



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

January 2023

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:
 - Reporting Entities that need to submit data to the Open Payments system to comply with regulatory and reporting requirements
 - Covered Recipients who want to review and possibly dispute payment records associated with them that have been reported to Open Payments
- Learning objective:
 - Understand 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 (NPPs) and teaching hospitals receiving payments or other transfers of value from Applicable Manufacturers and Applicable Group Purchasing Organizations (AM/GPOs)
 - NPPs include Physician Assistant (PA), Nurse Practitioner (NP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist or Anesthesiologist Assistant (CRNA/AA) and Certified Nurse-Midwife (CNM)

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 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

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)

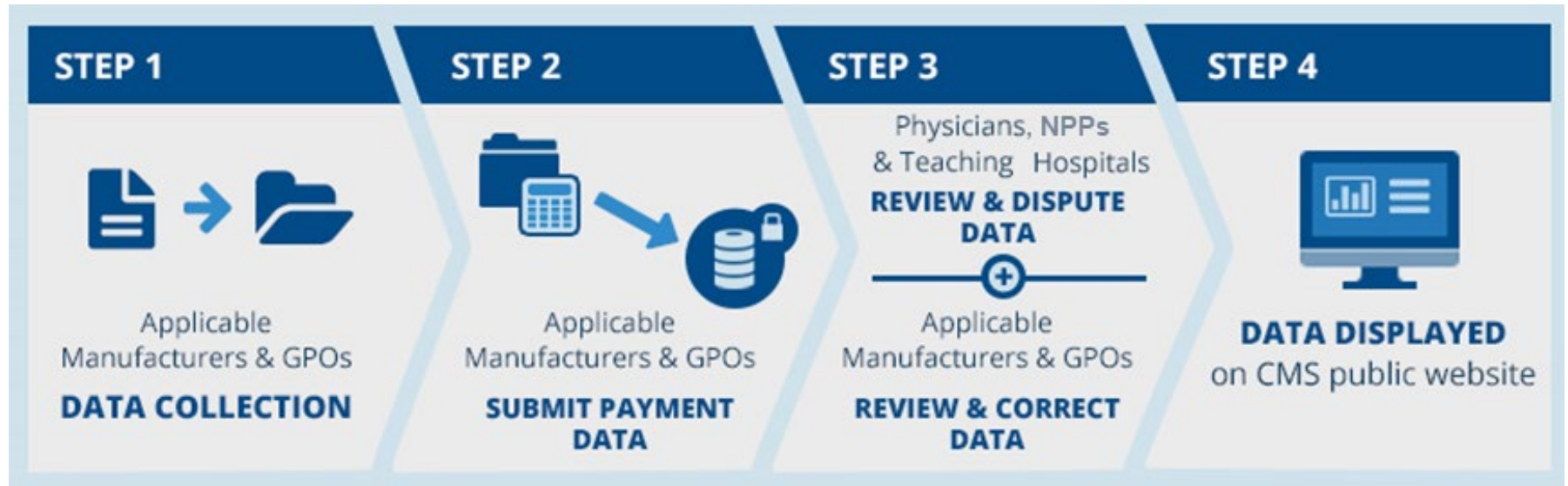
Covered Recipient Teaching Hospitals

- 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 for Reporting Entities page of the Open Payments website at <https://www.cms.gov/OpenPayments/Resources/Reporting-Entities>

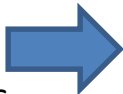
Types of Payments

- **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



Covered recipients review and, if necessary, dispute submitted data. Reporting entities resolve disputes



Program year data is published for public viewing in accordance with the publication guidelines

Program Year 2022 Timeline



Note: Review and Dispute activities start on April 1st and can continue until end of the calendar year. The end dates provided on this slide are the cutoff for disputes and corrections to appear in the June 30, 2023 data publication.

***Anticipated date**

Open Payments System Enhancements

Hard Error for Device Validation

- CMS enhanced the Open Payments system to generate hard error messages for a failed validation of device or medical supply.
- On General and/or Research payment records, the system generates a hard error, if the Medical Device or Medical Supply Name and Primary Device Identifier (PDI) combination is not valid.
- The Reporting Entity user must correct the field(s) for successful validation before proceeding with the submission process.
- The hard error validation affects both new submissions and resubmissions of payment records for General and Research payment records.

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

Home Submissions Review and Dispute Manage Entities My Profile Messages Resources

Add Research Payment

Overview Recipient Demographics **Products** Payments Principal Investigator Demographics Review & Save

Associated Related Products

A field with an asterisk (*) is required.

You have the following errors on the page:

- Error: The Marketed Name of Drug, Device, Biological, or Medical Supply and Primary Device Identifier combination does not match. (Name : 12345)

Select "Yes" or "No" from the Related Product Indicator drop-down list. If "Yes" is selected, enter the applicable information for the Associated covered drugs, devices, biologicals, or medical supplies. Select "Add" after completing each entry. At least one product must be added if the Related Product Indicator value is set to "Yes". You may enter up to five drugs, biologicals, devices, or medical supplies for each record.

To Download the list(s) of Drug Names & National Drug Codes (NDC) and/or Medical Device or Medical Supply Names and Primary Device Identifiers with respective instruction document(s), see the [Resources](#) tab.

*Related Product Indicator:
Yes

Associated Drug, Device, Biological, or Medical Supply Information

*Covered or Non-Covered Product Indicator: Covered
*Indicate Drug, Device, Biological, or Medical Supply: Device
*Product Category or Therapeutic Area: Product

*Marketed Name of Drug, Device, Biological, or Medical Supply: Name
Associated Drug or Biological NDC: 9999-9999-99 OR 99999-999-99 OR 99999-9999-9
Primary Device Identifier: 12345

Cancel Back Add Continue

Hard Error for Device Validation

- The “List of Medical Device or Supply Name and Primary Device Identifier” CSV reference file and Instructions Document is available on the Open Payments System Resources page and the CMS Open Payments Resources for Reporting Entities page.
- For successful validation, the Reporting Entity should use the PDI and Medical Device or Medical Supply Name combination as provided in the reference dataset.
- This dataset is updated annually in January with the latest data received from FDA.

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

Home Submissions Review and Dispute Manage Entities My Profile Messages Resources

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 \(NDC\)](#)
- [List of Medical Device or Medical Supply Names and Primary Device Identifier](#)

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 \[CSV\]](#)
- [PY 2021 and Onwards CSV Template File: Research Payments \[CSV\]](#)

General

- [PY 2013 - 2015 CSV Template File: General Payments \[CSV\]](#)
- [PY 2016 - 2020 CSV Template File: General Payments \[CSV\]](#)
- [PY 2021 and Onwards 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 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, Non-Physician Practitioners 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, Non- Physician Practitioners 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

Available Resources

- Review available resources on the Resources page of the CMS Open Payments website at <https://www.cms.gov/OpenPayments/Resources>
 - 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.
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