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Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Administrator Tavenner:

We thank the Centers for Medicare & Medicaid Services (CMS) for finalizing the rule for the Physician Payments Sunshine Act, or PPSA, enacted as Section 6002 of the Patient Protection and Affordable Care Act in 2010.

The intent of the PPSA is to bring needed transparency to the financial relationships between physicians and pharmaceutical manufacturers and medical device companies. We believe that the final rule for implementation of the PPSA represents important and thoughtful progress in meeting the original intent of the statute, and we appreciate the time and consideration that CMS has devoted to this effort.

In this letter, we identify issues that require more clarification and guidance to ensure that manufacturers can appropriately implement the final rule, and to enable consumers to benefit from the transparency reports when CMS publishes them. Such clarification could take place via any or all of the following avenues:

- Sub-regulatory guidance documents.
- Frequently Asked Questions (FAQs) on the Open Payments website.
- Fact sheets on the Open Payments website.
- The Medicare Learning Network and other platforms designed to inform and educate health care providers.

Issues that require further guidance include the following:

I. CMS SHOULD CLARIFY WHICH NATURE-OF-PAYMENT CATEGORY WILL CORRESPOND WITH PAYMENTS TO PHYSICIANS FOR PROMOTIONAL SPEAKING AND DIFFERENTIATE THESE PAYMENTS FROM THOSE FOR UNACCREDITED CONTINUING EDUCATION.¹

Accurate collection and reporting of payments to physicians for promotional speaking should be a particularly high priority for CMS as it implements the PPSA. Promotional speaking, often through a speakers bureau, represents a significant proportion of industry marketing efforts.² The Institute of Medicine has recommended that academic medical centers forbid faculty from giving such talks because they can create conflicts of interest,³ and the Association of American Medical Colleges “strongly discourages” them.⁴ Furthermore, the legislative record of the Sunshine provisions shows that the issue of unreported payments for promotional speaking has been a major concern and was

identified by Senator Chuck Grassley as a significant impetus for the introduction and passage of the provision.^{5,6}

Unfortunately, ambiguities in the final rule will make it difficult for manufacturers to determine how to categorize such payments, potentially undermining the transparency sought by Congress.

Promotional speaking should be clearly distinguished from unaccredited continuing education programs.

According to the final rule, two categories refer to activities for which physicians are paid by manufacturers to give unaccredited talks to other health care providers:

1. "Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program."
2. "Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program."

CMS recommends that "promotional or marketing activities" be reported under "Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program." However, it does not provide guidance to manufacturers on how to distinguish promotional programs from unaccredited educational programs.

Guidance on this issue is crucial, because industry trade groups and manufacturers often do not differentiate between promotional and educational events. For example, in its Code on Interactions With Healthcare Professionals, the Pharmaceutical Research and Manufacturers of America uses terms such as "speaker programs," "educate and inform," and "promotional programs" interchangeably:

"Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks and appropriate uses of company medicines. Any healthcare professional engaged by a company to participate in such external promotional programs on behalf of the company will be deemed a speaker for purposes of this Code."⁷

Furthermore, manufacturers use widely varying terms on their websites to describe promotional programs, including "expert-led forums,"⁸ "promotional speaker programs,"⁹ "educational programs,"^{10,11} "peer-to-peer educational programs,"¹² and "promotional (non-CME) medical education activities."¹³ Because manufacturers have different interpretations of whether non-CME (continuing medical education) speaking events are promotional or educational, it is likely that some will categorize promotional talks erroneously as unaccredited educational talks, because the latter activity has been less controversial.

Recommended criteria for educational versus promotional programs

The Food and Drug Administration, or FDA, defines promotional programs as “activities (programs and materials) performed by, or on behalf of, the companies that market the products.”¹⁴ Such programs are subject to the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act, whereas independent educational programs—whether CME or non-CME—are not.

Thus, being regulated by the FDA is a key criterion of a program that is promotional. To ensure that there is no ambiguity, we recommend that CMS publish a list of criteria and examples to help applicable manufacturers determine whether a speaking payment should be considered promotional or educational.

I. *CMS should clarify that “promotional speaking” meets one or more of the following criteria:*

- FDA regulates the event as pharmaceutical advertising.
- A company directly pays the physician, through its marketing budget, to speak about its products.
- The physician signs a contract with the company agreeing to allow the company final review and approval of all slides and other educational material to be presented.
- The physician is required to participate in a speakers training program sponsored by the manufacturer.

II. *CMS should clarify that non-CME educational speaking meets the following two criteria:*

- A company pays a third-party organization to create a non-CME course that does not explicitly promote the company’s product, and the third party, not the company, pays the physician.
- The educational event is not regulated by FDA guidelines on product advertising.

Suggested FAQs related to promotional versus educational speaking

Question: *How should manufacturers distinguish between “promotional speaking” and “unaccredited continuing education”?*

Answer: Any activity in which the manufacturer pays the physician directly for a talk that is given on behalf of the manufacturer is regulated by FDA as product advertising and is therefore considered to be promotional.¹⁴ However, if the manufacturer funds a third-party organization that hires and pays

the physician, and if the manufacturer has no control over the content of the talk, then it should be considered unaccredited continuing education.

Question: *In which nature-of-payment category should manufacturers report payments to physicians for promotional speaking?*

Answer: These payments should be categorized under “Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.” Such payments should not be categorized under “Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.”

Question: *Other than payments to physicians for promotional speaking, are there any other payments that applicable manufacturers should categorize under “Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program?”*

Answer: No. This category is designed to contain payments for promotional speaking. Although physicians may engage in other kinds of promotional activities, such as writing or consulting on product advertisements, such activities are more appropriately categorized under “consulting services.”

Examples of speaking events and suggestions on appropriate nature-of-payment categories

- *Event:* A company sponsors a non-CME dinner course held at a hotel adjacent to a convention center where a major professional association is holding a national meeting. The topic is the diagnosis and treatment of schizophrenia, a condition for which the company is about to release an FDA-approved medication. Several physicians speak, all of whom were recruited and paid by a third-party medical education company.

Which category? “Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.” Because there is no direct financial or contractual relationship between the sponsor and the speakers, this is an unaccredited continuing education program.

- *Event:* A company has rented out a restaurant function room and has invited 10 physicians to listen to a talk on the use of the company’s new cardiac stent. The speaker is a cardiologist in the company’s speakers bureau. The invitation states that this is an “educational program” sponsored by the company and also states that “this is not a CME event.”

Which category? “Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.” Although the event is labeled an educational program, it does not qualify as an unaccredited educational program

because it meets several of the promotional event criteria, including direct payment to the physician and the existence of a contract.

- *Event:* A company has contracted with a medical information technology company to sponsor a series of non-CME mini-lectures on diabetes that physicians can download from their mobile devices while looking up medication information. Although the IT company selects and pays the expert giving the lectures, the manufacturer provides suggestions for possible speakers and stipulates that it may review content for approval.

Which category? “Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.” Although the company does not pay the speaker directly, it does provide input, and it maintains control of content, qualifying this as a promotional rather than an educational program. If the manufacturer had no such stipulations, this would be an unaccredited educational program.

Recommendations for clarifying meaning of categories to consumers

As currently worded, the unaccredited educational and promotional categories may cause confusion for consumers once payments are posted on the website. Therefore, we recommend that the promotional category be reworded to highlight its distinction from the educational programs category.

Original wording: “Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.”

Suggested revision: “Compensation for serving as faculty or as a speaker for a promotional program.”

Rationale: The vast majority of payments in this category will refer to promotional programs, so the term should be in the title. We also recommend that the phrase “services other than consulting” be removed from the promotional programs category to improve specificity. CMS should clarify that any payment that is not promotional and is not for consulting should be categorized as “honoraria.”

II. CMS SHOULD CLARIFY THAT THE EXEMPTION FOR BUFFET-STYLE MEALS AND SMALL PAYMENTS AT CONFERENCES APPLIES ONLY WHEN COVERED RECIPIENTS CANNOT BE EASILY IDENTIFIED.¹⁵

CMS has clarified that industry should report the value of any meals or beverages provided to physicians in nearly all settings. The agency exempts buffet meals, snacks or coffee, and gifts worth less than \$10 when these transfers of value occur at large-scale conferences—places where “it would be difficult to establish the identities of the physicians who partook in the meal or snack.” CMS goes on to clarify that “we do not intend this to apply to meals provided to select individual attendees at a conference where the sponsoring applicable manufacturer can establish the identity of the attendees.”

This portion of the rule creates ambiguities that would benefit from clarification.

CMS should clarify that “large-scale conferences” are defined as comprising approximately 500 or more attendees.

It is not clear what type of conference would be defined as a large scale-conference under the rule. This is an important distinction, because the smaller the conference, the easier it is for manufacturers to establish the identities of covered recipients.

For example, here are some typical medical conference scenarios:

- A small local symposium for interventional cardiologists attracts 20 specialists. This is clearly not a large-scale conference.
- A state medical society holds a primary care educational conference for its members, and attendance is 350. Although identifying covered recipients would not be onerous, a manufacturer could label such a conference as large scale in order to avoid reporting requirements.
- A national professional association holds its annual meetings, and 30,000 physicians attend. This would unequivocally qualify as a large-scale conference.

The definition of large scale is subjective, and we do not believe it is feasible for CMS to create a bright line definition. However, as a loose guideline, *we suggest that approximately 500 attendees is an intuitive and reasonable dividing line between “small-scale” and “large-scale” conferences.* If attendance is well below 500, it would not be onerous for manufacturers to track small gifts and meals, but if many more than 500 attend, such a task would be onerous.

CMS should clarify that in the case of large-scale conferences in which manufacturers already establish the identities of “select individual attendees,” these payments should be reported.

Assuming that a meeting clearly meets CMS’ criterion for a large-scale conference, such a gathering is typically broken up into smaller symposia and other lectures. For example, a large exhibit hall may contain cordoned-off areas or adjacent rooms for industry-sponsored events. Manufacturer representatives manage the flow of attendees into these areas and scan their badges as they receive box lunches or dinners. Such meals can have a large monetary value, in part because food prices at conference facilities are notoriously high. For example, one study documented that the cost of lunches at CME course venues ranged from \$49 in Atlanta to \$117 in New York City.¹⁶ The final rule does not clarify whether applicable manufacturers should attribute payments for these meals to the covered recipients. Although such events may theoretically be open to any of thousands of conference attendees, only a small fraction will attend any particular industry-sponsored event, and the technology required to identify such attendees is readily available, inexpensive, and easy to use.

This situation applies equally to small gifts given at exhibit booths, where manufacturers often require attendees to wait in a line and have personal contact with company employees before receiving a gift. Again, attendee badges are typically scanned. Like free meals, small gifts can predispose physicians positively toward a company's product,¹⁷ and therefore the manufacturer should report these transfers of value when it can reasonably ascertain the recipient's identity.

On the other hand, when a manufacturer provides a rest area with snacks and drinks for all attendees wandering through a large exhibit hall, and when there are no efforts to ascertain the identity of attendees, such food would *not* be reportable under this rule.

To clarify this issue, we request that CMS issue the following guidance:

- *In large-scale conferences, if a manufacturer makes an effort to identify recipients in any way, CMS should consider these recipients to be "select individual attendees" and require the manufacturer to report payments and other transfers of value to them.*
- *When a manufacturer leaves small gifts or meals in a public area with no employees designated to ascertain the identity of the recipients, CMS should not require the manufacturer to report these transfers of value.*

Suggested FAQs related to exemptions at conferences

Question: *What does CMS consider to be a "large-scale" conference for the purposes of the meal and gift exemption?*

Answer: Although there is no absolute definition of a large-scale conference, CMS suggests that manufacturers use 500 participants as an approximate demarcation between small and large scale. In conferences with fewer than approximately 500 participants, manufacturers are expected to ascertain the identities of any covered recipients receiving meals or gifts of any value.

Question: *At large-scale conferences, are there any situations in which gifts under \$10 in value or meals and beverages are reportable?*

Answer: Yes. In any situation in which manufacturer employees have personal contact with individual covered recipients before meals or gifts are dispensed, CMS considers these to be "select individual attendees" and expects that applicable manufacturers will identify the recipients and attribute value of items to them for later reporting purposes.

Question: *At large-scale conferences, in what situations are meals and small gifts clearly not reportable?*

Answer: There are various scenarios in which such items are not reportable. For example, if an area of an exhibit hall is reserved as a refreshment area for all attendees to come and go as they please, and

manufacturers are making no efforts to ascertain the identities of attendees, such refreshments are not reportable.

Examples of reportable versus non-reportable meals and gifts given at large-scale conferences

A professional association holds its annual meeting at a major convention center, and the attendance is 20,000. In the exhibit hall, a variety of gifts and refreshments are offered by different companies that have rented exhibit hall space. Below are two scenarios, along with guidance about what would be reportable as transfers of value to covered recipients.

- In the center of the hall there is a large area with tables set up containing box lunches and beverages. A sign indicates that the refreshment area is sponsored by an applicable manufacturer. Attendees are free to enter the area, choose a meal, and sit at any of a number of tables. Convention center staff members are present to ensure that the area is properly stocked and organized, but they do not obtain any personal information about attendees. *These items would not be reportable.*
- A manufacturer has an exhibit booth, in the center of which is an area where its employees are providing cups of frozen yogurt from a machine with various flavors. Meeting attendees wait in line to order a flavor, and before they receive their yogurt, they are asked to answer several questions about their knowledge of the manufacturer's new medication for asthma. Their badges are scanned as part of the process. *This food would be reportable, because the manufacturer has a process for identifying each recipient.*

III. CMS SHOULD CLARIFY THAT INDIRECT PAYMENTS GIVEN THROUGH PROFESSIONAL PHYSICIAN ORGANIZATIONS ARE NOT EXEMPT FROM REPORTING, UNLESS MANUFACTURERS DESIGNATE THAT THEY ARE FOR NONPHYSICIANS ONLY.¹⁸

CMS should clarify that if an applicable manufacturer makes a payment or transfer of value (whether restricted or unrestricted) to a physician organization it is presumed that physicians will benefit. If the manufacturer later finds out the identities of these covered recipients, it must report them.

In its preamble, CMS' final rule states that grants given to professional physician organizations are reportable as payments to specific physicians if the following two criteria are met: first, the manufacturer designates the grant for physician use, and second, the manufacturer becomes aware of the specific recipient(s) benefiting from the grant within the first two quarters of the year following the payment.

However, the final rule's preamble also specifies that if the manufacturer provides a grant to the same type of organization but does not specifically designate the grant for physician use (calling it an "unrestricted donation") then the payment will not be reportable, regardless of how the grant is used.

This creates a significant loophole that undermines the goal of the law, which is to provide transparency in these financial relationships.

For example, a manufacturer could award an “unrestricted grant” to a professional medical association with the understanding that the money would be used to fund a non-CME educational event (note that we are discussing *non*-CME events only, and we understand that the final rule is clear that accredited CME events are not reportable.) The association may then use that money to make substantial payments to physicians, including honoraria to lecturers, and to provide free admission and meals to attendees. These payments would not be reportable, simply because the manufacturer has labeled the grant “unrestricted.”

As a solution to this potential problem, we propose that CMS clarify in the FAQ section of the Open Payments website that when an applicable manufacturer provides a grant to a physician professional organization, regardless of how the grant is labeled, it is assumed that there is a possibility that the organization may use all or a portion of that funding for physician benefit. Accordingly, if the manufacturer determines within the first two quarters of the following year that specific physicians received transfers of value, these payments would be reported.

This rule would not be onerous, because a manufacturer could stipulate in the grant that the receiving organization must inform the sponsor of any physicians benefiting from the grant within the relevant time frame. Nor would it be burdensome for the physician organization, because attendees could be required to sign in as they arrive at events. The sign-in sheet could require the name of the physicians and their National Provider Identifiers (NPIs) or medical license numbers. Transferring these names to an electronic database to send to the sponsoring company is a simple administrative task.

On the other hand, we recommend that if a manufacturer wishes to make a grant to a physician professional organization to be used for a purpose *other* than physician benefit, CMS should suggest a best practice of explicitly designating that the grant is not for physician use. Such grants would clearly not be reportable, and neither the manufacturer nor the physician organization would be required to track this type of donation.

Suggested FAQs related to indirect payments through physician professional organizations

Question: *Under what circumstances are grants given to physician professional organizations subject to reporting?*

Answer: Any grant given to a physician organization is assumed to be for physician benefit unless the grant is specifically designated otherwise. When a grant is given without a non-physician benefit stipulation, the reporting rules are as outlined in the preamble to the final rule. If the manufacturer determines the identity of physicians in the organization receiving transfers of value within the first two quarters of the year following the grant, these transfers will be attributed to these physicians.

Question: *How can manufacturers ascertain the identities of specific physicians benefiting in the future from grants to organizations?*

Answer: The mechanism for identifying the identities of physicians benefiting from grants will be at the discretion of the granting manufacturer. Potential mechanisms include:

- The manufacturer’s grant can require the physician organization to forward a list of any covered recipients receiving transfers of value during the relevant time period.
- The physician organization can educate its members about the terms of the grant and request that any recipients inform the manufacturer directly if they receive a transfer of value related to the grant.
- The manufacturer can provide members of the physician organization with software in the form of applications for mobile devices that can create a communication portal to facilitate collection of data to reduce the need to extra administrative support.

Examples of reportable versus non-reportable indirect payments via physician professional associations:

- A manufacturer gives a \$500,000 grant to a national pain association and describes the grant’s purpose as “the creation of an educational website on the treatment of chronic pain.” The association uses \$300,000 to pay nonphysician technical consultants to build the site, and \$200,000 to physicians specializing in pain management to create content. If the manufacturer is informed of the specific physicians receiving payments within the first two quarters of the year following the awarding of the grant, it must report these payments.
- A manufacturer gives a \$300,000 grant to an orthopedic association to educate consumers about hip replacement surgery and specifies that “no portion of this grant may be paid to physicians.” The association hires nonphysician medical writers to prepare a series of consumer-friendly brochures and creates an online and in-person distribution network. There are no transfers of value to physicians, and therefore there are no reportable payments.

* * * * *

We ask CMS to consider these clarifications to the PPSA final rule in order to ensure its successful implementation so that the public will benefit from full disclosure of payments and gifts to physicians. CMS’ leadership in this regard will allow all stakeholders to meet their obligations as delineated in the statute and will assist in minimizing any potential confusion in the coming months. Thank you again for considering our suggestions to enhance the benefits of the Physician Payments Sunshine Act for consumers.

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