Open Payments
Overview and Enhancements

OPEN PAYMENTS
Creating Public Transparency into Industry-Physician Financial Relationships

January 2020

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
• Preparing for Program Year 2019 Submission
• 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 Program Year 2019 timeline and system 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 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
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 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.
Preparing for Program Year 2019 Submission
Program Year 2019 Timeline

Note: Review and Dispute activities start on April 1st and 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 30th 2020 data publication.

*Anticipated date
Two-Step Registration Process

1. Before registering for the Open Payments system, an individual must first register with the CMS Enterprise Identity Management (EIDM) system and request access to the Open Payments system.

2. Once the individual has successfully registered with EIDM, that individual can register him- or herself (and if necessary, their reporting entity) with the Open Payments system.

*Note: If an individual has registered for EIDM and requested access to Open Payments system in the past, it is not necessary to do so again.*
EIDM Overview

- Successful registration in both EIDM and the Open Payments system is required for each individual who wishes to access the Open Payments system and perform any system-related functions.

- Individuals who request electronic access to CMS-protected information or systems (such as EIDM) must first have their identities verified.

- For returning EIDM users who need help with User ID or password, visit [https://portal.cms.gov](https://portal.cms.gov) or Phone at 1-855-326-8366 or TTY line call at 1-844-649-2766.

- EIDM will lock a user account after 60+ days of inactivity.

- EIDM will deactivate a user account after 180+ days of inactivity.

- For step-by-step instructions on EIDM registration, refer to the Quick Reference Guide “Enterprise Identity Management (EIDM) Registration,” available on the Resources page on the Open Payments website ([https://www.cms.gov/OpenPayments/About/Resources.html](https://www.cms.gov/OpenPayments/About/Resources.html)).
Open Payments System Registration

Reporting Entity Registration:

– Reporting entities must register in the Open Payments system to submit, attest, correct, and view records of payments, other transfers of value, and ownership/investment interests

– Open Payments system registration can only be completed after EIDM registration

– Reporting entities must be registered and individuals who wish to use the system on behalf of a reporting entity must also register
Covered Recipient Registration:

– Covered recipients must register in the Open Payments system in order to dispute payment records associated with them

– Hospital-based physicians must register as physicians, unless they are reviewing and disputing records on behalf of the teaching hospital; users registering as teaching hospital users must be appropriately authorized by the hospital administration to review and dispute payments made to the hospital
Open Payments System Registration (cont’d)

• Prepare the required information before beginning registration

• Registration must be completed in one session users cannot save partially completed entries for completion at a later time. Sessions are timed out after 30 minutes of inactivity

• For a complete list of required information for registration, refer to Open Payments System Quick Reference Guide “Required Fields for Registration” available for download on the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html) and the “Create Profile” page within the Open Payments system

• For additional guidance on system registration, refer to the quick reference guide “Applicable Manufacturer and Applicable GPO Registration and Recertification” and the Open Payments User Guide, both available on the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html)
Reporting Entity Recertification

Reporting entities that registered in any previous calendar year must recertify to perform any Open Payments system functions

- Recertification confirms that details in the Open Payments system are accurate
- Recertification can only be performed by an active user who holds an officer role
- If a reporting entity does not have an active officer, contact the Open Payments Help Desk for assistance
- Entity information can be updated at any time.
- Re-vetting of the reporting entity will occur if any of the following fields in the entity’s profile change:
  - Entity’s Legal Name; State; and Country
  - Tax Identifier Number (TIN)/Employee Identification Number (EIN)
  - Dun and Bradstreet DUNS Number (D&B)
Reporting Entity Recertification (cont’d)

• Reporting entities due for recertification are given a status of “Pending Recertification”

• **Recertification starts on January 1 of each calendar year**

• To view all of the entities you are affiliated with, including entities due for recertification, navigate to the “Manage Entities” tab in the Open Payments system

• After recertification, user role management activities for the entity can be performed and previously submitted data can be viewed and downloaded

• New data submission, data editing, and data deletion cannot be performed until the submission period begins

• **Recertification is not required for physicians or teaching hospitals**
Data Submission Resources

- Resources to help reporting entities with data submission include:
  - Validated Physician List
    - Accessed through the Open Payments system
  - Teaching Hospital Lists
    - All Teaching Hospital Lists are available on the Resources page of the Open Payments website
    - 2020 Teaching Hospital list is now available for use for data collected between January 1 – December 31, 2020
    - 2013 – 2019 Teaching Hospital lists are also available for preparing data from previous program years
Open Payments System Enhancements
• This system is enhanced to allow the reporting entity’s nominees (Officer, Submitter, Attester and Compliance), Physicians and Authorized Representatives to register/nominate with a foreign address in the Open Payments system.
ZIP Code Validation

• The system is enhanced to verify the 5-digit ZIP code entered by the User is a valid United States ZIP code and is within the boundaries of the state entered during the registration and/or submissions process.

• The user will receive an error message if the validation fails.
Validating and Standardizing Drug Information

- The system is enhanced to validate the Drug or Biological information against the CMS approved Drug and National Drug Code (NDC) dataset and provide a warning message when invalid data for related product information on a general and/or research payment record is submitted.

- The following validations are performed and the submitter receives a warning accordingly:
  - The Drug or Biological Name entered by the user is valid against the CMS approved data set.
  - The Drug or Biological Name and NDC combination is valid (if NDC provided) against the CMS approved dataset.
Validating and Standardizing Drug Information (Cont.)

• The Drug Name and National Drug Code (NDC) reference file and PDF Instructions document are zipped together and made available within the Open Payments Resources tab for all users to download.
Validating and Standardizing Drug Information (Cont.)

- Users can search the records with Drug Name and/or NDC warnings by the “Record Warnings” field within the search criteria on the Payment Category page for general and research payments.
This system enhancement is to provide the matching errors and/or warnings on the Overview page when the submitter edits payment records with matching errors/warnings.

These messages will stay on the Overview page until the edited record is saved and resubmitted, at which point, the record goes through the matching process again.

If there are no matching errors and warnings after the latest matching process, the matching errors and warnings are cleared from the Overview page.
The File ID Link in the Review File Status Page

- This system enhancement provides links to access the File ID Details page for each New Submission or Resubmission file that has not been rejected or deleted (i.e., in Submitted Successfully, Submitted with Errors, or Processed with Warning status) on the Review File Status page.

- Each hyperlink directs the reporting entity submitter to the respective File ID Details page. The submitter can take actions (view file details, download error log file and delete file) as they can on the File ID page accessed via the Payment Category page.
• This system enhancement is to provide reporting entity submitters the ability to copy/duplicate payment details across multiple program years through the User interface (UI).

• New “Copy” button/hyperlink is provided in two places within the application. This will allow the user to copy the existing record.

• The Copy hyperlink is in the Payment Category page, record view grid for every record under the Action column, regardless of the record status.
• The other Copy Button is on the view Record ID Page.

• The copied record will have to be saved for successful creation of the record.
License Expiration Prior to Start of Program Check

- The existing matching process is enhanced to reject a payment record if it is determined that the license information on the payment record is not active in any program year starting from 2013.

- If the license cited on the reported payment record is inactive throughout the Open Payments program, then the record is rejected.
This system enhancement is to default the required country field for teaching hospital recipients to “United States” during manual submission and create system generated errors when a foreign country is submitted for teaching hospital recipients in both manual and bulk-file submissions.
Submission Template Naming Convention Update

The names of the General and Research payments submission templates is updated to “PY 2016 and Onwards” and Ownership/Investment template has been updated to “PY 2013 and Onwards”. The submission template links are updated within the Open Payments System Resources page as follows.

- PY 2016 and Onwards CSV Template File: Research Payments [CSV]
- PY 2016 and Onwards CSV Template File: General Payments [CSV]
- PY 2013 and Onwards CSV Template File: Physician Owner/Investor [CSV]

The CSV sample files to be used for submitting payments are renamed on the CMS Open Payments Resources page as below:

- PY 2016 and Onwards CSV Sample File: General Payments [CSV]
- PY 2016 and Onwards CSV Sample File: Research Payments [CSV]
- PY 2013 - Onwards CSV Sample File: Physician Owner/Investor [CSV]
Inactive Physician License List per Calendar Year - VPL Supplement file

- Physician licenses/profiles which are not active from the start of the Open Payments program (2013 onwards) are being removed from the Validated Physician List (VPL).

- The Physician profiles with one or more inactive license per program year are part of the Inactive Physician License List per Program Year.

- All supplement files are made available to reporting entities for download via the Open Payments system, to provide a reference to validate physician information before reporting any payments for such physicians to Open Payments.
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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<tbody>
<tr>
<td>New Reporting Entities</td>
<td>• Register in EIDM and request access to the Open Payments system  &lt;br&gt; • Register self and reporting entity (if applicable) in the Open Payments system &lt;br&gt; • Assign user roles</td>
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<tr>
<td>Returning Reporting Entities</td>
<td>• Ensure EIDM account has not been deactivated due to inactivity and reset password if necessary  &lt;br&gt; • Recertify reporting entity information and provide required review and dispute contact information &lt;br&gt; • 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>
</tr>
<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