

**Frequently Asked Questions (FAQs) regarding the
National Physician Payment Transparency Program (Open Payments)
[initiated by the Physician Payments Transparency Act (PPSA)]**

These FAQs are intended as a resource for CMSS member organizations to create their own guidance document. The answers are based on the guidance that is publicly available as of August 23, 2013. This is a new reporting program, and many of the questions are still being clarified. Societies may take different positions on some of these questions. Readers of this document are encouraged to consult their attorneys, funding organizations, and CMS for interpretations of the Physician Payment Sunshine Act (PPSA) and the regulations operationalizing it. The information in this document is not legal advice.

I. To Whom Does “Sunshine” Reporting Apply?

1) Why should I care about the Physician Payment Sunshine Act (PPSA), what CMS now terms its “Open Payments” Program?

Section 6002 of the Affordable Care Act requires manufacturers of covered drugs, devices, biologicals, and medical supplies operating in the United States to report to the Centers for Medicare and Medicaid Services (CMS) any payments or transfers of value they make to teaching hospitals or physicians¹. CMS will collect the data annually, requiring data to be submitted by manufacturers to CMS by March 31, 2014. CMS will then aggregate the data and publish it on a public website. **As of August 1, 2013, manufacturers are required to collect data** on payments or transfers of value they make.

2) Are any physicians excluded from being covered by the Physician Payment Sunshine Act?

Only medical residents are excluded from the Sunshine Act’s application. The final rule exempted payments to medical residents from the reporting requirements solely due to operational and data accuracy concerns regarding aggregation of payments or other transfers of value to residents, many of whom have neither a National Provider Identifier (NPI) nor a State professional license. CMS has said because these same concerns do not generally apply to

¹ CMS defines a physician under the Physician Payment Sunshine Act using its 1861(r) Medicare definition. Therefore, a physician is a Doctor of Medicine, Doctor of Osteopathy, Doctor of Dentistry, Doctor of Dental Surgery, Doctor of Podiatry, Doctor of Optometry, or a Doctor of Chiropractic Medicine.

physicians in Fellowship training, payments to **Fellows are not exempt from the reporting requirements.**

3) The federal “Sunshine” Act also mandates pharmaceutical and medical device manufacturers, as well as GPOs, report payments or transfers of value made to teaching hospitals. How can I find a list of teaching hospitals?

The following link provides a list of hospitals CMS defines as “teaching hospitals,” thus eligible for GME funding, that can be publicly reported if they accept Sunshine Act “reportable” payments or transfers of value from applicable manufacturers:

<http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Teaching-Hospital-List-for-2013-Open-Payments-Program-Cycle-20130501-pdf.pdf>.

4) What does CMS mean when it says Group Purchasing Organizations (GPOs)², in addition to physicians and teaching hospitals, must refer any payments or transfers of value they receive from pharmaceutical or medical device manufacturers?

CMS means GPOs must report information on ownership and investment interests held by physicians and their immediate family members, as well as any payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest in the GPO at any point during the reporting year.

5) What is the intent behind CMS’s “Open Payments Program?”

CMS wants to shed light on relationships between industry and physicians and industry and teaching hospitals.

II. What Must Be Reported?

1) Payments or Transfers of Value Exceeding \$10

In general, payments or transfers of value exceeding \$10 must be reported. If a PPSA exclusion³ applies, it can supersede the “\$10 or greater” reporting rule and result in manufacturer reporting not being mandated.

² A GPO is defined as an entity that is created to leverage the purchasing power of a group of businesses to obtain discounts from vendors based on the collective buying power of the GPO members.

³ The following are excluded from being reported under the PPSA: certified and accredited CME, buffet meals or snacks at large-scale events, product samples not intended for sale but for patient use, in-kind items used for the

2) Non-Accredited/Non-Certified Continuing Medical Education (CME)-

The PPSA creates blanket reporting rules for transfers or payments of value arising from being the faculty speaker OR a physician attendee at a non-accredited/non-certified CME event. All tuition and educational fees arising from non-accredited/non-certified CME, as well as any lodging, meals, speaker fee, or travel funds the speaker physician receives must be reported

3) Educational Materials Given to the Physician Not Meant to be of Benefit to the Patient or Not Used With the Patient-

The PPSA requires reporting of medical textbooks (e.g., reference manuals, the *DSM-5*, casebooks, guidebooks and other similar materials) and journal reprints **provided by an applicable pharmaceutical or medical device manufacturer or GPO** to a physician.

4) Meals at Meetings When the Physician is Identifiable to the Manufacturer

In instances in which the value of a meal funded by an applicable manufacturer or GPO exceeds \$10, and the persons receiving the meal are “readily identifiable” at the time the meal is being provided to the applicable manufacturer or GPO, the meal is reportable.

5) Indirect Transfers Made to a Third Party When the Manufacturer “Requires, Instructs, or Directs” the Payment or Transfer of Value be Provided to A Physician

CMS does not exclude indirect payments or transfers of value that an applicable manufacturer or GPO makes to a third party, such as a physician organization, from being reported, when the manufacturer *requires, instructs, or directs* the payment or transfer of value be provided to a specific physician or intended generally for physicians. It does not matter that the manufacturer does not know the name of the physician or physicians benefiting from the indirect transfer, if the manufacturer is *requiring, instructing, or directing* the transfer be made to a physician or group of physicians. CMS establishes an independence test when assessing whether an indirect transfer must be reported. If the manufacturer retains the independence in

provision of charity care, discounts, the loan of a medical device for the short-term, transfers of value and payments made to a physician in return for non-physician services from the physician (e.g., physician who is also a lawyer providing legal services to an applicable manufacturer or GPO), items or services provided under a contractual warranty, a dividend or other profit distribution, or ownership or investment interest in a publicly traded security and mutual fund.

determining whether a physician or group of physicians benefits from the payment, CMS mandates the indirect transfer be reported.

6) Payments or Transfers of Value for Research

The physician serving as the principal investigator gets reported, as well as the institution performing the research.

III. Administration of “Sunshine”

1) What are the key dates for the Physician Payment Sunshine Act’s “Open Payments” reporting?

Applicable manufacturers and GPOs must begin to collect the required “Sunshine” data by August 1, 2013 and report the data collected through December 31, 2013 to CMS by March 31, 2014.

By September 30, 2014, CMS will publish the reported data on a publicly available website.

2) If I receive a payment or transfer of value from a pharmaceutical or medical device manufacturer or GPO, can the manufacturer require me to provide my NPI number?

Yes. One of the main requirements under the Sunshine reporting provisions is that applicable manufacturers and GPOs include in its report to CMS a physician's name, address, NPI number, and other identifying information all based on information in the NPPS database. To see the **template** of information manufacturers must use for **reporting payments or transfers of value made to physicians in a non-research context**, go to <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/General-Payments-OMB-No-0938-1173.pdf>.

To see the **template** of information manufacturers must use for reporting payments or transfers of value made to physicians **for furthering research**, go to <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Research-Payments-Submission-File-Specifications.pdf>.

To see the **template** **GPOs** must use for reporting payments or transfers of value made to physicians who have ownership or investment interests in GPOs, go to <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-Ownership-Submission-File-Specifications.pdf>.

3) How will I track whether or not my name is mentioned in a manufacturer’s report to CMS?

CMS is creating a portal as part of its Open Payments Program website, where covered recipients like physicians and teaching hospitals can register to receive notifications on when their name is included within an applicable pharmaceutical or medical device manufacturer's submitted report to CMS. Being registered with the Open Payments portal allows physicians and teaching hospitals to receive timely notification on when they've been mentioned in a report. It also provides a forum in which they can dispute the information included within the manufacturer's report.

4) How can I correct an error that appears in an applicable manufacturer's report?

Once the manufacturer has submitted data listing the physicians' names to CMS, CMS must give the physicians 45 days to review and work with the manufacturer, or applicable Group Purchasing Organization (GPO), to correct the information. After the 45 days have passed, the manufacturer or applicable GPO will have an additional 15 days to submit correction based on any disputes identified by physicians and physician owners/investors. The review and correction period starts at least 60 days before the information is made public.

During the review and correction period, physicians and physician owners/investors can dispute information about them they do not think is correct. If data is disputed, CMS will notify the applicable manufacturer or applicable GPO that some of their data has been disputed. However, CMS will not mediate the dispute directly.

5) What happens when a reporting dispute is resolved?

Once the dispute is resolved, the applicable manufacturer or GPO must send CMS a revised report for the correct data and re-attest that it is correct. Though the review and correction system will be open year-round, only the data corrections noted during the 45-day review and correction period, and subsequent 15-day dispute resolution period, will be updated before publication.

CMS will update data from the current and previous year at least once annually, in addition to the initial data publication that followed data submission.

6) What happens when a dispute cannot be resolved?

CMS will publish the data most recently submitted by the applicable manufacturer or GPO on its website, and it will mark the data as disputed.

IV. What Is Excluded from PPSA Reporting?

1) Payments or Transfers of Value Less than \$10

CMS has said that a transfer of anything for which the value is less than \$10 need not be reported. However, if over the course of a calendar year the aggregate amount transferred to, requested by, or designated on behalf of the physician or teaching hospital by the applicable manufacturer or GPO exceeds \$100, the payment or transfer of value is reportable.

2) Speaker Physician's Fees, Travel, Meals, and Lodging Arising from an Accredited/Certified CME Event in instances in which all of the following criteria are met:

(1) the CME program meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association,

(2) the applicable manufacturer does not select or suggest the covered recipient speaker nor does it provide the third party vendor with distinct, identifiable individuals to be considered as speakers for the accredited or certified continuing education programs; AND

(3) the applicable manufacturer does not directly pay the covered recipient speaker.

3) Attendee Physician's Educational and Tuition Fees Arising from an Accredited/Certified CME in instances in which all of the following criteria are met:

(1) the CME program meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association,

(2) the applicable manufacturer does not select or suggest the covered recipient speaker nor does it provide the third party vendor with distinct, identifiable individuals to be considered as speakers for the accredited or certified continuing education programs; AND

(3) the applicable manufacturer does not directly pay the covered recipient speaker.

***Note:** Only the Speaker Physician at an accredited CME event qualifies for not reporting the meal, lodging, and travel fees which arise from his/her serving as faculty at an accredited CME. The Attendee Physician only gets a reporting exclusion for his/her tuition and educational fees arising from attending an accredited CME event. So any lodging, meals, or travel fees provided by the applicable manufacturer or GPO to the accredited CME attendee physician must be reported.

4) Educational Materials or Items Directly Benefiting Patients or Intended for Patient Use

To claim this reporting exclusion, the educational materials being used must directly benefit the patient be of benefit to the patient and/or be of use to the patient while he/she is seeing the physician. A human skeletal set would be an example of an item that could qualify for this reporting exclusion.

5) Buffet Meals, Snacks, Soft Drinks, or Coffee Generally Available to Physicians at Large-Scale Events

CMS excludes buffet meals, snacks, soft drinks, and coffee from being reported in instances in which the physician is receiving them from the applicable manufacturer or GPO **as part of a large-scale event, and the applicable manufacturer cannot readily identify who is consuming these items** at the time the items are being offered as well as a few months afterwards.

Additional PPSA reporting exclusions include:

- In-kind items used for the provision of charity care
- Discounts or rebates
- Loan of a medical device for the short-term
- Transfers of value and payments made to a physician in return for non-physician services from the physician (e.g., physician who is also a lawyer providing legal services to an applicable manufacturer or GPO)
- Items or services provided under a contractual warranty
- A dividend or other profit distribution, or ownership or investment interest in a publicly traded security and mutual fund.

V. General PPSA Inquiries

1) What are the definitions or financial limits defining “reportable” gifts of value? Who decides what the value is?

There are no financial limits on reportable gifts of value. Those gifts that are under \$10 limit as well as small items provided at conferences are not reportable. However, if a manufacturer provides a number of these *de minimus* items that are less than \$10 but amount to \$100 annually, then those items are reportable.

2) Will physicians/members be reported as having received a gift of value simply by being prorated as part of a larger group that collectively received such a gift, or does it only apply to individually given and received gifts of value?

Only those physicians who received the value of the gift will be reported, but all members of a group practice that receive the benefit of the gift will be reported for the value they received. So, if a pharmaceutical representative provides a dinner for a group practice, all members of the group who attend the dinner will be reported for the value of their individual dinner.

- 3) **If an individual member is identified or reported by industry as having received something of commercial value (pens, pads, bags, lunch, etc.), what will be required of them?**

Physicians have no legal obligations under the law. However, it is in their best interests to track transfers of value in order to respond quickly to inaccurate reports within the 60 day review and dispute period.

- 4) **What, if any, unintended consequences of the PPSA do medical societies anticipate?**

Media, patients, and members of the public may scrutinize physician-manufacturer relationships more closely, possibly resulting in questions or feedback for the physician. Some interactions may be disclosed on the Open Payments site that are not required to be disclosed under the societies' own policies. In addition, a society's "Key Leaders" under the CMSS Code for Interactions with Health Care Companies may receive a transfer of value that is reportable to the Open Payments website while still being allowable under the CMSS Code. For instance, attendance at a company-sponsored dinner or payments to an academic department for a research grant in which the Key Leader is a principal investigator would be disclosed but not restricted under the society's policies and the CMSS Code, and would be reportable to the Open Payments website.

- 5) **If in my capacity as President of my incorporated state medical society I sign a contract with a pharmaceutical or medical device manufacturer for the manufacturer to have an exhibit booth at the medical society's conference, can the transfer of funds for which I have signed be attributed to me and be reportable to CMS under the PPSA?**

No. A physician who signs a contract in his/her capacity as an executive or officer of an incorporated medical society or other organization is not personally receiving a transfer of value from the manufacturer. This individual should not be considered a covered recipient under the PPSA in the context of performing his/her incorporated medical society/organization officer duties.

VI. How does PPSA Affect Physician Societies?

- 1) **Will the PPSA be more likely to impact individual members or physician societies?**

PPSA will affect both physician members and their professional societies. It will affect physician members directly because they will be subject to being reported for covered payments from manufacturers. Societies will be indirectly affected because manufacturers that sponsor society functions will put pressure on the societies to provide

them with names of physician members who must be reported as a result of such sponsorships.

2) Can member physicians be unaware of having been reported as receiving a gift of value? How will members know if a commercial entity reports a gift of value to them, of which they do not have actual knowledge?

Yes, CMS will provide a general notice to physicians registered through its Open Payments website portal that the manufacturer data is available for review. However, if a physician does not sign up on the CMS website and/or regularly check the OPEN PAYMENTS website, then he or she will not receive such notification and may miss the opportunity to review and dispute manufacturer reports. Note that this only a general notification – it will not notify specific physicians when their names are reported by manufacturers.

3) Are there any actions a physician society can take on the collective behalf of its members to assist in compliance or education about their role and rights under the PPSA?

Physician societies should educate their members about internal tracking, signing up for CMS notifications, and raising general awareness of the Sunshine Act and its potential implications. Physician societies should also notify their members when they provide those members' names to particular manufacturers in connection with industry-sponsored events these members attend.

4) Is the federal “Sunshine” Act the only law under which physicians may be reported by pharmaceutical or medical device manufacturers and/or GPOs for receiving payments or transfers of value from them?

Some states enacted their own “Sunshine” reporting laws prior to the implementation of Section 6002 of the federal Affordable Care Act, known as the Physician Payment Sunshine Act.

The rule operationalizing the federal Physician Payment “Sunshine” Act clarifies that any provisions of existing state “Sunshine” reporting laws which directly conflict with manufacturers being able to fulfill the provisions of the federal “Sunshine” Act are preempted, thus superseded, by the applicable provision of the federal “Sunshine” Act.

To see whether your state has its own “Sunshine” physician payment law, go to the AMA’s chart of state “Sunshine” laws at <https://www.ama-assn.org/resources/doc/washington/state-sunshine-laws-chart.pdf>.