CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR PROGRAM INTEGRITY

Open Payments

2015 Open Payments Program Overview and Enhancements

OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY INTO INDUSTRY-PHYSICIAN FINANCIAL RELATIONSHIPS

January 2016

Agenda

- 2015 Open Payments Program and System Overview

- Getting Ready for Program Year 2015

- 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

  - Physicians, teaching hospitals, and principal investigators who want to review and possibly dispute payment records associated with them that have been reported to Open Payments

- Learning objectives:

  - Provide an overview of the 2015 Open Payments program year

  - Discuss the 2015 program timeline and system enhancements

2015 Open Payments Program and 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 entity 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 <u>AND</u> entities under common ownership with applicable manufacturers who also provide assistance and support 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

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

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

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 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 http://cms.gov/openpayments
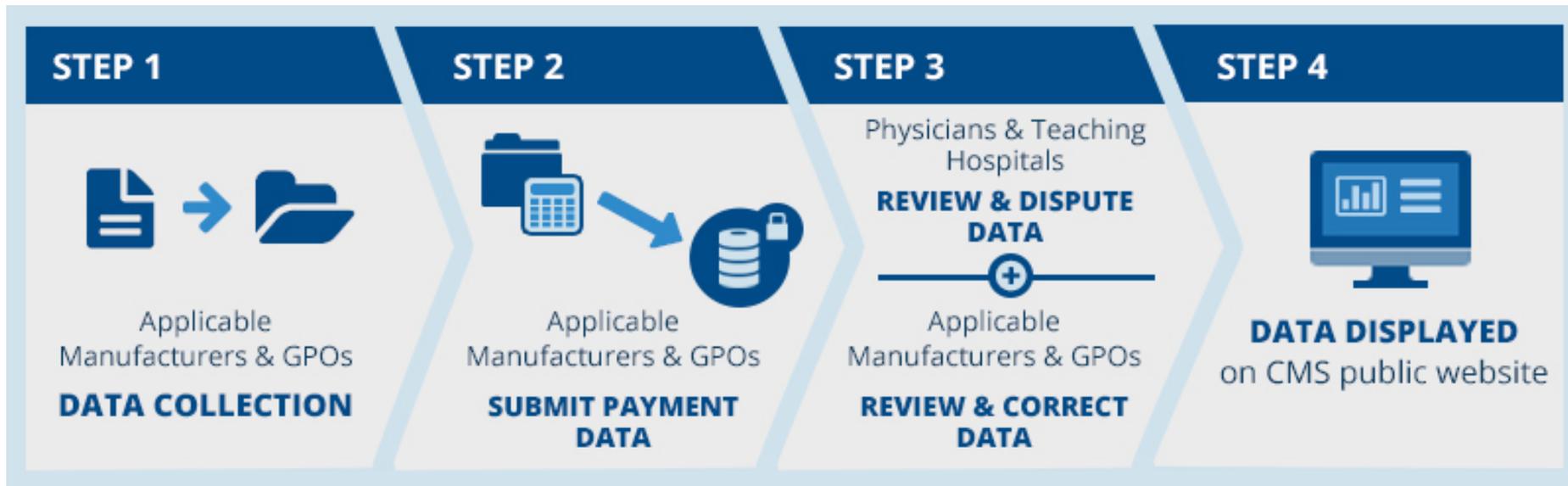
Physician Owners or Investors

- 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

Types of Payments

1. <u>General Payments</u>: Payments or other transfers of value not made in connection with a research agreement or research protocol

2. <u>Research Payments</u>: Payments or other transfers of value made in connection with a research agreement or research protocol

3. <u>Ownership or Investment Interest</u>: 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	STEP 2	STEP 3	STEP 4
Applicable Manufacturers & GPOs **DATA COLLECTION**	Applicable Manufacturers & GPOs **SUBMIT PAYMENT DATA**	Physicians & Teaching Hospitals **REVIEW & DISPUTE DATA** + Applicable Manufacturers & GPOs **REVIEW & CORRECT DATA**	**DATA DISPLAYED** on CMS public website

Reporting entities collect payment data for a program year, which runs from January 1 to December 31

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Reporting entities submit their data for the program year to the Open Payments system

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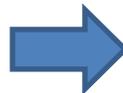
Physicians and teaching hospitals review and, if necessary, dispute submitted data. Reporting entities correct the data to resolve any disputes

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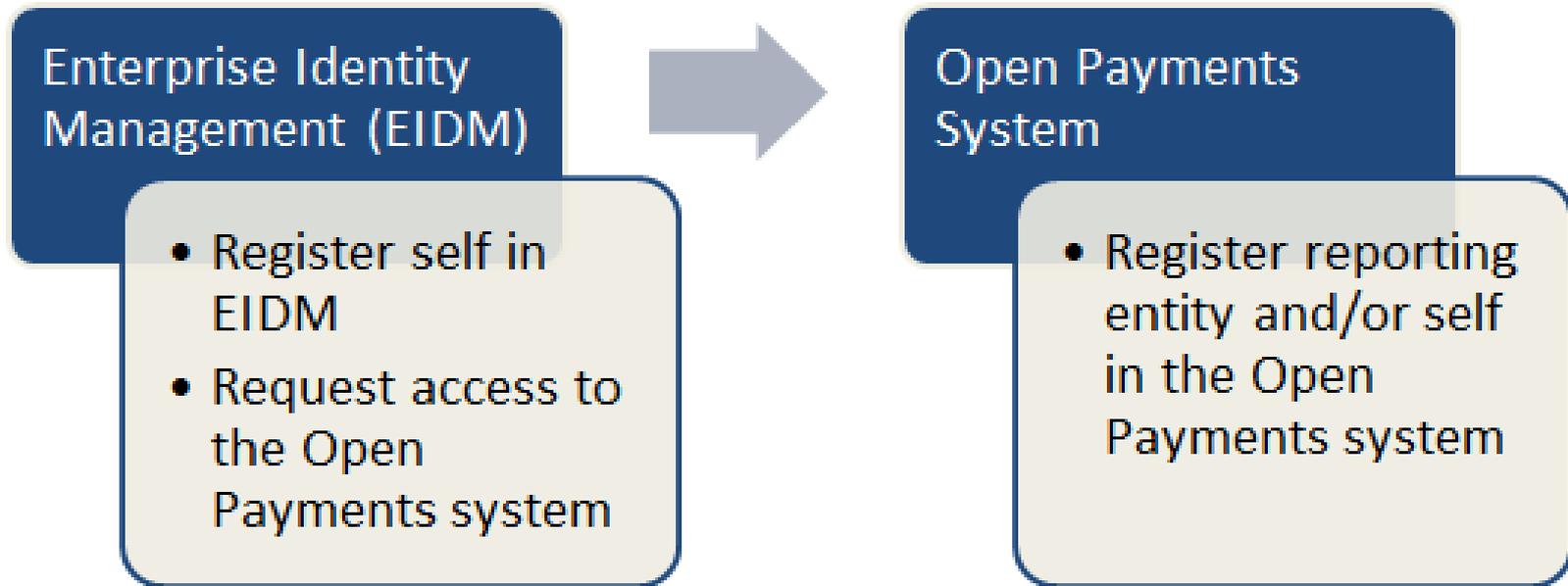Data for that program year is published for public viewing in accordance with the publication guidelines

Getting Ready for Program Year 2015

2015 Program Year Timeline

STEP 1	STEP 2	STEP 3	STEP 4
Applicable Manufacturers & GPOs **DATA COLLECTION**	Applicable Manufacturers & GPOs **SUBMIT PAYMENT DATA**	Physicians & Teaching Hospitals **REVIEW & DISPUTE DATA** ⊕ Applicable Manufacturers & GPOs **REVIEW & CORRECT DATA**	**DATA DISPLAYED** on CMS public website

2015 PROGRAM YEAR

January 1 – December 31, 2015	February 1 – March 31, 2016*	April – May 2016* / May – June 2016*	June 30, 2016

*Anticipated dates

Two-Step Registration Process

Enterprise Identity Management (EIDM)

- Register self in EIDM
- Request access to the Open Payments system

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Open Payments System

- Register reporting entity and/or self in the Open Payments system

1. Before you can register for the Open Payments system, you must first register yourself with CMS's Enterprise Identity Management System, EIDM and request access to the Open Payments system

2. Once you have successfully registered with EIDM, you can register with the Open Payments system

   If you registered for EIDM and requested access to Open Payments last year, 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

- For step-by-step instructions on how to register in EIDM, refer to the Quick Reference Guide "Enterprise Identity Management (EIDM) Registration," available on the Resources page on the Open Payments website

Open Payments System:
Reporting Entity Re-Certification

- For reporting entities that registered in any previous calendar year, re-certification is required in order to perform any Open Payments system functions

- Re-certification confirms that details in the Open Payments system are accurate

- Re-certification can only be performed by an active user who holds the officer role

- If a reporting entity does not have an active officer, contact the Open Payments Help Desk for assistance

- Outdated or inaccurate reporting entity profile information can be updated during re-certification

- Reporting entities due for re-certification are given a status of "Pending Recertification"

- Users can view all of the entities they are affiliated with, including entities due for recertification, by navigating to the "Manage Entities" tab in the Open Payments system

- Re-certification is not required from physicians or teaching hospitals

Open Payments System: Data Submission and Attestation

- Resources to help reporting entities ensure accurate data submission:

  – Validated Physician List

    - Accessed through the Open Payments system

  – Teaching Hospital List

    - 2016 Teaching Hospital list available for program year 2016 data collection

    - 2013-2015 Teaching Hospital lists also still available

    - All Teaching Hospital Lists available on the Resources page of the Open Payments website

Program Year 2015 System Enhancements

Program Year 2015 System Enhancements Overview

- This section provides a high-level overview of the Program Year 2015 Open Payments system enhancements

- For a detailed list of all enhancements, refer to the "Program Year 2015 Open Payments System Enhancements" document on the Open Payments website

Open Payments System Enhancements: Registration

1. Special characters are now allowed in all fields throughout the Open Payments system

   - All special characters allowed listed on the United States keyboard layout (ANSI) are permitted
   - Excludes fields where specific formatting is required

2. Reporting entity Registration ID now displayed in three locations:

   1. Manage Entities page
   2. Entity Details page
   3. Update Entity page (Officers only)

3. Reporting entities must provide contact information for review and dispute activities

   - Reporting entities must provide this during initial entity registration or during entity re-certification
   - Review and dispute contact information is made available to covered recipients to assist with the dispute resolution process
   - Information is displayed on the "Entity Details" page for reporting entities "Record ID" pages

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Open Payments System Enhancements: Data Submission and Attestation

1. Deleting previously attested-to records requires re-attestation
   - Records deleted by submitters will be placed in "Marked for Deletion" status
   - Records remain in "Marked for Deletion" status until re-attestation is complete; they will then be removed from the Open Payments system
   - Records that remain in "Marked for Deletion" status and are not re-attested to are visible to covered recipients and eligible for publication
2. Records in "System Processing" status can now be deleted if needed
3. Covered recipient information and recipient type cannot be changed after final submission occurs
   - Once a record has undergone final submission in the Open Payments system, the covered recipient identifying information cannot be changed
   - To change this information, the submitter must delete the record and resubmit a new record with the updated covered recipient information

Open Payments System Enhancements:
Data Submission and Attestation

1. When reporting a National Drug Code (NDC), it is now required to report the name of the covered drug or biological in the corresponding name field

2. NDC's must be reported in one of the following formats: 9999-9999-99; 99999-999-99; 99999-9999-9

3. Reporting entities can now download up to approximately 400k records from the Payment Category page into a CSV file

4. Users will now receive an email notification when submitted records fail the matching process

5. Research records with the recipient type of "Non-Covered Recipient Individual" will now pass the matching process as long as valid physician principal investigator information is supplied

6. Open Payments system will not accept records where the payment value is $0.00

   – For General and Research payment records, the payment value must be greater than zero

   – For Physician Owner/Investor payment records, either the "Dollar Amount Invested" OR the "Value of Interest" must contain a value greater than zero

Open Payments System Enhancements: Data Submission and Attestation

1. Records will be rejected when records containing covered recipient information for two different types of recipients (e.g., teaching hospital and physician) on the same record are submitted via bulk file upload. A record may contain data only in the fields applicable to the selected recipient type

2. For payments reported as Travel and Lodging under "Nature of Payment," the "State of Travel" is captured only if the "Country of Travel" is the United States

    –   A record containing a "Country of Travel" other than the United States that has data in the "State of Travel" field will be rejected

3. Records that indicate a "Y" in the "Principal Investigator Covered Recipient Physician Indicator" field must provide the corresponding principal Investigator identifying information which cannot be the same as the covered recipient physician's information (i.e., the physician and principal investigator in a record cannot be the same individual)

    –   The Open Payments system will generate an error if the covered recipient information is duplicated for any reported principal investigators

    –   If the covered recipient physician is also a principal investigator, that individual should be listed only as the covered recipient and the value of "Principal Investigator Covered Recipient Physician Indicator" should be set to "N"

Open Payments System Enhancements: Data Submission and Attestation

- Physician and principal investigator license number field character limit increased to 25 characters

For Reporting Entities	For Physicians
• Applies to both manual entry and bulk file upload submissions • Bulk File Upload: License format remains the same but field size increases to 28 to allow for state and hyphen • E.g. MD-XXXXXXXXXXXXXXXXXXXXXXXXX • Manual Data Entry: Select state from drop-down menu, enter up to 25 characters in "Physician License Number" or "Covered Recipient Physician License Number" field	• Affects registration and addition of new license numbers • When adding new license number, select state from drop-down menu and enter up to 25 characters in "License Number" field

Open Payments System Enhancements: Review and Dispute

1. Reporting Entity Review and Dispute contact information provided during registration is now made available to physicians and teaching hospitals through the "Record ID" page

2. Physicians and teaching hospitals can now download up to approximately 400k records from the Review and Dispute page into a CSV file

3. Reporting entities can also download a report of disputes initiated against their records

4. The physician user interface is being made more intuitive to facilitate identification of whether a physician was reported as recipient of a payment or as affiliated with a research payment as a principal investigator

Next Steps & Available Resources

Next Steps

For New Reporting Entities

- Register in EIDM and request access to the Open Payments system
- Register self and reporting entity (if applicable) in the Open Payments system
- Assign user roles
- Continue collecting 2015 payment data, and prepare to report it in early 2016

For Returning Reporting Entities

- Ensure EIDM account has not been deactivated due to inactivity and reset password if necessary
- Re-certify reporting entity information and provide required review and dispute contact information
- Confirm user roles
- Continue collecting 2015 payment data and prepare to report it in early 2016

For New Physicians and Teaching Hospitals

- Register in EIDM and request access to the Open Payments system
- Register self and reporting entity (if applicable) in the Open Payments system

For Returning Physicians and Teaching Hospitals

- Ensure EIDM account has not been deactivated due to inactivity and reset password if necessary
- No other actions required at this time

Available Resources

- Review available resources on the Resources page of the CMS Open Payments website at http://www.cms.gov/openpayments
  - Open Payments User Guide
  - Tutorials
  - Quick Reference Guides
  - Register for the CMS listserv via the Open Payments website to receive e-mail updates about Open Payments
- Open Payments Help Desk:
  - openpayments@cms.hhs.gov
  - 1-855-326-8366