

PHYSICIAN PAYMENTS SUNSHINE ACT **(“PPSA”)**

A Physician’s Guidance Document for Practical Navigation:

If you are like most physicians, you have been hearing more and more about “physician payments,” “the Sunshine Act,” or the “PPSA.” Maybe, you have seen these phrases in your monthly medical journal or overheard a conversation at a cocktail party? Whatever the case -- these words are moving into the modern physician’s vernacular.

To some, these are little more than buzz words; to others, a minor source of anxiety. But whatever your grasp of the Physician Payments Sunshine Act (“PPSA”), this document is designed to serve as a practical roadmap to educate you on the fundamentals of the PPSA, provide guidance on understanding its purpose and potential impact, and to help you navigate its parameters as we move toward the next reporting period for the 2015 calendar year.

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Why is This Important to Me?

Background: The Physician Payments Sunshine Act (“PPSA”) Open Payments Program enacted at Section 6002 of the Affordable Care Act in 2010 and finalized in the Final Rule at 42 CFR Parts 402 and 403 in 2013, requires the Centers for Medicare and Medicaid Services (“CMS”) to collect and display information reported by applicable manufacturers and group purchasing organizations (“GPOs”) **for payments and other value transfers that these organizations make to physicians, physicians’ immediate family members, and teaching hospitals.** CMS collects this information for each calendar year, and it is published in June of the following calendar year. Although manufacturers are not required to report value transfers less than \$10 or small value transfers (payments less than \$10) that when combined over a year are less than \$100 in the aggregate, many companies have chosen to report payments of any dollar amount.

In addition to payments and other value transfers to physicians, applicable manufacturers and GPOs must also report to CMS:

- Certain ownership or investment interests held by physicians or their immediate family members;
- Payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year; and
- Instances in which a physician was not directly paid by industry but was responsible for a major component of the work, such as serving as a principal investigator on an industry-funded research grant.

Intention: CMS views the PPSA Open Payments Program as “a national resource for beneficiaries, consumers, and providers to know more about the relationships among physicians, teaching hospitals, and industry.”

For additional info, please refer to page 1 of **CMS’s PPSA Fact Sheet for Physicians:**
<https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf>

How Can I be Vigilant?

Given the visibility that the PPSA Open Payments Program creates for physicians’ and their immediate family members’ financial interactions with applicable manufacturers and GPOs, physicians and physician owners/investors are encouraged to:

- Become familiar with the information that will be reported about you;
- Keep records of all payments and other transfers of value received from applicable manufacturers or applicable GPOs;
- Register with CMS and subscribe to the list serve to receive updates regarding the program;
- Look at the information that manufacturers and GPOs have attributed to you; and
- Once registered, engage in the Review, Dispute, and Correction process to ensure that information regarding payments and other value transfers attributed to you are complete and accurate.

Please note that manufacturers and GPOs can provide physicians or physician owners/investors with the opportunity to review payment and other value transfer information before such manufacturers and GPOs submit it to CMS. This process is voluntary, and CMS does not oversee such pre-submission review.

However, CMS encourages such pre-submission review by physicians and physician owners/investors to increase the likelihood that the information posted about you is complete and accurate. It should be noted that industry is not required by CMS to *resolve* disputed payments, and payments may be posted to the public website whether or not a physician or teaching hospital agrees that the disputed payment has been resolved.

For additional info, please refer to page 4 of **CMS's PPSA Fact Sheet for Physicians**: <https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf>

Open Payments Mobile Application for Physicians – Track Payments from your Phone

The Centers for Medicare and Medicaid Services (“CMS”) released two mobile apps called Open Payments. One app is for physicians and the other app is for healthcare industry users. The goal of the Open Payments app is to help physicians track real-time payments received from industry. However, please note that current reviews of the Open Payments app indicate that a number of “bugs” remain despite software updates being published to “fix” such issues.

For additional FAQs, downloading instructions, or trouble-shooting for the *Open Payment Mobile for Physicians* app, click on the following link:

[https://www.cms.gov/OpenPayments/Downloads/Mobile-App-FAQs-\[December-2013\].pdf](https://www.cms.gov/OpenPayments/Downloads/Mobile-App-FAQs-[December-2013].pdf)

What Information does CMS Collect and Display?

Applicable manufacturers and GPOs must report the following information to CMS regarding payments and other value transfers made to physicians and physician owners/investors:

- Name
- Primary Business Address
- Licensure/Specialty/National Provider Information
- Amount of Payment or Value Transfer
- Date of Payment or Value Transfer
- Related Covered Drug, Device, Biological or Medical Supply
- Nature of Payment to Physician, Physician Owner/Investor, or Immediate Family Member, to include:
 - Consulting Fees
 - Compensation for Services other than Consulting, including serving as faculty or as speaker at an event other than a continuing education program
 - Honoraria
 - Gift

- Entertainment
- Food and Beverage
- Travel and Lodging
- Education
- Research

With respect to the reporting categories, manufacturers and GPOs **are required to report each payment under the “Nature of Payment” category (Bullet 7 above) that most closely describes the payment**; the absence of a nature of payment category that closely describes the payment does not constitute a basis for not reporting an otherwise reportable payment or other transfer of value.

For a more exhaustive list of payment types, please refer to page 3 of **CMS’s PPSA Fact Sheet for Physicians**: <https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf>

Please also note the following reporting exclusion as it applies to “Product Samples.” Manufacturers are **not required** to report to CMS “product samples that are not intended to be sold and are intended for patient use,” that they provide to physicians. While such transfers are excluded from reporting requirements for manufacturers, **physician acceptance of such samples runs contrary to UPMC policy and is prohibited.**

On a related note, manufacturers need not report the provision of “Non-Disposable Devices and Disposable or Single Use Devices” to physicians if such devices are for purposes of evaluation. But if a manufacturer provides a specific disposable or single use device for more than 90 days in the aggregate over a 12-month period (even if provided over non-consecutive dates), the products provided beyond the 90-day supply will be subject to reporting requirements. Just as for samples, **physicians are prohibited from accepting such devices under UPMC policy.**

Although manufacturers need not report all payments or value transfers, the language of the Final Rule is very broad, mandating manufacturers to report payments that they **“require, instruct, direct, or otherwise cause”** a physician to receive. As a result, manufacturers tend to be very inclusive in their reporting to avoid potential audits and penalties. Physicians who are not accepting payment or transfers of value must make their non-acceptance clear to manufacturers so that these items are not attributed to them. For example, meals dropped off at a physician’s office (by a sales representative, for instance) must be reported, and physicians who do not want these meals must clarify that they will not accept them. Such refusal **is required under UPMC policy.**

How Do I Review, Dispute, and Correct Inaccurate Information?

Between the times CMS collects payment and other value transfer information from manufacturers and GPOs and such information is made public, **physicians and physician owners/investors registered on the CMS Open Payments Portal website can review payments and other value transfers for accuracy, dispute them if inaccurate, and correct any inaccuracies.** This Review, Dispute, and Correction Period occurs over a 60-day period, with 45 days dedicated to physician and physician owner/investor review, dispute, and correction. An additional 15 days are available for companies to correct any remaining inaccuracies if necessary, but again, they are not required to do so. The Open Payments data does indicate if a physician has disputed the payment.

Please note that physicians and physician owners/investors must work with manufacturers or GPOs directly to correct disputed information. CMS does not mediate these accuracy disputes.

While 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 correction period, will be updated before the initial June publication. CMS will update data from the current and previous year at least once annually, in addition to the initial data publication that followed the data submission.

If the manufacturer or GPO and physician or physician owner/investor cannot resolve a dispute within the 60-day Review, Dispute, and Correction period, they should continue to work toward a resolution.

Data corrections made by the manufacturers and GPOs may be made at any time, and the associated corrections will be updated on the public website with the next data refresh.

For additional info on the Review, Dispute, and Correction process, please refer to page 4 of **CMS's PPSA Fact Sheet for Physicians:** <https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf>

For more details on the **timing for Review, Dispute and Correction** please also see: [https://www.cms.gov/OpenPayments/Downloads/Quick-Reference-Guide-Review-and-Dispute-Timing-and-Data-\[April-2015\].pdf](https://www.cms.gov/OpenPayments/Downloads/Quick-Reference-Guide-Review-and-Dispute-Timing-and-Data-[April-2015].pdf)

Refer to the CMS Open Payments Data Website to see what payments and value transfers have been attributed to you: <https://openpaymentsdata.cms.gov/>

Are There Consequences for Not Setting the Record Straight?

CMS will monitor the frequency of disputes reported by physicians and the volume of disputes unresolved between physicians and applicable manufacturers or GPOs.

As noted above, CMS has developed this website as a national resource available to public and private agencies. Beyond potential reputational damage for physicians, physicians should be

aware that governmental agencies, media, and other interested parties can mine the data. Investigations into data, linked with other information and evidence, have the potential to launch anti-fraud, anti-kickback, Stark law, and False Claims Act investigations, as well as tax audits and inquires related to violations of private employment contracts.

The manufacturers and GPOs may be audited for compliance with the program requirements to submit timely, accurate, and complete data. Therefore, CMS requires all applicable manufacturers and GPOs to keep all records related to payments and other transfers of value and/or ownership or investment interests for at least five years from the date the transaction is published on the CMS website.

For information on potential ramifications for physicians and applicable manufacturers and GPOs please see: <http://www.policymed.com/2014/06/physician-payments-sunshine-act-comments-regarding-dispute-resolution.html>

How do I Register to Review, Dispute and Correct Inaccurate Information?

Prior to Physician Registration on the Open Payments system, you must first register in the Enterprise Identity Management (EIDM) System.

Please see CMS's "Open Payments System Reference Guide – Enterprise Identity Management (EIDM) Registration" for registration instructions:

<https://www.cms.gov/OpenPayments/Downloads/Enterprise-Identity-Management-System-Registration-%E2%80%93-Quick-Reference-Guide-.pdf>

Once you have registered and are approved for your EIDM credentials, you may register as a physician on the Open Payments system.

Please see CMS's "Open Payments System Quick Reference Guide – Physician Registration" for registration instructions: <https://www.cms.gov/OpenPayments/Downloads/Physician-Registration---Quick-Reference-Guide.pdf>

Frequently Asked Questions (FAQs):

As the PPSA Open Payments Program takes the forefront and continues to evolve, there are a number of online resources to help you as you navigate the PPSA Open Payments Program process.

Please see below for additional tools and resources to address questions that arise during the process:

CMS Website for PPSA Open Payments Program Resources:

<https://www.cms.gov/OpenPayments/About/Resources.html>

CMS Website for FAQs about the PPSA Open Payments Program:

<https://questions.cms.gov/faq.php?id=5005&rtopic=2017>

Policy and Medicine website, which is dedicated to tracking significant changes in regulation for pharmaceutical companies, medical device manufacturers, hospitals, and physicians:

<http://www.policymed.com/>

FAQs addressed at Policy and Medicine:

<http://www.policymed.com/.services/blog/6a00e5520572bb883400e5520572c88834/search?filter.q=FAQs>

For other questions you may also reach out to UPMC's Ethics and Compliance COI Office at conflicts@upmc.edu