Open Payments
Overview and Enhancements

September 2019

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 (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 (GPOs)

- **Covered Recipients** – refers to physicians and teaching hospitals receiving payments or other transfers of value from applicable manufacturers and 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](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 an applicable manufacturer or applicable GPO
Open Payments Process Flow

**STEP 1**
Applicable Manufacturers & GPOs
DATA COLLECTION

**STEP 2**
Applicable Manufacturers & GPOs
SUBMIT PAYMENT DATA

**STEP 3**
Physicians & Teaching Hospitals
REVIEW & DISPUTE DATA
Applicable Manufacturers & GPOs
REVIEW & CORRECT DATA

**STEP 4**
DATA DISPLAYED on CMS public website

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
Main Navigation Bar

• The main navigation bar is re-designed for all users by adding icons and removing descriptive text on the main navigation bar as shown below. The descriptive text will be displayed on hover over and focus of the navigation link.
Ability to Track Messages for All Users

This enhancement is to allow users (Reporting Entity or Covered Recipient) to view the system generated messages associated with their organization within the application. The following feature is added.

- Introduced the Messages tab to provide a view of all the email messages at the organization level that are generated by the Open Payments system.

Note: these are specifically the system generated emails and are not related to the Open Payments listserv subscription.
Download Compliance Communications

- This enhancement is to provide the ability for the reporting entity Officers and Compliance users to view the compliance communication information and download associated PDF files uploaded by the CMS Open Payments compliance team.
- The system will allow a reporting entity to assign two users the compliance role.
- An email notification will be sent to the reporting entity’s Officer, Compliance User(s) and the Primary Point of Contact when a new compliance communication is uploaded by CMS.
Physician’s Profile ID Lookup Utility

- This utility is for the Teaching Hospital users to look up Physician’s Open Payments Profile ID by the National Provider Identifier (NPI) via bulk upload. The added features are:

  ➢ On the Teaching Hospital UI, a new “Utilities” tab is added. The Teaching Hospital users can access this Utilities tab to navigate to the Utilities page as shown below.
  ➢ A new template, “Physician’s_Profile_ID_Lookup_Template.csv”, is made available for the users to download from Utilities tab and use the same to upload the physician’s NPI.
Upon successful upload of the NPI list, a downloadable results link is available. The result file will include the associated Open Payments Physician Profile ID for the NPI if there are any payments reported for the covered recipient NPI listed in the input file.

The result file is available only until the new file is uploaded or the user logs out of the Open Payments application.
Validation Utility for Matching Physician Information

This system enhancement allows reporting entity submitters to validate the physician profile information prior to using it on the payment record by navigating to the Submission Tab. At the conclusion of this validation process, the user can download the results file for physicians that failed the matching process. The features are:

- Reporting entity submitters can submit physician information using the upload functionality on the Physician Validation page.

- A file named as “Physician_Validation_Template.csv” is made available. It can be accessed from the right sidebar of the Physician Validation page under the “Download the Validation Template” section.

- The submittter can download the result file which will contain the profiles that failed matching and related error code(s) comma separated in case of multiple matching errors. The successfully matched profiles will not be part of the result file.
The downloadable result file will be available for 90 days from the upload date.
Next Steps and Available Resources
# Next Steps for Reporting Entities

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<tr>
<th>New or Returning?</th>
<th>Next Steps</th>
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<tr>
<td>New Reporting Entities</td>
<td>• Register in EIDM and request access to the Open Payments system</td>
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<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</td>
<td>• Ensure EIDM account has not been deactivated due to inactivity and reset password if necessary</td>
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<tr>
<td>Entities</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 and Teaching Hospitals</td>
<td>• Register in EIDM and request access to the Open Payments system&lt;br&gt;• Register self and teaching hospital (if applicable) in the Open Payments system</td>
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<tr>
<td>Returning Physicians and Teaching Hospitals</td>
<td>• Ensure EIDM account has not been deactivated due to inactivity and reset password if necessary&lt;br&gt;• 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/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