

Open Payments (Sunshine Act) Program Overview and Prepare to Review Reported Data

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Target Audience & Learning Objectives

Target audience:

 Physicians, teaching hospitals, and physician office staff who need to view and possibly dispute data submitted about them by reporting entities (applicable manufacturers or applicable group purchasing organizations (GPOs))

Learning objectives:

- By the end of the teleconference, the participant should be able to identify the parts of the review, dispute and correction process
- By the end of the teleconference, the participant should be able to recognize how to take appropriate actions in the Open Payments system.



Open Payments Program and Timeline

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
 - An indirect payment is a payment or other transfer of value made by an applicable manufacturer, to a physician or teaching hospital, through a third party, where the applicable manufacturer 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

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 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

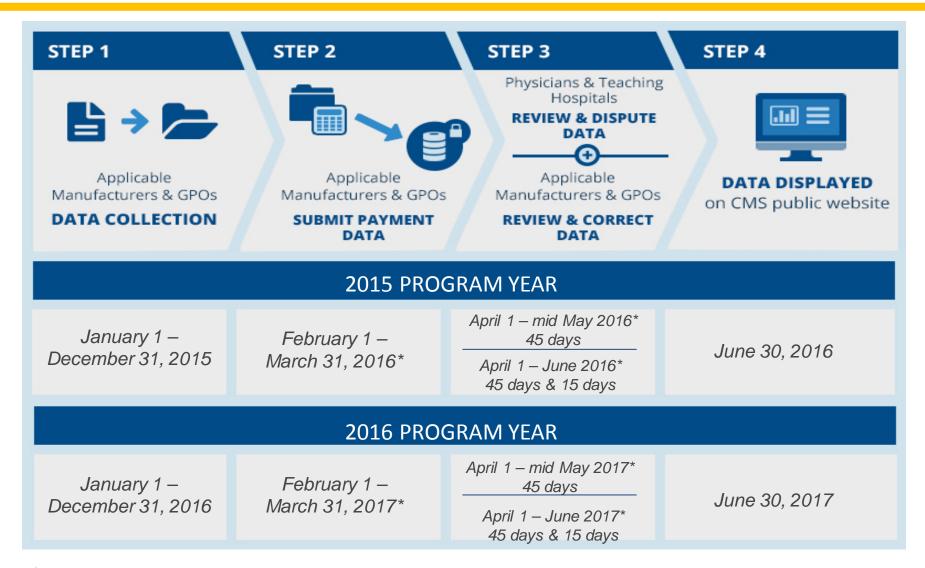
- Physicians who are owners or investors of an applicable manufacturer or applicable GPO
- Immediate family members who have ownership or investment interest in an applicable manufacturer or applicable GPO: spouse, natural or adoptive parent, child, or sibling, stepparent, stepchild, stepbrother, or stepsister, father, mother-, daughter-, son-, brother-, or sister-in-law, grandparent or grandchild, spouse of a grandparent or grandchild



Types of Payments

- General Payments: Payments or other transfers of value not made 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: Ownership or investment interest in an applicable manufacturer or applicable GPO

2015 and 2016 Program Year Timelines



*Anticipated date



Overview of Published Data

Total – All Program Years







Total Companies Making Payments

1,615



Total Physicians with Payment Records

682,000



Total Teaching
Hospitals
with Payment Records

1,144

Open Payments Registration Process Overview



Two-Step Registration Process

Enterprise Identity Management (EIDM)

- Register self in EIDM via CMS Enterprise Portal at https://portal.cms.gov (only individuals – physicians, etc.) register in EIDM)
- Request access to the Open Payments system for yourself

Open Payments System

 Register teaching hospital (if applicable) and self in the Open Payments system

Successful registration in <u>BOTH</u> EIDM and the Open Payments system is required to be able to perform any Open Payments system-related functions

Registration Process Overview

- To review and dispute any data reported in the Open Payments system prior to its publication, users must follow the two-step registration process to register for the Open Payments system
- Physicians and teaching hospitals who registered during program year 2013 or 2014 do not need to register again
- A physician may nominate one authorized representative to perform system functions on their behalf
- Teaching hospitals can designate up to 10 authorized representatives and authorized officials to act on its behalf in the Open Payments system

Registration Process Overview Cont.

- 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



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)
 - If you changed your name in NPPES after Dec. 31, 2015, use the earlier version of your name that was in NPPES
- Enter NPI, if available
 - 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

Review, Dispute, and Correction Process Overview



Review, Dispute, and Correction Overview

- Physicians, teaching hospitals, and principal investigators can review, then affirm and/or dispute records submitted about them by reporting entities
- Physicians, teaching hospitals, and principal investigators may take the following actions on any data record:
 - Affirm records
 - Initiate disputes
 - Withdraw disputes

Review, Dispute, and Correction Overview Cont.

- Dispute resolution takes place outside of the Open
 Payments system CMS does not mediate disputes
- New this year Reporting entities were required to enter contact information to facilitate the Review and Dispute process
 - Contact information can be found on the "Record Detail" page; select the "Record ID" hyperlink (for each individual record)

Review, Dispute, and Correction Timing

- The review, dispute, and correction period consists of:
 - -45 days for data review and dispute by physicians and teaching hospitals; corrections can also be made by reporting entities
 - 15 days immediately following the 45-day period for reporting entities to continue to make corrections
- Physicians, teaching hospitals, and principal investigators have until the end of the 2016 calendar year to initiate disputes of data published in 2016

Review, Dispute, and Correction Timing Cont.

- 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 http://www.cms.gov/openpayments)

Review, Dispute, and Correction Record Statuses

- <u>Initiated</u> The dispute has been initiated by a physician, teaching hospital, or principal investigator
- <u>Acknowledged</u> The dispute has been acknowledged by the reporting entity
- Resolved No Change The reporting entity and physician, teaching hospital, or principal investigator have resolved the dispute in accordance with the Final Rule and no changes were made to the disputed record
- Resolved The dispute has been resolved by the reporting entity with updates made to the record
- <u>Withdrawn</u> The dispute has been withdrawn by the physician, teaching hospital, or principal investigator

Review and 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

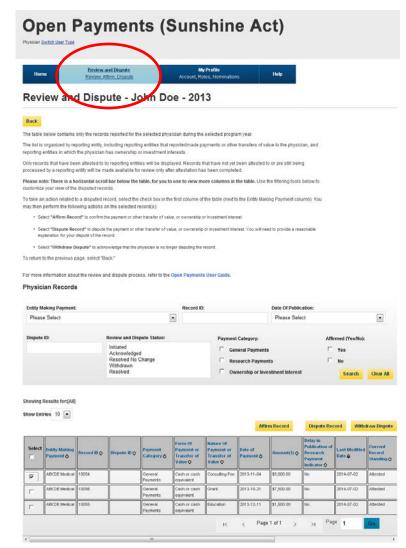
Initiate disputes for inaccurate data records

4. Withdraw Disputes

 Withdraw a previously initiated or acknowledged dispute

1. Review Records

- Physicians, teaching hospitals, and principal investigators may review data records associated with them
- Go to the "Review and Dispute" tab and select the physician, principal investigator, or teaching hospital you are associated with





2. Affirm Records

- Affirming records means that the physician, teaching hospital, or principal investigator 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 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)
- Records that have been affirmed can still be disputed at any time

3. Initiating Disputes

- Physicians, teaching hospitals, and principal investigators may initiate disputes on records they believe to be flawed
- The reporting entity will receive an email notification of the dispute initiation – they may then acknowledge the dispute in the Open Payments system
- The physician, teaching hospital, or principal investigator 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 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 http://www.cms.gov/openpayments)

Resolving Disputes

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 <u>no changes</u> made to the disputed record
- Physicians, teaching hospitals, and principal investigators receive email notifications of resolution status
- If the physician, teaching hospital, or principal investigator 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 will not mediate disputes
- Reporting entities, physicians, teaching hospitals, and principal investigators should work outside of the Open Payments system to resolve disputes
- If a dispute is resolved by re-assigning a record to another physician, teaching hospital, or principal investigator, the record will no longer appear in your view

Resolving Disputes (cont.)

- 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 physician, teaching hospital, or principal investigator will receive an email notification

Review, Dispute, and Correction Impact on Data Publication

- Data corrections made by reporting entities after the 45day review and dispute period, and the subsequent 15-day correction period will not be reflected in the June 30, 2016 public posting
- Data corrections made by reporting entities may be made at any time; data will be updated in the next publication
- CMS will update data at least once annually, in addition to the initial data 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"

Next Steps

- Register in CMS Enterprise Portal 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
 - Withdraw disputes if appropriate
 - Participate in dispute resolution activities with reporting entities

Available Resources

- Resources which are on the CMS Open Payments website (http://www.cms.gov/openpayments) "Resources" page include:
 - Open Payments User Guide
 - Open Payments System Quick Reference Guide
 - Physician and Teaching Hospital Review and Dispute Process
- 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**
 - Help Desk hours are noted on the Open Payments website

Question & Answer Session



Evaluate Your Experience

- Please help us continue to improve the MLN Connects® National Provider Call Program by providing your feedback about today's call.
- To complete the evaluation, visit http://npc.blhtech.com
 and select the title for today's call.

CME and CEU

This call is being evaluated by CMS for CME and CEU continuing education credit. For more information about continuing education credit, review the *CE Activity Information & Instructions* document available at the link below for specific details:

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/CEInfo-MLNConnects-TC.pdf



Thank You

- For more information about the MLN Connects® National Provider Call Program, please visit http://cms.gov/Outreach/NPC/index.html.
- For more information about the Medicare Learning Network®, please visit http://cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html.

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