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](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, stepsister, 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.
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.
Next Steps and Available Resources
## Next Steps for Reporting Entities

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

<table>
<thead>
<tr>
<th>New or Returning?</th>
<th>Next Steps</th>
</tr>
</thead>
</table>
| New Physicians and Teaching Hospitals     | • 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 | • 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           | • 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.

• **Date of document issuance:** 2/15/2021

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

• **Agency Identifier:** CPI DASG/CPI DTP/DASG/CPI 1043

• **Summary of Document:** An overview of the Open Payments program year enhancements that were implemented in January 2021.

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