FAQ: Physician Payment Sunshine Act: Lessons Learned in Preparation and Implementation

The following answers to questions from a webinar held on September 4th titled: Physician Payment Sunshine Act: Lessons Learned in Preparation and Implementation.

Views expressed in this Q&A represent the opinions of the presenters and not the corporate positions of Rockpointe, Polaris Management Partners, PharmaLeaders or Policy and Medicine and do not represent legal advice. We recommend that in addition to this FAQ you discuss these questions with your internal and external legal counsel.

1. Can a manufacturer pass fines back to third party vendors who have provided data to them?

No. This law applies only to applicable manufacturers and group purchasing organizations. Thus, penalties will only be applied to those entities as defined by CMS in the final rule. Manufacturers will have to resort to their own solutions with third parties that may be responsible for errors that cause penalties (e.g., firing, penalty clauses, etc.)

2. 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.

Finally, it is unlikely that CMS would consider a CME department of a teaching hospital as a “nonhealthcare department.” However, the CME Coalition intends to seek further clarification on this issue from CMS to determine whether CME departments would be considered “nonhealthcare departments,” rendering grants to such departments as non-reportable. (Final Rule 9468).

3. **If a $10,000 grant payment is made to a Teaching Hospital (direct payment) and the applicable manufacturer is aware that $2,000 is for speaker fees (unaccredited event) is it reported as $10,000 to Teaching Hospital or $8,000 to Teaching Hospital and $2,000 to physician?**

The answer to this question will likely depend on a case-by-case approach surrounding the nature of the grant. However, if the grant or contract included these specific delineations—$8,000 to the teaching hospital and $2,000 for the speaker—using the rational above, the manufacturer should report the values separately to avoid double...
counting. Thus, the teaching hospital would have $8,000 attributed to it, and $2,000 attributed to the physician.

4. How will CMS treat educational programs that have accredited and non-accredited components?

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.

In addition, 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. For shipping costs that must be reported, does that include postage for sending evaluation products, consulting payments, etc?

Postage should be included in shipping costs in calculating the total payment or transfer of value. CMS finalized that in calculating the total transfer of value or payment, manufacturers or GPOs must include “all aspects,” including, but not limited to “tax and shipping.”

6. How should manufacturers calculate the TOV of a reprint? Is the cost to produce the reprint divided by number of HCPs the reprint is distributed to a good method?

CMS recently finalized an FAQ addressing this question. Specifically, the agency stated that “the value of a journal reprint should reflect the cost that an applicable manufacturer or applicable group purchasing organization paid to acquire the reprint from the publisher or other distributor. Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document clarifying any assumptions made to determine the value of journal reprints.”
7. As a device manufacturer, do the state laws that a surgeon practices in need to be known and followed by the manufacturer?

Yes. The Sunshine Act sets a floor, not a ceiling. Thus, state laws may impose greater and additional requirements on applicable manufacturers separate and apart from the Sunshine Act.

8. What groups, individuals, or entities will use or look at this data?

The data will be posted on CMS' public website, so virtually anyone and everyone will be able to see and use this data. Various government—both federal, state and local—entities will use this data including FDA, HHS, HHS-OIG, CMS, DOJ, FTC, IRS, and many more. Additionally, private lawyers representing plaintiffs in medical malpractice, divorce, and product liability will also use the database.

9. Would assistance in drafting a manuscript for a physician, which was funded by a pharmaceutical company to a vendor, be considered a reportable TOV?

If a physician requests medical writing or manuscript assistance, this would likely be a reportable TOV that must be attributed to the physician.

However, if a manufacturer provides such assistance or support as part of the written agreement or contract with the physician, such assistance would not likely be considered a TOV.

10. How should an applicable manufacturer value a product loan over 90 days?

CMS has provided two (2) FAQs on this area. The 90-day period begins when the applicable manufacturer provides the covered device to a covered recipient. CMS stated that the 90-day supply should be calculated for exclusion purposes not on a per-patient basis but rather on a per-covered recipient usage basis regardless of the number of patients that are treated during that 90-day period. The Open Payments reporting exclusion for providing a 90-day supply of single-use/disposable devices for the purpose of enabling covered recipients to evaluate the items is limited to the aggregate supply that covered recipients would be expected to use during 90 days of average use. If the device is purchased within 90 days, the manufacturer does not need to report the loan since the loan was less than 90 days.

In the event that loan period exceeds 90 days (for the calendar year), the manufacturer should start reporting as if the loan began on day 91. Thus, each applicable manufacturer will need to determine its own method for determining the value of the device on day 91—whether that is list or contract price or wholesale value, etc.
11. Does the ruling on meals supplied as “Buffets” as being not reportable, apply to buffet meals provided at Investigator Meetings? How are alcohol costs included?

The ruling on meals as “buffets” does not likely apply to Investigator Meetings. For the meal exemption to apply, the meals must be provided in buffet format in a large-scale conference or event where it is difficult to establish the identity of individuals that partook in the meal. It is unlikely that a scheduled investigator meeting would be large enough to make it difficult to identify who partook in the meal, particularly if the identities of the investigators are known ahead of time. Accordingly, meals provided at investigator meetings will need to be reported under the special rules for meals unless they are included in the research contract and protocol.

With respect to alcohol served at buffets, if the event is reportable (e.g., Investigator Meeting), the manufacturer must follow the specific meals rules promulgated by CMS. Thus, the manufacturer must determine the per person cost of the buffet, including the costs of alcohol. Accordingly, manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients such as office staff). If alcohol is included, manufacturers may want to have a total cost of the meal with and without alcohol. Then, manufacturers can ask physicians (e.g., before, during or after the program) to indicate whether the physician partook in the meal and if so, whether the physician consumed alcohol to more accurately reflect the payment or TOV.

12. Can a physician charge a manufacturer for his time spent correcting erroneous data if the dispute was not resolved?

The answer to this question will depend on the nature of the contract and services entered into between the physician and the manufacturer. If the contract includes a clause requiring payment for such time, then it is possible.

13. Will food/beverage be looked at by the IRS as “earned income”?

If the only payment or TOV the physician receives from a manufacturer for a particular transaction is food or beverage, it is unlikely that this would be considered earned income by the IRS. The IRS states that earned income “includes all the taxable income and wages you get from working.” The IRS stated that there are two ways to get earned income: you work for someone who pays you; or you own or run a business. Thus, unless the food and beverage is included in a larger contract or agreement, food and beverage would not likely be considered earned income since it would not qualify as “wages, salaries, tips or other taxable employee pay.

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1 http://www.irs.gov/Individuals/What-is-Earned-Income%3F
14. **Will there be a registration fee to register with CMS, similar to some states?**

There is no registration fee for applicable manufacturers or GPOs and no fee for physicians or teaching hospitals at this time.

15. **What if the exact name of the hospital you are working with is not on the teaching hospital list, the TIN does not match, or the address does not match. Is it OK to say this is not a teaching hospital?**

It is incumbent upon applicable GPOs and manufacturers to use the list provided by CMS to determine if the entity is a covered recipient teaching hospital. Applicable GPOs and manufacturers should also confirm with the entity any incorrect spellings, addresses, or alternate TIN’s that the entity may be listed under to ensure strict compliance with the Sunshine Act.

16. **For peer-reviewed journal publications that were sponsored by a company, would journal fees - everything from a $300 submission fee to a $100K supplement fee - be considered a TOV to the authors?**

No. When dealing with Sunshine Act areas where there is no "clear cut" answer provided by CMS in FAQs or the regulations, we are recommending that assumption documents be created to support the Applicable Manufacturer’s reasoning in reporting, or not reporting, in the manner so chosen.

With respect to your question, applying an allocation of (1) the costs of editorial support and/or (2) fees to publishers for educational materials can be considered in this area - neither are directly address by a CMS FAQ.

We believe, after many discussions and negotiations with CMS prior to release of the final rules, is that while the spirit of Sunshine is to report transfers of value, there has to be a reasonable expectation that the covered recipient is receiving value under the scrutinized payment - whether in cash or in kind.

While the payments in your scenario could be considered an "in kind" transfer of value for services other than consulting, we believe that because the CR is not being paid an honoraria for the actual services rendered, no reporting is required for the (1) or (2) above.

Essentially our analysis relies upon the last sentence of subsection (ii) of 42 CFR §403.904(c)(10) Payments to third parties - that expressly does NOT require AMs to report such payments (because there is no payment to the CR and any payment to the third party was not directed by or for the benefit of the CR). In the case of (1) above, there is no transfer of value - the value is retained by the AM because the data is getting published in a timely, accurate and expert fashion - something that is of primary value to
the AM. In the absence of editorial support, the paper may be delayed or never published.

With respect to publisher fees, allocating these costs again is not a transfer of value, as the value is retained by the AM and not transferred to the CR since there is no payment offered or accepted by the CR (many AMs have CIAs that forbid payment for authorship, so this seems to be another factor for not reporting editorial support or publisher fees.)

While arguments can be made to the contrary, we believe CMS would not require reporting of educational support and publisher fees.

Optionally, the statute states AMs may report to designate that payment as being made on behalf of the author - but again, a well versed assumption document would defend the AM in a negotiation with CMS in the event of CMPs for non-reporting were at stake.

In the alternative, considering the CIA forbids authorship honoraria, the AM may consider an imputation of honoraria for the services had the author been permitted to be paid.