Open Payments
Overview and Enhancements

OPEN PAYMENTS
CREATING PUBLIC TRANSPARENCY INTO INDUSTRY-PHYSICIAN FINANCIAL RELATIONSHIPS

January 2022

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?

<table>
<thead>
<tr>
<th>Covered Recipient Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Doctors of medicine or osteopathy legally authorized to practice medicine or surgery by the state</td>
</tr>
<tr>
<td>• Doctors of dental medicine or dental surgery legally authorized to practice dentistry by the state</td>
</tr>
<tr>
<td>• Doctors of Podiatric Medicine licensed by the state and legally authorized to practice podiatry by the state</td>
</tr>
<tr>
<td>• Doctors of optometry legally authorized to perform as a doctor of optometry by the state</td>
</tr>
<tr>
<td>• Chiropractors licensed by the state and legally authorized to perform by the state</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Physician Owners or Investors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Physicians who are owners or investors of an applicable manufacturer or applicable GPO</td>
</tr>
<tr>
<td>• 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</td>
</tr>
</tbody>
</table>
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.
Open Payments System Enhancements
Expansion of Covered Recipient - Non-Physician Practitioners

- The Centers for Medicare & Medicaid Services (CMS) expanded the definition of a “covered recipient” in the Open Payments program to include the following Non-Physician Practitioners:
  - Physician Assistant (PA)
  - Nurse Practitioner (NP)
  - Clinical Nurse Specialist (CNS)
  - Certified Registered Nurse Anesthetist and/or Anesthesiologist Assistant (CRNA/AA)
  - Certified Nurse-Midwife (CNM)
Beginning with Program Year 2021, reporting entities are required to report data for Non-Physician Practitioners.

Similar to the existing functionality for Physicians and Teaching Hospitals, NPPs are allowed to create a profile as a covered recipient in the Open Payments system. In addition, registered NPPs can perform functions like review and dispute, view system messages, and have the ability to add, modify or remove an Authorized Representative.
The Open Payments system allows Reporting Entities to navigate to the Payment Category page in two ways:

- **“Review Submitted Payment Records”:** On the Submissions landing page under the “Review Submitted Payment Records” section, Reporting Entities may select, payment type, reporting entity and program year. This will take them directly to the “Payment Category” page via the “Review Detail” button.

- **“Review Records – Summary”:** On the Submission landing page under the “Review Records – Summary” section, Reporting Entities can select entity and program year and access the Payment Category page via the “Review Summary” button by selecting “View All”.

![Open Payments System Screenshot](image-url)
Natures of Payment Categories

• There are three new Nature of Payment categories and two Nature of Payment categories have been combined into one.

• The following two Nature of Payment categories are combined and named as, “Compensation for serving as faculty or as a speaker for a medical education program”
  – Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
  – Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program

• The above two Nature of Payment categories are reportable and editable until Program Year 2020. Beginning with Program Year 2021 the above two Nature of Payment categories are reportable under the new category name, “Compensation for serving as faculty or as a speaker for a medical education program.”
Natures of Payment Categories

- The following Nature of Payment categories are added and reportable beginning with Program Year 2021:
  - Debt Forgiveness
  - Long-Term Medical Supply or Device Loan
  - Acquisitions
- The three new Nature of Payment categories operate prospectively and are not reportable for previous Program Years prior to 2021.
Validating and Standardizing Medical Devices Information

• CMS enhanced the Open Payments system to validate the medical device or medical supply name. The new field of “Primary Device Identifier” is added to the Associated Related Products page for general and research payments only.

• The name of the marketed medical device or medical supply must be provided when:
  – The product indicator is selected as “covered”
  – The product indicator is selected as “non-covered” and the Primary Device Identifier is provided.
Validating and Standardizing Medical Devices Information (Cont.)

- On general and/or research payment records, the system generates a warning, if the Medical Device or Medical Supply Name and Primary Device Identifier combination is not valid. However, the user can continue with the record submission without fixing the warning message(s).
Validating and Standardizing Medical Devices Information (Cont.)

• 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.

Open Payments (Sunshine Act)

Applicable Manufacturer or Group Purchasing Organization Switch User Type

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 FAQs [PDF]
  • CMS Resources Website
  • Error Code Key [XLSX]
  • List of Drug Names and National Drug Codes (NDC)
  • List of Medical Devices 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]
Supported Browsers

• The Open Payments web-based application no longer supports Internet Explorer (IE).
• The Open Payments web-based application will continue to support the following browsers:
  – Google Chrome (Version 89 or higher)
  – Microsoft Edge (Version 89 or higher)
  – Safari (Version 13.1.2)
  – Mozilla Firefox (Version 83 or higher)
Hard Error for Drug Validation

- CMS enhanced the Open Payments system to generate hard error messages for a failed validation of Drug or Biological Name and National Drug Code (NDC) fields.
- 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.
Separate Error and Warning Logs for Download

- CMS enhanced the Open Payments system to separate the log for errors and warnings into two individual .csv files.
- The separated error and warning logs will continue to be available for download on the same screens where the current error log is available.
Final Submission

• CMS enhanced the Open Payments system to display an updated confirmation message to the Reporting Entity user after the user clicks the “Submit as Final Submission” button on the Final Submission Confirmation Page.

• The user will now have the ability to navigate within other areas of the Open Payments system while Final Submission is processing.

• An email notification will automatically be sent to the Reporting Entity’s submitters when the final submission is processed successfully.
Compliance Messages

- CMS enhanced the Open Payments system compliance portal. Reporting Entities may now:
  - Respond to CMS communication with a file to be viewed by CMS
  - View a chain of communications via the Communication ID

- Users may respond to CMS communication by submitting a file on the “Upload Response to Compliance Communication” page.
Next Steps and Available Resources
# Next Steps for Reporting Entities

<table>
<thead>
<tr>
<th>New or Returning?</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>
</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>
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</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                                                                                                     |
| Non-Physician Practitioners                   | • Non-physician covered recipient registration opens February 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/Resources](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
• **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 2022

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

• **Agency Identifier:** CPI DASG/CPI DTP/DASG/CPI 1604

• **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