Open Payments
Overview and Enhancements

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.
• 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](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

Step 1: Applicable Manufacturers & GPOs  
DATA COLLECTION

Step 2: Applicable Manufacturers & GPOs  
SUBMIT PAYMENT DATA

Step 3: Physicians, NPPs & Teaching Hospitals  
REVIEW & DISPUTE DATA  
REVIEW & CORRECT DATA

Step 4: DATA DISPLAYED  
on CMS public website

2022 PROGRAM YEAR

January 1 – December 31, 2022

February 1 – March 31, 2023*

April 1 – May 15, 2023* 
May 16 – May 30, 2023*

On or by June 30, 2023*

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.
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.
Next Steps and Available Resources
# Next Steps for Reporting Entities

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<thead>
<tr>
<th>New or Returning?</th>
<th>Next Steps</th>
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<tbody>
<tr>
<td>New Reporting Entities</td>
<td>• Register in IDM and request access to the Open Payments system</td>
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<tr>
<td></td>
<td>• Register self and reporting entity (if applicable) in the Open Payments system</td>
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<td>• Assign user roles</td>
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<tr>
<td>Returning Reporting Entities</td>
<td>• Ensure IDM account has not been deactivated due to inactivity and reset password if necessary</td>
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<td></td>
<td>• Recertify reporting entity information and provide required review and dispute contact information</td>
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<td>• Confirm user roles</td>
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# Next Steps for Covered Recipients

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<tr>
<td>New Physicians, Non-Physician Practitioners and Teaching Hospitals</td>
<td>• Register in IDM and request access to the Open Payments system</td>
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<tr>
<td></td>
<td>• Register self and teaching hospital (if applicable) in the Open Payments system</td>
</tr>
<tr>
<td>Returning Physicians, Non-Physician Practitioners and Teaching Hospitals</td>
<td>• Ensure IDM account has not been deactivated due to inactivity and reset password if necessary</td>
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<tr>
<td></td>
<td>• No other action is required at this time</td>
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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.

- **Activities/persons addressed by this document**: Guidance for Reporting Entities and Covered Recipient on overview of the Open Payments system and enhancements.

- **Date of document issuance**: January 2023

- **Replacement / Revision Status**: Revision to previous version

- **Agency Identifier**: CPI DASG/CPI DTP/DASG/CPI 2860

- **Summary of Document**: An overview of the Open Payments program year enhancements that were implemented in July 2022.

- **Citation to statutory provision / regulation applicable to this document**:
  - **Statute citation**: Social Security Act SEC. 1128G. [42 U.S.C. 1320a-7h]
  - **Rule citation**: 42 C.F.R. §403.900-14