exempt as part of the “educational activity.”

payments made to CME vendors that are used to subsidize attendees' tuition fees for continuing education events," including educational materials. 78 Fed. Reg. 9492. To qualify for this exclusion, the outcome survey or measure (1) must not contain any CME sponsor information; (2) must be related to the CME program; (3) the value is de minimis, and (4) the funds used for the survey must come from the same CME program grant." As a result, payments or transfers of value associated with outcomes surveys or measures that meet the above recommendations and the requirements outlined by CMS should be excluded from reporting under the CME exemption.

VI. MEALS & TRAVEL

22. Are payments for travel, lodging and meals to speakers and faculty of accredited or certified CME events that meet all three conditions established in the final rule included in the total compensations that are exempt from reporting?

Yes. Lodging, travel and meals for speakers of an accredited or certified CME event meeting all three requirements will be deemed to be included in the total speaker compensation and, therefore, exempt from reporting under Open Payments, pursuant to CMS' clarification in its FAQ.

23. If a CME commercial supporter/applicable manufacturer indicates that no funds from a grant may be used towards food and beverage for physician-attendees, must the event avoid any availability of beverage or food?

No. If the CME provider earmarks and segregates physician-paid attendance fees to cover the food/beverage provided to attendees, the money used for the physician meals is not being provided by an applicable manufacturer and as such, the cost of the meal is not reportable as a physician payment. In effect, the physicians are buying their own meals.

The ACCME SCS prohibits commercial supporters from providing any input or direction as to how commercial funds are used at anytime during the CME lifecycle. However, it is entirely within the discretion of the commercial supporter to include terms and conditions regarding any funding requests for grants, including the prohibition of grant funds for food and beverage. Further, commercial supporters may require CME providers to certify their compliance with not using grant funds for food and beverage. If a commercial supporter prohibits the use of grant funds for food and beverage, and the CME provider accepts such funds, they must abide by these rules or otherwise risk having to refund the grant funds.

24. How could an applicable manufacturer be expected to report the value of non-exempt or plated meals for CME if they do not have a list of attendees and CME providers are not required to provide one?

If plated or otherwise non-exempt meals are provided to physicians, the applicable manufacturer *should* report and/or track the value of such meals because they may constitute reportable indirect payments if the manufacturer becomes aware of the meal recipient. The final rule does not, however, require indirect payments, such as plated meals at CME programs, to be reported if

the applicable manufacturer is “unaware” of the identity of the physician receiving the meal for 1.5 years following the payment or transfer of value. CMS clarified that an applicable manufacturer is unaware if it “does not know the identity of the covered recipient.” CMS defined “know” as actual knowledge of the identity or acts in deliberate ignorance or reckless disregard of the identity. CMS’ “intent” is to require reporting of indirect payments where applicable manufacturers “know or should know the identity of the covered recipients who receive them.”

Under these broad standards and definitions, applicable manufacturers may wish to track and report plated meals at CME programs to avoid penalties under the Sunshine Act. It is possible that an applicable manufacturer will become aware of the identities of the physicians who attended the program within the 1.5 year period under the final rule and the manufacturer cannot deliberately ignore or recklessly disregard such information. For example, a physician may post information about their attendance online or in their CV, a sales representative may learn of the physician’s attendance at a supported CME program during an interaction, or the manufacturer may later contract with that physician and learn of the physician’s attendance firsthand. Moreover, the 1.5 year timeframe may be difficult to track because some manufacturers may report payment on the date of the CME program while others may report the date payment is made. Thus, applicable manufacturers should consider tracking and reporting plated meals at CME programs.

25. If an accredited CME provider chooses to provide plated or otherwise non-exempt meals, are they required to track and report names of physician-attendees who partake in the meal? Does the definition of “unaware” in the final rule require the commercial supporter to request the list of attendees?

The Sunshine Act does not require CME providers to track or report names of physicians who partake in certain non-exempt meals; however, commercial supporters are not prohibited from imposing such obligations through letters of agreement (LOAs), request for proposals (RFPs), or other contractual agreements or arrangements.

If an applicable manufacturer approves grant funding or commercial support for a CME program that includes plated meals, it may wish to report the value of this meal, as noted above. As a result, the commercial supporter may require the CME provider to collect information regarding the physicians that partook in the meal. Accordingly, CME providers should keep two things in mind. First, CME providers should clarify in their RFPs or grant requests whether plated or non-exempt meals will be provided, and if so, how many physician attendees are expected, and the estimated total budget for such meals. This will assist the manufacturer in determining the per person cost of meals to determine if reporting and or tracking will be necessary.

Second, CME providers may need to use a sign-in sheet or other tracking method to determine which physician-attendees partook in the plated meals. 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 the 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.

If a commercial supporter does impose a requirement in an LOA or RFP to report or track plated meals to ensure compliance with the Sunshine Act, the CME provider must continue to maintain strict compliance with the ACCME Standards for Commercial Support and remain independent from the commercial supporter. The list of physician-attendees should *never* 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).

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.

Accordingly, it is incumbent upon all CME providers to closely read all RFPs and LOAs from commercial supporters to determine any new obligations regarding the Sunshine Act that they will be held to in order to avoid any problems.

26. Do “boxed lunches” meet the definition of buffet for the meals exemption?

Yes. When provided at a Sunshine-exempt CME event, boxed lunches, or any meal or beverage that is provided on a communal table at a group setting, are considered exempt from the Act’s reporting/tracking requirement.

27. If a commercial supporter / applicable manufacturer awards a grant to an accredited CME provider, and the CME provider provides a stipend to a teaching hospital that pays for a buffet at an accredited CME program, is this food reportable?

This question will likely require a case-by-case analysis to determine if the payment to the teaching hospital is a reportable indirect payment, however, this can be structured in such a way as to avoid a reporting requirement. In general, an applicable manufacturer that provides an accredited CME provider with a grant for a Sunshine-exempt CME program will not have to report any value associated with physician-attendee meals if they are served in a buffet form in a group setting. However, if a CME provider uses funds from the applicable manufacturer and transfers them to a teaching hospital, this may create an indirect payment from the manufacturer to the teaching hospital. To avoid creating a reportable indirect payment, the CME provider should provide the food and beverage directly to the teaching hospital through the applicable grant funds as part of the CME program, rather than providing a separate stipend to the teaching hospital.

Otherwise, the manufacturer will have to determine if the payment from the CME provider to the teaching hospital is a reportable indirect payment. Important questions to determine include:

- Did the commercial supporter require, instruct, direct or otherwise cause the funds to be given to the teaching hospital?
- Is the commercial supporter “unaware” of the teaching hospital’s identity?
- Did the original grant request from the CME provider indicate that funds would be used for this purpose?
- Is the meal being provided as part of the accredited CME program that the CME provider has accredited and is hosting at the teaching hospital?
- Did the commercial supporter intend for the payment to be a “pass through” to the teaching hospital?

28. For the purpose of determining the reportability of buffet meals at non-Sunshine exempt events, how should one define the term “large-scale conference” or similar events for the meal guidelines? Is there a number of participant’s threshold?

CMS has not provided any clarification as to what constitutes a “large-scale conference” for the purposes of determining the reportability of certain meals at non-CME events. However, as noted above, CMS clarified that in the context of accredited or certified CME, “[t]he excluding characteristic for meals is when allocating the cost of the meal among covered recipients in a group setting where the cost of each individual covered recipient’s meal is not separately identifiable.”

Thus, the key is not to focus on a specific bright line *number* of attendees. Rather, as long as the CME program takes place in a “group setting” and the meals are provided in a buffet or self-serve format where the cost of each physician’s meal is not separately identifiable, the meals are not reportable and tracking is not required.

In the context of larger CME programs or annual meetings, CMS defined “large-scale conference” or similar events in the context of an event where it would be “difficult for [an] applicable manufacturer[] to definitively establish the identities of the physicians who partake in the food or beverage.” CMS clarified that for such “large-scale events,” even when non-accredited, reporting would not be required for situations where the applicable manufacturer provides a large buffet, meal, snack or coffee, which are made available to all conference attendees.” This exception does not apply to meals provided to select attendees at a conference where the sponsoring applicable manufacturer can establish the identity of the attendees.

At large meetings or annual conferences, there may be accredited and unaccredited events that serve either plated or buffet-style meals. Thus, CME providers and stakeholders will have to approach large events on a case-by-case basis and work with commercial supporters and meeting planners to identify which individual programs or events are reportable and tracking is required. CME providers should also keep in mind the recommendations with respect to sign-in sheets and communication with commercial supporters.

29. Let’s say a CME activity meets all three “exemption” criteria. It is a live meeting, includes 100 attendees and they serve a plated meal. Must an applicable manufacturer report the cost of that meal for the CR?

Assuming that the meal value attributed to each commercial supporter is over \$10, this meal would be reportable because it is a plated meal. The size of the audience does not matter for plated meals, only for buffets. One would need to divide the total cost of the meal by whoever partook in it (including office staff or non-physicians) to get to the true value per physician. If the meal is under \$10 per person, it would still need to be tracked for the \$100 annual aggregate reporting requirement.

30. How should commercial supporters report payments to speakers/faculty and physician-attendees when there are multiple commercial supporters? Is there a formula on how each supporter needs to report this?

If three (3) supporters provided \$1,500 for *plated* meals (\$500 each), and there were 100 attendees, then each supporter would not have to report such payment because the total amount would calculate to \$5 per attendee, per supporter; however, they would be required to track the payment for purposes of the \$100 annual aggregate reporting requirement.

If the three (3) supporters provided \$3,000 (\$1,000 each), then they would be required to report such payments since the \$10 threshold would be met. To avoid such concerns, multiple supporters can agree to providing meals through buffets.

As previously noted, commercial supporters cannot direct CME providers regarding how to use any funds for a CME program. However, some commercial supporters may prohibit the use of funds for meals as part of the LOA or RFP. As a result, multiple supporters will need to determine which companies funds the CME provider *actually* used for food. Again, to avoid such concerns, multiple supporters can agree to providing meals through buffets.

31. For a Sunshine-exempt CME program that serves reportable plated meals, will the manufacturer also have to report a “related covered drug, device, biological, or medical supply” associated with the CME program?

No. CME programs and related payments are not considered “education” for the purposes of the final Sunshine Act regulations. Thus, any reportable value a manufacturer must report associated with a Sunshine-exempt CME program (e.g., plated meals), should indicate in the related covered product item in the reporting template, “none”, “n/a” or leave this item blank.

As noted in the CME Coalition Guidebook and other FAQs, almost all costs associated with a Sunshine-exempt CME program are excluded from reporting. Certain non-exempt meals are reportable. However, no “related” covered product is required to be reported along with the meal because CME is not considered “education” for the purposes of the final rule.

The final Sunshine Act regulations require applicable manufacturers to report the name of the covered drug, device, biological or medical supply associated with that payment, if the payment

is related to “marketing, education, or research” of a particular covered drug, device, biological, or medical supply (78 Fed. Reg. 9474).

However, the final rule clearly distinguishes between continuing education (CE) or CME and “education.” Specifically, the final rule indicates that the category of “education” applies to “classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a profession.” Whereas, CMS recognizes CE or CME as those programs meeting the three requirements to be exempt from reporting. In addition, CMS does not indicate anywhere in its discussion of CME the need to report related covered products.

Moreover, the reporting of a related covered product associated with a physician’s attendance at a Sunshine-exempt CME program may raise concerns under the ACCME SCS. In particular, ACCME SCS 4.2 prohibits “Product-promotion material or product-specific advertisement of any type ... in or during CME activities.” The standard also states that, “the juxtaposition of editorial and advertising material on the same products or subjects must be avoided.” Further, ACCME SCS 4.3 prohibits educational materials that are part of a CME activity from containing any “trade name or product-group message.”

As a result, applicable manufacturers who must report certain non-exempt meals associated with Sunshine-exempt CME programs should not report any “related” covered product associated with the CME program because such reporting is not required and this would avoid raising concerns under the ACCME SCS and with individual physicians.

32. Does a registration fee paid by physician-attendees affect Sunshine Act reporting?

No. A physician’s payment of a registration or attendance fee will not affect an applicable manufacturer’s reporting obligations under the Sunshine Act. However, if such fees are collected to pay for physician-attendees’ food and beverage, an applicable manufacturer will not be required to report any value or payments associated with the meals at that CME program, so long as all funds for the meals are used from registration fees and not commercial support. Thus, CME providers might want to ensure that registration fees will adequately cover all food and beverage provided to ensure no use of commercial support that could render the meals reportable. CME providers should take pains to account for these funds with a great deal of clarity.

VII. FACULTY, SPEAKER AND PHYSICIAN-ATTENDEE IDENTITY

33. How should CME providers handle participants that are pre-registered for a CME program or a symposium or event that requires RSVPs (so identifiable)?

In order to ensure exempt status and compliance with the ACCME SCS, CME providers should never share with manufacturers a list of pre-registered attendees, and the manufacturer should never be aware of registrants prior to the CME program or at any point before the program is fully complete (including evaluation and outcomes measures, if applicable). A list of physician-attendees should only be provided to a manufacturer, as noted above, if the CME program

provides plated or otherwise reportable meals and the CME provider is required to provide such information by the LOA or RFP. Again, such a list would not be necessary if the meals are provided in group setting and buffet-style format.

34. In grant application, if a list of potential faculty is provided but not guaranteed as speakers, does this conflict with the three (3) conditions of exemption? Can an accredited provider supply a “proposed” list of faculty to an AM during the grant submission process?

We recommend that you do not include the names of *any* potential speakers or faculty, whatsoever. CMS may see the listing of faculty names as a suggestion or listing, even if unsolicited by the manufacturer. In other words, by approving the grant, CMS may consider that such approval was conditioned on those speakers, even if it was expressly not guaranteed. Thus, if a commercial supporter/grantor has knowledge of the faculty prior to awarding the grant (e.g., names in the proposal), this program would not likely be eligible for Sunshine-exemption.

35. When CME providers reconcile with manufacturers, if they include faculty names at that point, does it trigger a reporting obligation?

No. As long as all three conditions are met for Sunshine exemption, and the manufacturer is unaware of the identity of speakers and faculty prior to the grant payment actually being made (not necessarily when the CME provider is given approval), including speaker or faculty names at the point of reconciliation does *not* trigger a reporting obligation, as the payment would *not* be an indirect payment, and thus the awareness standards would *not* apply.

36. What should a CME provider do if a commercial supporter asks or requires names of faculty members or speakers before an accredited, Sunshine-exempt program is complete?

CME providers should not divulge the names of faculty members or speakers at accredited, Sunshine-exempt programs because this may violate the conditions outlined by CMS, as well as the ACCME SCS.

37. How should third parties handle a physician-faculty member or speaker at a non-exempt promotional or educational program who refuses to provide their NPI number or state license number?

Certain payments or transfers of value associated with a physician serving as faculty or speaker at a non-exempt educational or promotional program will be reportable (e.g., meals, travel, compensation, consulting, etc.). Third parties that receive grants from applicable manufacturers to host reportable educational or promotional meetings should ensure that all contracts with physician-faculty members or speakers include a requirement that the physician disclose their NPI number, State license number, and all other required information necessary to ensure compliance with the Sunshine Act (e.g., name, address, specialty, email). While the reporting obligation is on the applicable manufacturer, the manufacturer may require a third party to collect such information as part of the grant funding contract. Accordingly, third parties

receiving such grants and hosting these reportable events should update their contracts to ensure physician compliance with the new Sunshine Act reporting obligations.

VIII. GENERAL QUESTIONS

38. What does data collection as of August 1, 2013 mean? Activities that occur after August 1, grants approved after August 1, or payments made after August 1?

In general, *any* payment made on or after August 1st that is reportable must be reported. If a grant or activity occurred prior to August 1st, but any payment for that activity is made after August 1st, it must be reported. For a Sunshine-exempt CME program, no payment or value will be attributed to the speaker or faculty-physician for participating in a program on or after August 1st; however, plated meals will be reportable to physician-attendees.

For CME programs that do not meet all three CMS requirements for exemption, applicable manufacturers will have to report all payments or transfers of value necessary for both physician-faculty/speakers and attendees (e.g., meals, travel, educational value, speaking fee, etc.) made on or after August 1st.

39. Must an applicable manufacturer report any physician who comes to a focus group to talk about an ad?

Yes, this would be reported if the payment is over \$10 (and tracked if under \$10). This could be reported as:

- Consulting fee (including separate travel and meals); or
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a CE program (including separate travel and meals)

The manufacturer will also be required to report the associated covered product for which the ad is about (e.g., the drug or device).

40. How should fundraisers be considered under Sunshine?

If the fundraiser is for a tax-exempt organization, and is *not* in exchange for any benefit or service, payments from manufacturers to the tax-exempt organization would be reportable as charitable contributions. If the organization is not tax-exempt, or the payment is in exchange for a benefit or service, the payment would be considered a “gift.” Manufacturers must also realize that a physician cannot merely designate his payment for services to a charity—such payment would still be reported for the service (e.g., consulting), but the entity or individual charity that gets the payment would also be reported.

Manufacturers must be careful about these payments, which may appear suspect if other payments to the same physician appear, suggesting that the charitable contribution may have been intended as a type of payment.

41. If a professional society has a research fund with donations from industry and uses this fund to award grants (for education or research), are these reportable? If so, how should such funds be reported with multiple supporters?

This question will likely require a case-by-case analysis. Important questions to determine include:

- Were the grants restricted or unrestricted?
- Is the manufacturer aware of the identity of the covered recipient?
- Did the manufacturer require, instruct, direct or otherwise cause the funds to be given to a covered recipient?
- Are the donations indirect payments or meant as a pass through?

In general, if the grant provided to a professional society is unrestricted, it will not be reportable. CMS' example of unrestricted is a donation in which the organization has the sole discretion to use the funds in any manner it chooses. Thus, if the professional society accepts *only* unrestricted grants, then it is likely that none of the funds would be reportable if the society later decides to use such funds for education or research award grants. However, if the society accepts funds with restrictions, the applicable manufacturer will likely request how the funds were apportioned by the society to fund particular physicians.

Accordingly, professional societies will want to keep track of which funds are restricted and unrestricted, and in awarding restricted grants, will likely need to keep track of which or what proportion of a manufacturer's funds are used for a particular physician's award and the purpose of that award (e.g., speaking, education, research, etc.).

42. How are poster receptions reported where finger foods or snacks are provided?

Applicable 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 similar large-scale event. Similarly, small incidental items under \$10 (such as pens and note pads) provided at large-scale conferences and similar large-scale events are exempt from the reporting and tracking requirements. Thus, if the poster reception is at a large-scale event, such finger foods and snacks are excluded from reporting and tracking. However, CMS has yet to issue guidance as to the definition of a "large-scale" event.

43. What nature of payment category will applicable manufacturers report educational materials (not given at a Sunshine-exempt CME) that do not directly benefit patients?

Gifts. CMS clarified in the final rule that this category "will often include anything provided to a covered recipient that does not fit into another category." Such payments or transfers of value would probably not be categorized as education because CMS clarified that this category includes "classes, activities, programs or events" rather than materials. However, if such

materials were provided at a class, activity, program or event, the value of the materials could be included in this payment and categorized as “education.”