Open Payments
Overview and Enhancements

Open Payments
Creating Public Transparency into Industry-Physician Financial Relationships

January 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
• Preparing for Program Year 2018
• 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 Program Year 2018 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 (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 an applicable manufacturer or applicable GPO (collectively referred to as 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 an 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

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
<th>STEP 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Applicable Manufacturers &amp; GPOs</strong>&lt;br&gt;Data Collection</td>
<td><strong>Applicable Manufacturers &amp; GPOs</strong>&lt;br&gt;Submit Payment Data</td>
<td><strong>Physicians &amp; Teaching Hospitals</strong>&lt;br&gt;Review &amp; Dispute Data</td>
<td><strong>Data for that program year is published for public viewing in accordance with the publication guidelines</strong>&lt;br&gt;Data Displayed on CMS public website</td>
</tr>
</tbody>
</table>

**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.
Preparing for Program Year 2018
Program Year 2018 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 2019 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 or contact the Open Payments Help Desk at openpayments@hhs.cms.gov or 1-855-326-8366.
- EIDM will lock a user account after 60+ days of inactivity.
- EIDM will deactivate a user account after 180+ days of inactivity.
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, as 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](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](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
    - 2019 Teaching Hospital list is now available for use for data collected between January 1 – December 31, 2019
    - 2013 – 2018 Teaching Hospital lists are also available for preparing data from previous program years
Open Payments System Enhancements
Manual Submission Redesign

- Redesigned screens for manual data entry to reduce the amount of scrolling
Manual Submission Enhancements (cont’d)

• Introduced the Payment Navigation Bar to provide a visual indicator of the page the user is on within the record

• The hyperlinks on the Payment Navigation Bar also allow the user to navigate to each page out of order/sequence assuming there are no errors on the page the user is currently on.
Bulk File Validation Errors

• The system will validate the **Taxonomy Code** entered on records submitted via bulk file upload

• If the Taxonomy Code is not in the CMS approved valid Taxonomy list, the following error codes will be displayed in the Error log
  – E-802 displays for an Invalid **Physician** Taxonomy Code
  – E-832 displays for an invalid **Principal Investigator** Taxonomy Code

<table>
<thead>
<tr>
<th>File ID</th>
<th>Record ID</th>
<th>Home System</th>
<th>Payment Record Status</th>
<th>Error Message ID</th>
<th>Data Element Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>307</td>
<td>2187</td>
<td></td>
<td>Failed Validation</td>
<td>E-802</td>
<td>0</td>
</tr>
<tr>
<td>307</td>
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</tr>
<tr>
<td>307</td>
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<td>Failed Validation</td>
<td>E-832</td>
<td>0</td>
</tr>
<tr>
<td>307</td>
<td>2189</td>
<td></td>
<td>Failed Validation</td>
<td>E-832</td>
<td>213S0103X</td>
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<tr>
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<td>2175</td>
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<td>Failed Validation</td>
<td>E-832</td>
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<tr>
<td>307</td>
<td>2179</td>
<td></td>
<td>Failed Validation</td>
<td>E-832</td>
<td>213S0103X</td>
</tr>
</tbody>
</table>
File Submission – Duplicate Check

• The system will prevent the user from uploading files with the same file name, extension and attributes (UI Selection Values - Payment Category, Reporting Entity and Program Year) while a file with the same name and attributes is being processed.

• When the system identifies a file with the same name and attributes in processing status an on-screen message will display.

• There are no restrictions on submitting duplicate files once the file is no longer being processed.
Review Records - Warnings

- General, Research or Ownership/Investment Interest payment records submitted with an expired license are now identified by a warning icon (⚠️) in the Record ID column on the Payment Category page.
- Records with warnings can be filtered using the “Record Warnings” field.
VPL Updates

To assist in creating accurate records, CMS has made physician and principal investigator information available through the Validated Physicians List (VPL).

The following enhancements have been made to the VPL:

- In addition to the existing list of physicians who have an NPI and have been reported on in the Open Payments system, a second list of physicians will be included who do not have an NPI and have been reported on in the Open Payments system

*The VPL is not an exhaustive list of all physicians who should be included in Open Payments reporting. It can only be accessed within the Open Payments system, on the “Submissions” page*
Review Records: Refresh Status

- During the Review of the records, the "Refresh Status" button will update the counts for all payment categories.
- Once the "Refresh Status" button is selected, all other buttons on the "Review Records" page will be disabled until the page has been refreshed.

**ABCDE Medical 2017 - Review Records**

Below are the records reported by the entity and categorized by the status for the selected program year. To edit records (available only for a user in a "submitter" role) or view the details of the reported records, select the "View All" button under a specific payment category (e.g., Research Payments, General Payments, etc.).

If all the records for the entity are in a "Ready for Attestation" or "Attested" status, a user in an "attester" role can attest by selecting the "Begin Attestation of All Records" button.

If you have further questions on how to make final submission of records, details on status definitions, or how to attest, use the link available on the right hand navigation.

Select "Notify Attester" to notify attesters that there are records that require attestation. All active attesters affiliated with the reporting entity will receive an email notification that there are records which require attestation.

Note: Previously attested records that have been marked for deletion have not yet been deleted from the Open Payments system. The attester must re-attest to all payments for the selected program year to complete the deletion. Records marked for deletion remain eligible for review, dispute, and publication, until re-attestation is complete.

Records counted as "Marked for Deletion" are also included in the "Attested" (†) record count.

**Program Year: 2017**

**Research Payments**

<table>
<thead>
<tr>
<th>Status</th>
<th>Record Count</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Processing</td>
<td>0</td>
<td>No Action</td>
</tr>
<tr>
<td>Failed Validation</td>
<td>0</td>
<td>Correction</td>
</tr>
<tr>
<td>Failed Matching</td>
<td>1</td>
<td>Correction</td>
</tr>
<tr>
<td>Ready for Submission</td>
<td>0</td>
<td>Final Submission</td>
</tr>
<tr>
<td>Ready for Attestation</td>
<td>0</td>
<td>Attest</td>
</tr>
<tr>
<td>Returned to Submitter</td>
<td>0</td>
<td>Correction</td>
</tr>
<tr>
<td>Attested †</td>
<td>0</td>
<td>No Action</td>
</tr>
<tr>
<td>Total Payments</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marked for Deletion</th>
<th>Record Count</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>† Attester to confirm deletion of previously attested records</td>
<td>0</td>
<td>Attester to Attest deletion action or Reject Deletion</td>
</tr>
</tbody>
</table>
Final Submission

- For a specific program year and payment category, the “Final Submission” button will be available to submitters if there are any records in “Ready for Submission” status and there are no records in “System Processing” status; **all records do not need to be corrected prior to final submission**
- Only records in Ready for Final Submission will be included in the final submission process
“Review Submitted File(s) Status” section has been added to the Submission landing page

- Submitters can select the “Review Files Status” button to view the processing status of their submitted files on the Review File Status page

- Only files submitted after 1/1/2019 will be available on this page
• Users can view the status of the submitted file(s) on the “Review File Status” page
GPOs Validation Errors

• The system will reject general/research payment records submitted by GPO users that specify Teaching Hospital as the Covered Recipient Type

• The onscreen error message will request the user to select a different Covered Recipient Type

• For bulk file upload, the system will update the record with a Failed Validation status and generate the following error code:
  – E-694: GPO submitted general/research payment record for a Teaching Hospital in the Error Log
• A new downloadable report will be available to GPO users to identify recipients in general or research records that are missing their corresponding ownership record in attested status, and therefore may not be compliant per the Open Payments final rule, 42 C.F.R. § 403.906

• GPO users have access to the “Download Recipients Missing Ownership Record” section. Under the section, “Download Report” button is available to review the selected entity report
GPOs Validation Errors (cont.)

- The report will provide information on physician covered recipients, principal investigators and their general/research records that do not have a corresponding **attested** ownership/investment interest payments for the program year submitted by the same GPO.

Note: Records that are marked for deletion do not count as attested, and will be included in this report.

<table>
<thead>
<tr>
<th>GPO Making Payment Name</th>
<th>GPO Making Payment Registration ID</th>
<th>Program Year</th>
<th>Covered Recipient First Name</th>
<th>Covered Recipient Last Name</th>
<th>General Payment-Sample Record ID(s)</th>
<th>Research Payment-S</th>
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</thead>
<tbody>
<tr>
<td>ABCD Medical</td>
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<td>2017</td>
<td>KAREN</td>
<td>MILLER</td>
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<td>SUSAN</td>
<td>JONES</td>
<td>[13635;13643;13645;13647;13649;13645;13664;13637]</td>
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<tr>
<td>ABCD Medical</td>
<td>100000000000</td>
<td>2017</td>
<td>MARY</td>
<td>DAVIS</td>
<td>[13635;13643;13637]</td>
<td>No</td>
</tr>
<tr>
<td>ABCD Medical</td>
<td>100000000000</td>
<td>2017</td>
<td>SUSAN</td>
<td>JONES</td>
<td>[13635;13643;13637]</td>
<td>No</td>
</tr>
<tr>
<td>ABCD Medical</td>
<td>100000000000</td>
<td>2017</td>
<td>KAREN</td>
<td>MILLER</td>
<td>[14069;14067]</td>
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<tr>
<td>ABCD Medical</td>
<td>100000000000</td>
<td>2017</td>
<td>KAREN</td>
<td>MILLER</td>
<td>[14069;14067]</td>
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<tr>
<td>ABCD Medical</td>
<td>100000000000</td>
<td>2017</td>
<td>MARY</td>
<td>DAVIS</td>
<td>[13635;13643;13637]</td>
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<td>MILLER</td>
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<td>ABCD Medical</td>
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<td>KAREN</td>
<td>MILLER</td>
<td>[13635;13643;13637]</td>
<td>No</td>
</tr>
</tbody>
</table>
The review and dispute functionality is enhanced for AM/GPO users as follows:

- AM/GPO users with the submitter role, can now delete a disputed record directly from the entity “Review and Dispute” page.

- The “Cancel Deletion” button has also been added to the “Review and Dispute” page to enable AM/GPO users to cancel the deletion of a record marked for deletion on the “Review and Dispute” page. Note: The record will be “Marked for Deletion” and an Attester will need to re-attest to delete the record from the system. If the record is in “Ready for Attestation” or “Returned to Submitter” status then it will be directly deleted from the system.
The “Resources” tab has been updated to include a direct link to the CMS Resources page as well as other additional resources within the Open Payments system.
Other Enhancements

• Country selection fields will display United States as the first option followed by all other countries displayed in alphabetical order

• Error messages have been updated to provide detailed information on how to fix the record per updated 508 guidance
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 EIDM 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 EIDM 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>
<tbody>
<tr>
<td>New Physicians and Teaching Hospitals</td>
<td>• Register in EIDM and request access to the Open Payments system</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
</tr>
<tr>
<td></td>
<td>• No other action is required at this time</td>
</tr>
</tbody>
</table>
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