



Open Payments

Overview and Enhancements

O P E N P A Y M E N T S

C R E A T I N G P U B L I C T R A N S P A R E N C Y
I N T O I N D U S T R Y - P H Y S I C I A N
F I N A N C I A L R E L A T I O N S H I P S

February 2021

CMS Disclaimer: This information is a summary of the final rule implementing Open Payments (Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests [CMS-5060-F], codified at 42 CFR Parts 402 and 403). The summary is not intended to take the place of the final rule which is the official source for information on the program.

Outline

- Open Payments System Overview
- Open Payments System Enhancements
- Next Steps and Available Resources

Target Audience & Learning Objectives

- Target audience:
 - Applicable Manufacturers and Applicable Group Purchasing Organizations (AM/GPOs) that need to submit data to the Open Payments system to comply with regulatory and reporting requirements
 - Physicians (including principal investigators) and teaching hospitals who want to review and possibly dispute payment records associated with them that have been reported to Open Payments
- Learning objective:
 - Provide an overview of the Open Payments system and enhancements

Key Terms

- **Reporting Entities** – refers to pharmaceutical and medical device manufacturers and their distributors who are required to report payments and other transfers of value to Open Payments; also referred to as Applicable Manufacturers And Applicable Group Purchasing Organizations (AM/GPOs)
- **Covered Recipients*** – refers to physicians, non-physician practitioners and teaching hospitals receiving payments or other transfers of value from Applicable Manufacturers And Applicable Group Purchasing Organizations (AM/GPOs)

For a complete list of key terms for Open Payments, refer to the Open Payments User Guide for Reporting Entities or Open Payments User Guide for Covered Recipients

*Reporting entities will collect data on the new covered recipients in CY 2021 and report that data beginning in 2022.

Open Payments System Overview

What is Reported?

- Direct or indirect payments or other transfers of value made to covered recipients (physicians and teaching hospitals), and physician owners or investors
 - A direct payment is a payment or other transfer of value made directly by reporting entities to a covered recipient (or a physician owner or investor)
 - An indirect payment is a payment or other transfer of value made by a reporting entity to a covered recipient (or a physician owner or investor) through a third party, where the entity requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient (or a physician owner or investor)
- Certain ownership or investment interests held by physician owners or investors, or their immediate family members

Who is Responsible for Reporting?

Applicable Manufacturers of covered products AND entities under common ownership with applicable manufacturers who also provide assistance and support are required to annually report to CMS.

- Operates in the United States
- Engages in the production, preparation, compounding, or conversion of a covered drug, device, biological, or medical supply.
This includes distributors or wholesalers that hold title to a covered drug, device, biological, or medical supply.

Applicable Group Purchasing Organizations (GPOs) are required to annually report to CMS.

- Operates in the United States
- Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Who is Reported On?

Covered Recipient Physicians

- Doctors of medicine or osteopathy legally authorized to practice medicine or surgery by the state
- Doctors of dental medicine or dental surgery legally authorized to practice dentistry by the state
- Doctors of Podiatric Medicine licensed by the state and legally authorized to practice podiatry by the state
- Doctors of optometry legally authorized to perform as a doctor of optometry by the state
- Chiropractors licensed by the state and legally authorized to perform by the state

Covered Recipient Teaching Hospitals

- The hospitals that CMS has recorded as receiving payment(s) under Medicare Direct Graduate Medical Education (GME), indirect medical education (IME), or psychiatric hospitals IME programs
- Each year, Open Payments publishes a list of these teaching hospitals; the list is available on the Resources page of the Open Payments website at <https://www.cms.gov/OpenPayments/About/Resources.html>

Physician Owners or Investors

- Physicians who are owners or investors of an applicable manufacturer or applicable GPO
- Immediate family members who have ownership or investment interest in an Applicable Manufacturer Or Applicable GPO: spouse, natural or adoptive parent, child, or sibling, stepparent, stepchild, stepbrother, or stepsister, father-, mother-, daughter-, son-, brother-, or sister-in-law, grandparent or grandchild, spouse of a grandparent or grandchild

Who is Reported On? (Cont.)

Covered Recipient Non-Physician Practitioners*

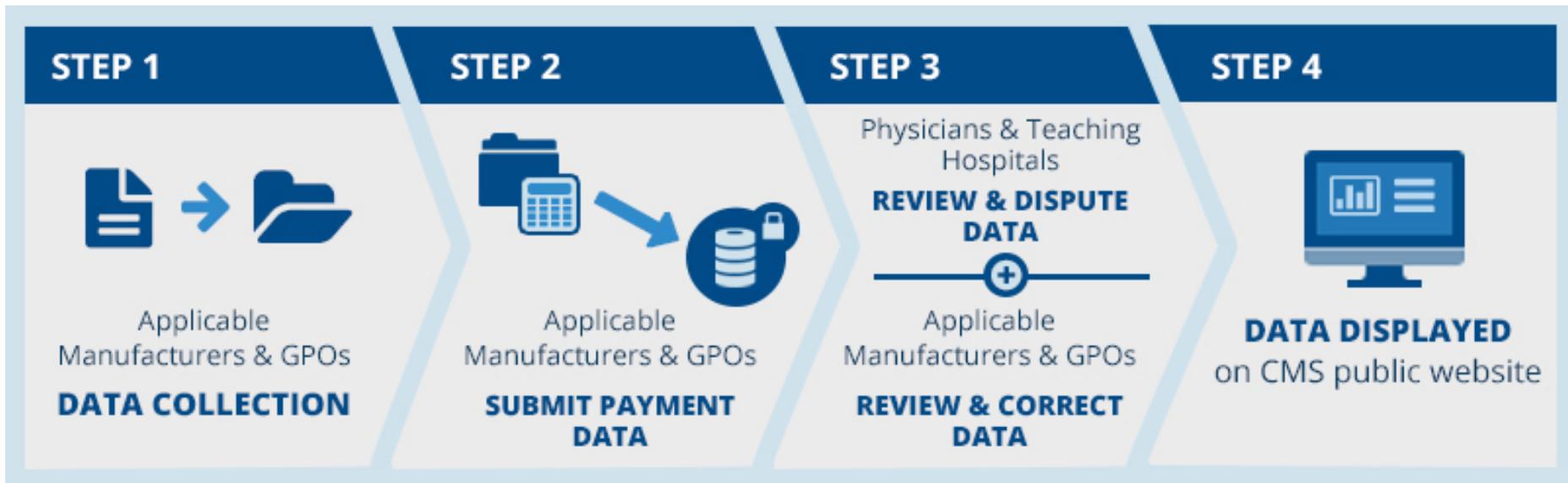
- Physician Assistant (PA)
- Nurse Practitioner (NP)
- Clinical Nurse Specialist (CNS)
- Certified Registered Nurse Anesthetist or Anesthesiologist Assistant (CRNA/AA)
- Certified Nurse-Midwife (CNM)

*Reporting entities will collect data on the new covered recipients in CY 2021 and report that data beginning in 2022.

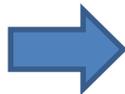
Types of Payments

- General Payments: Payments or other transfers of value made that are not in connection with a research agreement or research protocol
- Research Payments: Payments or other transfers of value made in connection with a research agreement or research protocol
- Ownership or Investment Interest: Information about physicians or their immediate family members who have an ownership or investment interest in a reporting entity

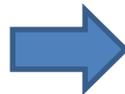
Open Payments Process Flow



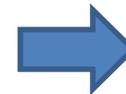
Reporting entities collect payment data for a program year, which runs from January 1 to December 31



Reporting entities submit their data for the program year to the Open Payments system



Physicians and teaching hospitals review and, if necessary, dispute submitted data. Reporting entities resolve disputes.



Data for that program year is published for public viewing in accordance with the publication guidelines

Open Payments System Enhancements

Messages - Compliance Tab

- The AM/GPO Officer(s), Compliance User(s), and the Primary Point of Contact users can view and download file types, such as excel, CSV etc.
- The AM/GPOs will receive only one generic email notification when multiple communications are finalized by the CMS Compliance user.
- The AM/GPOs will also be able to see all the past correspondence compliance communications uploaded by the CMS Open Payments compliance team.

Open Payments (Sunshine Act)
Applicable Manufacturer or Group Purchasing Organization [Switch User Type](#)

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Messages

System Compliance

The table below provides the ability to view and download the reporting entity's compliance communication uploaded by CMS.
The "Download" button allows users to download a copy of the compliance correspondence.
The "Communication Date" provides the date when the compliance correspondence was communicated by CMS compliance officer. Note: For New communications, it is the current date and for past communications (prior to January 2020), it is the date when the compliance correspondence was previously communicated to the reporting entity.
For more information on the actions you can take on this page, refer to the [Open Payments User Guide for Reporting Entities \[PDF\]](#).

Showing 10 of 21 Entries Page 2 of 3 Page 2

Subject	Receiving Entity	Date Received	Attachment
Current date	Message for Life	07-27-2020	Download
Officer and Compliance Recipient(s): Lali (lalima.sahni@cgifederal.com); Lali S (lalima.sahni@Cgifederal.com) Current date of 7/27/2020			
Communication Date: 07-27-2020			

Resolve Unexpected Errors During Entity Vetting

- The system is enhanced to avoid entities being stuck in an “Unknown Error” status after registration and/or updating entity profile.
- If the “Unknown Error” status is triggered in the Open Payments system, the Home page will display the status as “Vetting in Progress”
- If the vetting status remains in Vetting in Progress for 48 hours, users should contact Help Desk to resolve the issue.

Open Payments (Sunshine Act)

Applicable Manufacturer or Group Purchasing Organization [Switch User Type](#)

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Welcome to the Open Payments System

Entity Status

The following are entities you are affiliated with that are currently undergoing vetting or have failed vetting. Select the "Refresh Entity Status" button below to refresh the status of all entities listed. Note: You will not be able to take any actions in the Open Payments system for an entity listed below until vetting has been successfully completed. If the vetting status remains in Vetting In Progress for more than 48 hours, please contact Help Desk to resolve the issue.

Your entity's name will display with a hyperlink on the home page only if vetting fails after the first or second attempt. After the third failed attempt, the name will display without a hyperlink and you will no longer be able to edit the entity details. At this point, contact Help Desk to resolve the issue.

Name	Vetting Status	Refresh Entity Status
Mid Tenn Monument Service	Vetting In Progress	
Lexton Construction, LLC	Vetting Failed	
Levin Productions Inc	Vetting Failed	
ABCDE Medical	Vetting Failed	

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The OMB control number for this information collection is 0938-1237. The time required to complete this information collection can range from 1 to 30,000 hours per entity depending on the size and type of organization. This information collection may involve registration, data submission, attestation, dispute and dispute resolution processes. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.



- [Access the Open Payments User Guide \[PDF\]](#)
- [Need help with the website? Contact Us by email](#)
- [Review the Open Payments Privacy Policy \[PDF\]](#)

Next Steps and Available Resources

Next Steps for Reporting Entities

New or Returning?	Next Steps
New Reporting Entities	<ul style="list-style-type: none">• Register in IDM and request access to the Open Payments system• Register self and reporting entity (if applicable) in the Open Payments system• Assign user roles
Returning Reporting Entities	<ul style="list-style-type: none">• Ensure IDM account has not been deactivated due to inactivity and reset password if necessary• Recertify reporting entity information and provide required review and dispute contact information• Confirm user roles

Next Steps for Covered Recipients

New or Returning?	Next Steps
New Physicians and Teaching Hospitals	<ul style="list-style-type: none">• Register in IDM and request access to the Open Payments system• Register self and teaching hospital (if applicable) in the Open Payments system
Returning Physicians and Teaching Hospitals	<ul style="list-style-type: none">• Ensure IDM account has not been deactivated due to inactivity and reset password if necessary• No other action is required at this time
New Non-Physician Practitioners	<ul style="list-style-type: none">• Non-physician covered recipients can begin Registration from February 1, 2022 and perform Review and Dispute starting from April 1, 2022• Please refer to the tutorial for “Expansion Of Covered Recipient, Device and Nature Of Payment” on the CMS resources page

Available Resources

- Review available resources on the Resources page of the CMS Open Payments website at <https://www.cms.gov/OpenPayments/About/Resources.html>
 - Open Payments User Guide for Reporting Entities
 - Open Payments User Guide for Covered Recipients
 - Tutorials
 - Quick Reference Guides
- If you are looking for information on the Covered Recipient expansion, new nature of payment categories, or device IDs, refer to the tutorial for “Expansion Of Covered Recipient, Device and Nature Of Payment” on the CMS resources page
- Register for CMS email notifications via the Open Payments website to receive e-mail updates about Open Payments
- For additional questions, contact the Open Payments Help Desk:
 - Email: openpayments@cms.hhs.gov
 - Phone: 1-855-326-8366 or for TTY line call 1-844-649-2766

Disclosure

- **Disclaimer:** The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.
- **Activities/persons addressed by this document:** Guidance for Applicable Manufacturers and Applicable Group Purchasing Organizations on overview of the Open Payments system and enhancements.
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 - **Rule citation:** 42 C.F.R. §403.900-14