



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

September 2020

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.

Agenda

- 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 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

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>

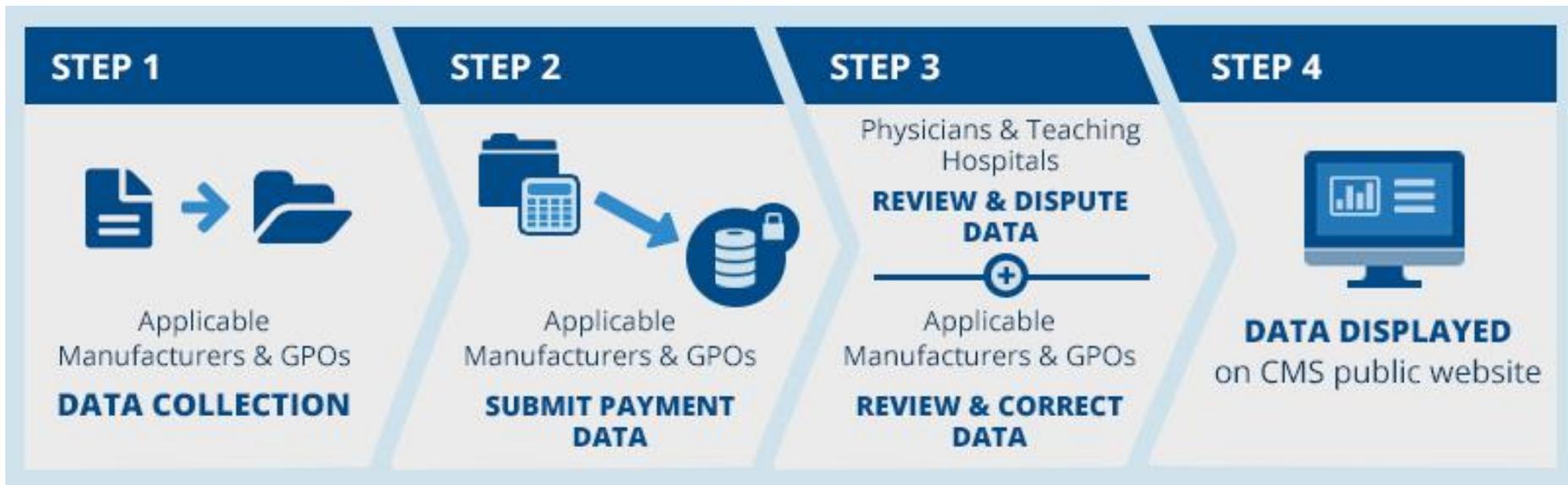
Physician Owners or Investors

- 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

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

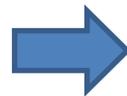
Open Payments Process Flow



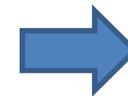
Reporting entities collect payment data for a program year, which runs from January 1 to December 31



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

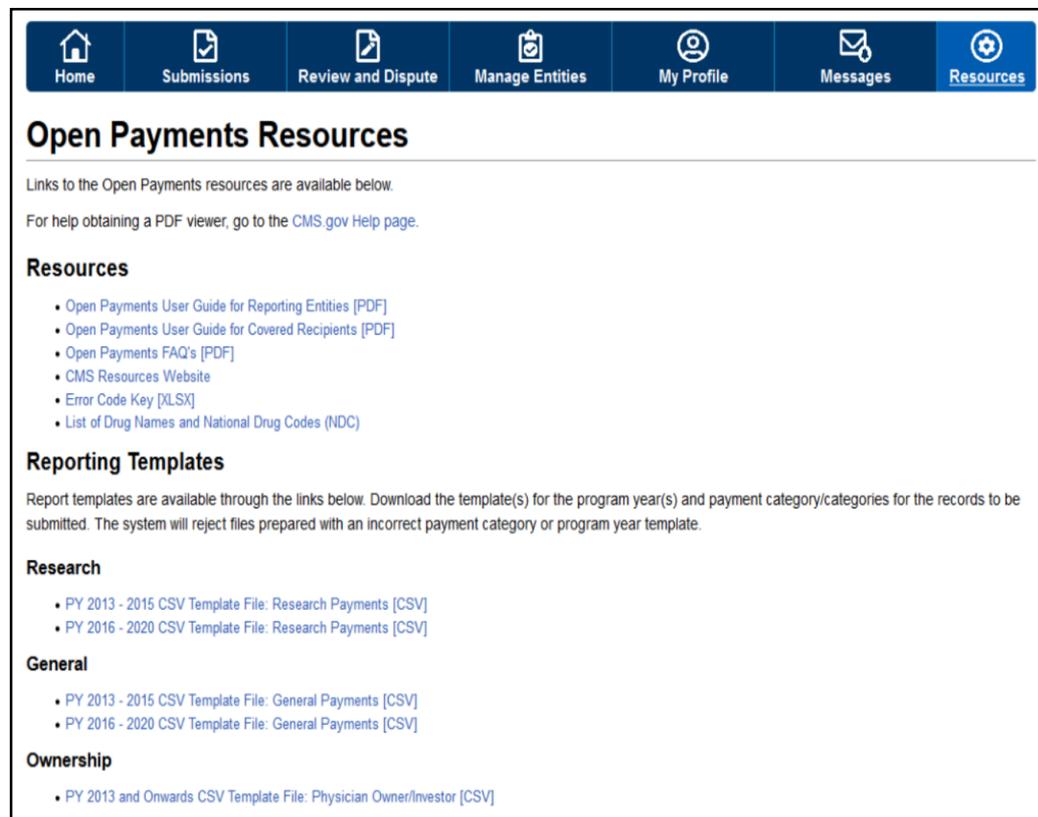
Open Payments System Enhancements

Physician Registration

- CMS has enhanced the system to send email notification to both the physician and the deactivated Authorized Representative (AR) user, when the AR is deactivated.
- **The subject of the email:** Authorized Representative Deactivation by the Physician in the Open Payments System.
- **Recipients of the email:** Deactivated Authorized Representative and Physician.

Data Submission

- The names of the Research Payments and General Payments submission templates have been updated to “PY 2016-2020”.
- The submission template links are updated within the Open Payments System Resources page as follows-:
 - **Research:** PY 2016-2020 CSV Template File: Research Payments [CSV]
 - **General:** PY 2016-2020 CSV Template File: General Payments [CSV]
- The CSV sample files for submitting payments are renamed on the CMS Open Payments Resources page as below:
 - Open Payments Research Template PY 2016-2020.csv
 - Open Payments General Template PY 2016-2020.csv



Open Payments Resources

Links to the Open Payments resources are available below.

For help obtaining a PDF viewer, go to the [CMS.gov Help page](#).

Resources

- [Open Payments User Guide for Reporting Entities \[PDF\]](#)
- [Open Payments User Guide for Covered Recipients \[PDF\]](#)
- [Open Payments FAQ's \[PDF\]](#)
- [CMS Resources Website](#)
- [Error Code Key \[XLSX\]](#)
- [List of Drug Names and National Drug Codes \(NDC\)](#)

Reporting Templates

Report templates are available through the links below. Download the template(s) for the program year(s) and payment category/categories for the records to be submitted. The system will reject files prepared with an incorrect payment category or program year template.

Research

- [PY 2013 - 2015 CSV Template File: Research Payments \[CSV\]](#)
- [PY 2016 - 2020 CSV Template File: Research Payments \[CSV\]](#)

General

- [PY 2013 - 2015 CSV Template File: General Payments \[CSV\]](#)
- [PY 2016 - 2020 CSV Template File: General Payments \[CSV\]](#)

Ownership

- [PY 2013 and Onwards CSV Template File: Physician Owner/Investor \[CSV\]](#)

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 EIDM 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 EIDM 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 EIDM 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 EIDM account has not been deactivated due to inactivity and reset password if necessary• No other action is required at this time

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
- 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