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A MEDICARE LEARNING NETWORK® (MLN) EVENT

Open Payments: The Program and Your Role

Key Terms in this Presentation

- 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/or GPOs.



Agenda

- Open Payments: The Program
- Your Role
- Review & Dispute and Corrections Process
- Review & Dispute Actions
- Dispute Resolution
- Question & Answer Session
- Available Resources



Open Payments: The Program



The Program

- Open Payments is a national disclosure program that promotes a more transparent and accountable health care system by making the financial relationships between applicable manufacturers and group purchasing organizations (GPOs) and health care providers (physicians and teaching hospitals) available to the public.
- Open Payments operates on a program timeline throughout which data is collected, reported, reviewed, and published.



Program Timeline

- The following is an example of the annual program timeline using Program Year 2017



*anticipated date



The Data

- The data consists of direct or indirect payments or other transfers of value made to covered recipients
 - An indirect payment is a payment or other transfer of value made to a third party, where the applicable manufacturer or GPO requires, instructs, directs, or otherwise causes the third party to provide the payment or other transfer of value, in whole or in part, to a physician or teaching hospital
- Certain ownership or investment interests held by physician owners or investors, or their immediate family members



Payment Categories

- The data reported is divided into three major payment categories
 - General Payments: payments or other transfers of value made that are not in connection with research agreements or research protocol. These payments may include but are not limited to honoraria, gifts, meals, consulting fees, and travel compensation
 - Research Payments: Payments or other transfers of value made in connection with a formal research agreement or research protocol
 - Ownership or Investment Interest: Information about the ownership or investment interest that physicians or their immediate family members have in the reporting entities



Published Data – Program Year 2016

- On June 30, 2017 CMS published Program Year 2016 data along with the refreshed data from previous program years (2013 – 2015)
- Before the Program Year 2016 data publication, covered recipients were provided an opportunity to review and if necessary dispute any records they believed to be inaccurate or incomplete
- Covered recipients were also able to review the published data and initiate any necessary disputes through December 31, 2017
- On January 17, 2018 the Open Payments data was refreshed to reflect any changes that had taken place following the initial data publication (June 30 2017)



Program Year 2016 Data



Total US Dollar Value
8.19 Billion



Total Records Published
11.96 Million

\$ General Payments

Amount \$2.78 Billion	Payments 11.30 Million
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🧪 Research Payments

Amount \$4.37 Billion	Payments 656,000
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📈 Value of Ownership

Amount \$1.03 Billion	Payments 3,646
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Total Physicians

Receiving Payments
631,000



Total Teaching Hospitals

Receiving Payments
1,146



Total Companies

Making Payments
1,479



Program Participants – Reporting Entities

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

Applicable Group Purchasing Organizations (GPOs) of covered products are required to annually report to CMS

What is an applicable manufacturer?

- Operates in the United States
- Engages in the production, preparation, propagation, 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

What is an applicable GPO?

- 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



Program Participants – Covered Recipients

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 legally authorized to perform 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 Open Payments website at <http://cms.gov/openpayments>

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



Open Payments: Your Role



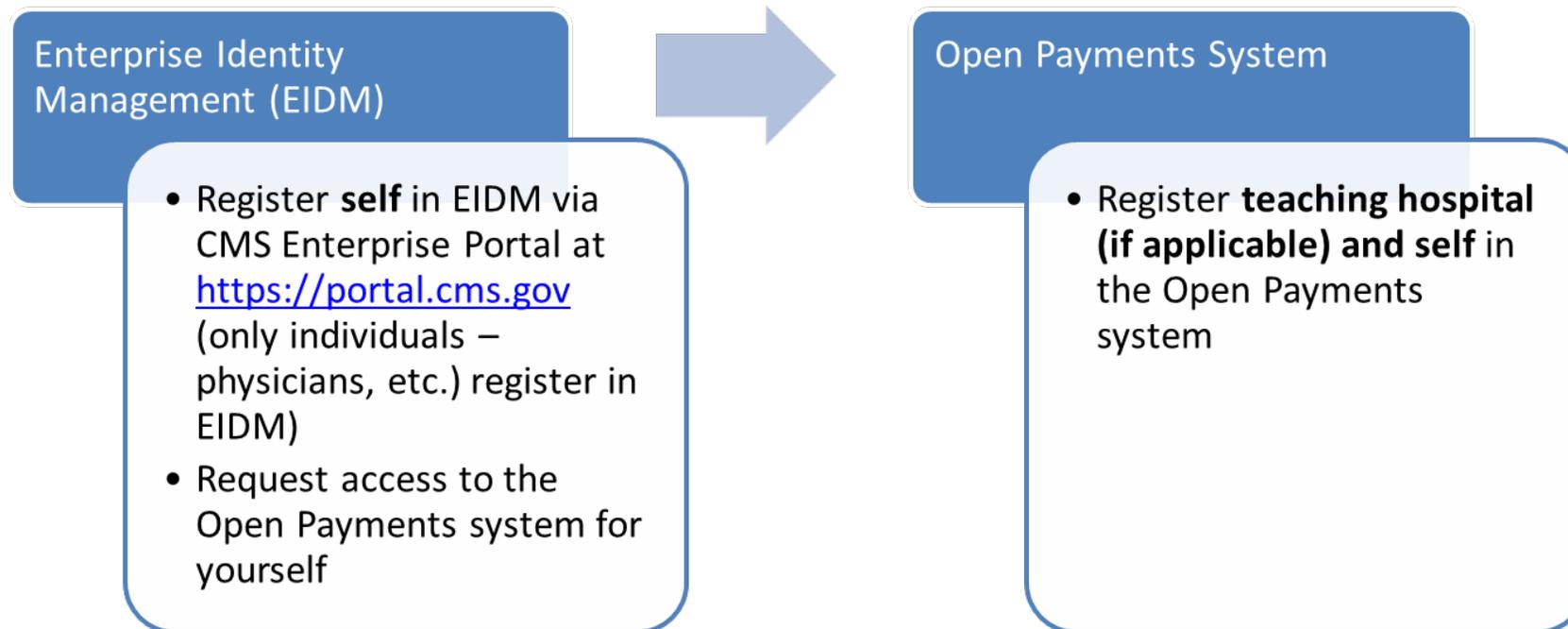
Your Role

- Covered recipients are provided an opportunity to review data that has been attributed to them before it is released to the public.
- In order to review data and take any actions on the data, covered recipients must register in the Open Payments system.
 - Once registered, there are a variety of options to accommodate timely and accurate review of the data, including nominating an authorized representative.
- Covered recipient participation in Open Payments is voluntary.
- CMS does encourage registration and participation as this ensures accuracy of the reported data.



The Registration Process

- Registration is a two step process
- Successful registration in **BOTH** the Enterprise Identity Management System (EIDM) and the Open Payments system is required to be able to perform any Open Payments system-related functions
- Registration is required in order for users to participate in the review and dispute process



Registration – Physicians

- Physicians who registered during previous program years do not need to register again
 - The EIDM locks accounts if there is no activity for 60 days or more. To unlock an account, go to the CMS Enterprise Portal, enter your user ID and correctly answer all challenge questions; you'll then be prompted to enter a new password.
 - The EIDM deactivates accounts if there is no activity for 180 days or more. To reinstate an account that has been deactivated, contact the Open Payments Help Desk.
- All physician profiles are vetted against CMS-approved sources to confirm that the registrant is a covered recipient physician
- Physicians are vetted using information supplied during Open Payments system registration, including:
 - First and last name
 - National Provider Identifier (NPI)
 - State license(s) information
 - Primary type (if no NPI is provided)
- Physicians will receive an email confirming vetting success or failure
- If vetting is unsuccessful, physicians should double check the information provided. If further assistance is needed, please contact the Open Payments Help Desk
- A physician may nominate one authorized representative to perform system functions on their behalf



Tips for Successful Vetting

- Make sure the name used for registration matches **exactly** with the name in the National Plan and Provider Enumeration System (NPPES)
 - Hospital based physicians **MUST** register as physicians, not as hospitals to view their records.
- Enter NPI, if you have one
 - Enter exactly as listed in NPPES for the current calendar year
- Enter all active state license(s)
- Provide as much information as possible – more information can speed vetting and ensure all records associated with the physician will be accurately matched to them



Registration – Teaching Hospitals

- Teaching hospitals who registered during previous program years do not need to register again
 - The EIDM locks accounts if there is no activity for 60 days or more. To unlock an account, go to the CMS Enterprise Portal, enter your user ID and correctly answer all challenge questions; you'll then be prompted to enter a new password.
 - The EIDM deactivates accounts if there is no activity for 180 days or more. To reinstate an account that has been deactivated, contact the Open Payments Help Desk.
- Teaching hospitals can designate up to 10 authorized representatives and authorized officials to act on their behalf in the Open Payments system
 - Please note that the maximum number of 10 is inclusive of both authorized representatives and authorized officials
- Tips for Teaching Hospitals:
 - Reference hospital information exactly as it appears on the published Teaching Hospital List located in the resources section of the Open Payments Website
 - Quick Reference Guides available on the Open Payments website



Your Role: Review, Dispute, & Corrections Process



Review, Dispute, & Correction

- Covered recipients may review, affirm and if necessary dispute attributed records
- Covered recipients may take the following actions on any data record:
 - Review records
 - Affirm records
 - Initiate disputes
 - Withdraw disputes
- Dispute resolution takes place outside of the Open Payments system
 - Physicians and Teaching Hospitals should work directly with reporting entities to resolve disputes
 - While reviewing records, contact information can be found on the “Record Detail” page; select the “Record ID” hyperlink (for each individual record)
 - **CMS does not mediate or facilitate disputes**



Review, Dispute, and Correction Timing

- The review, dispute, and correction period consists of:
 - 45 days for data review and dispute by covered recipients; resolutions can also be made by reporting entities
 - 15 days immediately following the 45-day period for reporting entities to continue to resolve disputes
- Covered Recipients have until the end of the 2018 calendar year to initiate disputes of data published in 2018.
- Records with a new dispute initiated after the 45-day review and dispute period will be published as original attested-to data in the initial data publication
- Additional details regarding disputes initiated after the 45-day review and dispute period are available in the *Open Payments System Quick Reference Guide – Review and Dispute Timing and Data Publication* (see Resources page of the Open Payments website)



Review, Dispute, and Correction Record Statuses

- Initiated – The dispute has been initiated by a covered recipient
- Acknowledged – The dispute has been acknowledged by the reporting entity
- Resolved – The dispute has been resolved by the reporting entity with updates made to the record
- Resolved No Change – The reporting entity and covered recipient have resolved the dispute in accordance with the Final Rule and no changes were made to the disputed record
- Withdrawn – The dispute has been withdrawn by the covered recipient



Your Role: Review & Dispute Actions



Review and Dispute Actions Overview

1. Review Records

- Review data records submitted by reporting entities

2. Affirm Records

- Confirm accuracy of data records

3. Initiate Disputes

- Initiate disputes for inaccurate data records

4. Withdraw Disputes

- Withdraw a previously initiated or acknowledged dispute



1. Review Records

- Covered recipients may review records attributed to them
- Go to the “Review and Dispute” tab and select the covered recipient you are associated with

Open Payments (Sunshine Act)
 Physician [Switch User Type](#)

Home **Review and Dispute** My Profile Help
 Review, Affirm, Dispute Account, Roles, Nominations

Review and Dispute - John Doe - 2013

[Back](#)

The table below contains only the records reported for the selected physician during the selected program year.
 The list is organized by reporting entity, including reporting entities that reported made payments or other transfers of value to the physician, and reporting entities in which the physician has ownership or investment interests.
 Only records that have been attested to by reporting entities will be displayed. Records that have not yet been attested to or are still being processed by a reporting entity will be made available for review only after attestation has been completed.
 Please note: There is a horizontal scroll bar below the table, for you to use to view more columns in the table. Use the filtering tools below to customize your view of the disputed records.
 To take an action related to a disputed record, select the check box in the first column of the table (next to the Entity Making Payment column). You may then perform the following actions on the selected record(s):

- Select "Affirm Record" to confirm the payment or other transfer of value, or ownership or investment interest.
- Select "Dispute Record" to dispute the payment or other transfer of value, or ownership or investment interest. You will need to provide a reasonable explanation for your dispute of the record.
- Select "Withdraw Dispute" to acknowledge that the physician is no longer disputing the record.

To return to the previous page, select "Back."

For more information about the review and dispute process, refer to the [Open Payments User Guide](#).

Physician Records

Entity Making Payment: Please Select Record ID: Please Select Date Of Publication: Please Select

Dispute ID: Review and Dispute Status: Payment Category: Affirmed (Yes/No):
 Initiated
 Acknowledged
 Resolved No Change
 Withdrawn
 Resolved
 General Payments
 Research Payments
 Ownership or Investment Interest
 Yes
 No
[Search](#) [Clear All](#)

Showing Results for: [All]
 Show Entries: 10

Select	Entity Making Payment	Record ID	Dispute ID	Payment Category	Form Of Payment or Transfer of Value	Nature Of Payment or Transfer of Value	Date of Payment	Amount(\$)	Delay in Publication of Research Payment Indicator	Last Modified Date	Current Record Standing
<input checked="" type="checkbox"/>	ADCDE Medical	10054		General Payments	Cash or cash equivalent	Consulting Fee	2013-11-04	\$5,000.00	No	2014-07-02	Attested
<input type="checkbox"/>	ADCDE Medical	10056		General Payments	Cash or cash equivalent	Grant	2013-10-21	\$7,500.00	No	2014-07-02	Attested
<input type="checkbox"/>	ADCDE Medical	10055		General Payments	Cash or cash equivalent	Education	2013-12-11	\$1,500.00	No	2014-07-02	Attested

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2. Affirm Records

- Affirming records means that the covered recipient confirms that the information in the record is correct
- Affirming records is optional
 - un-affirmed records will still be published
- Who can affirm records
 - Physicians
 - Physician authorized representatives
 - Note: physician authorized representatives must hold the “Dispute Records” access level to affirm, review, and/or dispute records associated with their physician
 - Teaching hospital authorized officials and authorized representatives
 - Principal investigators (any records they are associated with)
- Records that have been affirmed can still be disputed at any time



3. Initiating Disputes

- Covered recipients may initiate disputes on records they believe to be inaccurate
- The reporting entity will receive an email notification of the dispute initiation – they may then acknowledge the dispute in the Open Payments system
- The covered recipient will receive an email notification if the dispute has been acknowledged by the reporting entity
- The dispute status can be viewed in real-time on the Review and Dispute page in the Open Payments system



4. Withdrawing Disputes

- A dispute can be withdrawn after it has been acknowledged by the reporting entity
- Who can withdraw disputes
 - Physicians
 - Physician authorized representative
 - Note: physician authorized representatives must hold the “Dispute Records” access level to affirm, review, and dispute records associated with their physician
 - Teaching hospital authorized officials and authorized representatives
 - Principal investigators (any records they are associated with)
- *Open Payments System Quick Reference Guide: Physician and Teaching Hospital Review and Dispute Process* provides additional guidance (see “Resources” page of the Open Payments website at <https://www.cms.gov/OpenPayments/About/Resources.html>)



Your Role: Dispute Resolution



Resolving Disputes

- Reporting entities can resolve disputes in one of two ways:
 1. The dispute can be resolved with changes made to the disputed record
 2. The dispute can be resolved with no changes made to the disputed record
- Covered recipients receive email notifications of resolution status
- If the covered recipient believes that a dispute with a status of “Resolved” has not been sufficiently resolved, they may initiate another dispute on the same record



Resolving Disputes (cont.)

- **CMS does not mediate or facilitate disputes**
- Reporting entities and covered recipients should work outside of the Open Payments system to resolve disputes
- The “Review and Dispute” status of the record will automatically update to “Resolved” once the disputed record has been re-submitted and re-attested
- When the dispute status is updated, the covered recipient will receive an email notification



Review, Dispute, and Correction Impact on Data Publication

- Data corrections made by reporting entities **after** the correction period has closed will not be reflected in the June 2018 data publication
- Data corrections made by reporting entities may be made at any time; data will be updated in the next publication
- In the cases where a dispute cannot be resolved, the latest, attested-to data submitted by the reporting entity will be published and identified as “disputed”
- In addition to the annual data publication CMS updates the data at least once annually to include updates from disputes and other data correction made since the initial data publication.
 - Refresh data includes record updates, disputed records, and record deletions



Take Action

- Register in CMS Enterprise Portal (EIDM) and in the Open Payments system – required to review and dispute data
- For records associated with you in the Open Payments system:
 - Review records
 - Affirm records
 - Initiate disputes against any information you feel is incorrect
 - Participate in dispute resolution activities with reporting entities
 - Withdraw disputes if appropriate



System Enhancements

- Covered recipients will be able to see and will receive notifications when previously attested records available for review and dispute are deleted or being updated by reporting entity
- Review and Dispute Records Page now has two tabs:
 - Available for Review and Dispute: This tab displays all records that are currently available for review and dispute and are in “Attested” status.
 - Deleted or In Progress Records: This tab displays all records that were available for review and dispute in the current calendar year but were deleted or are in the process of being edited and are not yet available for re-review.
Note that dispute actions will not be allowed for these records as they are only available for viewing purposes.



Question & Answer Session



Resources

- Resources are available on the CMS Open Payments website (<http://www.cms.gov/openpayments>)
 - Resources include quick reference guides, user guides and tutorials for participation in Open Payments
- CMS listserv
 - Register via the Open Payments website to receive Open Payments email updates
- Open Payments Help Desk:
 - openpayments@cms.hhs.gov
 - 1-855-326-8366
 - Help Desk hours are noted on the Open Payments website



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