PREP Course #5: All About the Physician Sunshine Act/ Open Payments

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CME Disclosure Statement

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• Course Director and Course Planner, Kevin Tracey, MD and Tina Chuck, MPH have nothing to disclose.

• Georgie MacMullen and Emmelyn Kim have nothing to disclose.
Course Objectives

• Discuss Physician Sunshine Act/Open Payment requirements.

• Demonstrate how to evaluate and manage public payment information.
Content

• Describe regulatory requirements of Open Payments
• Discuss the type of information required for reporting
• Describe the process for managing and disputing claims
• Discuss techniques and electronic applications that can assist in recording and reviewing disclosures
What is Open Payments?

Open Payments

Creating Public Transparency of Industry-Physician Financial Relationships

The Official Website for Open Payments (the Sunshine Act)

Open Payments creates greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals. The program requires that the following information is reported annually to CMS:

- Applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report payments or other transfers of value they make to physicians and teaching hospitals to CMS.
- Applicable manufacturers and applicable group purchasing organizations (GPOs) to report to CMS certain ownership or investment interests held by physicians or their immediate family members.
- Applicable GPOs to report to CMS payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.
Enhanced Transparency

http://blog.ombud.com/2013/03/13/sunshine-act-esignatures/
Intent of Open Payments

Discourage Incentive-Based Relationships

Achieving Affordable Care

Prevent Increased & Unnecessary Costs

Provide insight and transparency

http://blog.ombud.com/2013/05/09/prepare-physician-payment-sunshine-act/
Who Does this Impact?

http://blog.ombud.com/2013/05/09/prepare-physician-payment-sunshine-act/
How is “Physician” Defined?

• Doctors of medicine or osteopathy
• Doctors of dental medicine or dental surgery
• Doctors of podiatric medicine
• Doctors of optometry
• Chiropractors

Medical residents are excluded from this definition
How is Industry or “Applicable Manufacturer (AM)” Defined?

- Operate in US; and
- Manufactures covered drug, device, biologic or medical supply; or
- Entities that operate under common ownership with an AM and provide assistance/support (in manufacturing, marketing, promotion, sale or distribution of covered product)
Reporting Timeline

**DATA COLLECTION**
AUG. 1 – DEC. 31 2013
Applicable manufacturers and applicable GPOs will collect data about their financial relationships with physicians and teaching hospitals.

**REGISTRATION & SUBMISSION**
EARLY 2014
Applicable manufacturers and applicable GPOs will register and submit data to CMS via the Open Payments system.

**REVIEW & CORRECTION**
MID 2014
Physicians and teaching hospitals will register and review the data. Applicable manufacturers and applicable GPOs will update data, as needed.

**PUBLICATION**
LATE 2014
CMS will post the data on the public website.

→ September 30th

What Types of Data are Reported by Industry/AMs?

http://greenphire.com/blog/sunshine-act-readiness-implications-for-clinical-trials/6768ac46-e652-494c-9e26-35c4c11a2bcb
Reporting Examples

Reporting of any TOV from applicable manufacturers to covered recipients.

Dr. Smith attends lunch hosted by an applicable manufacturer with her clinical team to discuss a new drug. She’s impressed by it, and spends 12 months traveling and speaking to promote it, with expenses and honoraria paid by the manufacturer.

Note: Items underlined are reportable payments or transfer of values
Treating Research Payments Differently

- Providing a balance between transparency and innovation is very important for this program
- Applicable manufacturers and applicable GPOs will report the total amount of the research payment included in a research protocol or agreement provided to a teaching hospital, physician, or non-covered recipient entity
- Additionally, applicable manufacturer or applicable GPOs will report the names of physician principal investigators involved in the research study
Delayed Reporting for Research

• AMs must indicate eligibility to CMS
• Certain research payments/TOV under product R&D agreement may be delayed from publication
  → R & D of a NEW drug, device, biologic, med supply
  → Clinical investigations regarding a NEW DDBMS (does not include investigations related to new applications of existing products)
• Info. must be reported to CMS by the 1st reporting date after FDA approval or 4 yrs after payment/TOV, (whichever is earlier)
What are Some Concerns?

• May be misleading to public
• Impact on:
  • Physician collaboration with industry
  • Medical research?
• Compliance costs
• Institutional/individual conflicts of interest

➔ Be prepared to answer questions!
Managing and Disputing Claims
Physician/Teaching Hospital Registration Overview & Instructions
Registration is required for physicians and teaching hospitals to review or dispute information reported about them by applicable manufacturers and GPOs:

Registration will be conducted in two phases this first reporting year:

**Phase 1**  CMS Portal Registration (EIDM) Began July 1, 2014

**Phase 2**  Open Payments System Registration; and, Review and Dispute Process
EIDM registration is required for access to the Open Payments system

EIDM registration process is the same for all users

You may already have an EIDM account if you use the Health Insurance Oversight System (HIOS), the Medicaid and CHIP Program System (MACPro), or other CMS systems
Phase 1: EIDM Identify Verification Overview

CMS’ EIDM is how CMS verifies user identities

Identity verification is the process of providing information (e.g. identity history, Credentials, or documents) for the purpose of providing that a person is the same person he or she claims to be

Individuals requesting electronic access to CMS protected information or Systems must first have their identities verified

OOW questions asked for private data and contain information pulled from your Credit report such as mortgage lender name, previous employer name and auto lender name

OOW questions and answers are shared only between the EIDM registrant and the Verification service provider. Experian; the information is not stored in EIDM or in the Open Payment System
Phase 1: **Key EIDM Registration Steps**

Key steps in the process:

1. **Go to** CMS Enterprise Portal (https://portal.cms.gov) and Select “New User Registration”

2. **Accept** Terms & Conditions

3. **Enter** Personal Information

4. **Select** User ID, Password, and Challenge Questions

5. Registration **Complete**

6. **Log out**
Phase 1: Confirmation Email

From: donotreply@cms.gov
To: Doyle, Jennifer J (CGI Federal)
Cc: 
Subject: Enterprise Identity Management System (EIDM) Account Registration

Dear Jane Taylor

Thank you for registering. The User ID that you have chosen is OUTUSER21. You can log in to the CMS Portal using the following link with your User ID and Password. Please keep this E-mail for your records.
https://portalval.cms.gov

Thank you,
CMS Enterprise Identity Management System

Please do not reply to this system generated E-mail.
Phase 1: Unsuccessful EIDM Registration

1. Individuals with addresses outside of the United States may not register successfully in EIDM

2. They should contact the Open Payments Help Desk for assistance with EIDM registration

3. Any additional EIDM issues should be directed to the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366, Monday through Friday, from 7:30 a.m. to 6:30 p.m. (CT), excluding Federal holidays
Phase 2: Open Payments System Registration

Began on July 14, 2014

Physicians and teaching hospitals use EIDM registration credentials to Register in the Open Payments system

Once physicians are registered in the Open Payments system, they are Able to participate in the review and dispute process

Note: EIDM registration is a required first step before Open Payments System registration
Physician Registration—Open Payments System Overview

Physicians may register for the Open Payments system if they wish to review and dispute any information reported about them in the Open Payments system prior to its publication.

Registration creates a profile for the physician in the Open Payments system.

All physician profiles will be vetted to ensure the physician’s identity. Vetting occurs after the physician completes and submits his or her profile in the Open Payments system.

If the physician profile is modified, it may trigger re-vetting.
Phase 2: Physician Registration—Open Payments System Overview (Cont.)

• Physicians will be vetted using profile information including:
  – Business address
  – National Provider Identifier (NPI)
  – Drug Enforcement Agency (DEA) number
  – State license information

• Vetting will take roughly 24 hours

• Provide as much information as possible, as more information speeds vetting and ensures all records associated with you will be matched to your profile

• Vetting must be successful in order for the physician to perform actions within the Open Payments system before the authorized representative can do anything in the Open Payments system

• If vetting remains unsuccessful, physicians should contact the Open Payments Help Desk for assistance (openpayments@cms.hhs.gov)
Key Steps in the process:


2. Select “Open Payments”

3. On the “Welcome” page, click on the “Create My Profile” button

4. On the “Create Profile” page, scroll to the bottom of the page and click on the “Continue” button to begin the registration process by entering personal practice information

5. Follow the on-screen instruction to complete your registration and Designate an authorized representative (optional)

6. Select and “submit” button on the “Review and Submit Profile” page
Phase 2: On-Screen Registration Confirmation

Open Payments (Sunshine Act)

Physician: Switch User Type

Create Profile

- Select Profile Type
- Physician Information
- Authorized Representative
- Review and Submit Profile

You have successfully created your profile as a physician.

John Doe

You may now

- Go to Open Payments Home.
- Refer to the Open Payments User Guide for further information.

Note: You will not be able to take any actions in the Open Payments system related to this profile until the profile is registered. The profile will be registered once your identity as a physician is successfully vetted. This vetting process should be completed within 24 hours.

If you are not successfully vetted, contact the Open Payments Help Desk (openpayments@cms.hhs.gov) for next steps. More information on vetting is available in the Open Payments User Guide.
## Review & Dispute Review and Instructions

### Scenario

| ABCDE Medical Submits 1 record for Dr. Jones totaling $5,000 | Dr. Jones initiates a dispute for this record | ABCDE Medical acknowledges the dispute and begins researching the dispute | ABCDE Medical corrects the record, re-attests and marks the dispute as resolved | Dr. Jones receives an email notification that the dispute has been resolved |
• Corrections made after the initial 45 day review and dispute period will not be reflected in the Sept. 2014 public posting.

• Data corrections by reporting entities may be made at any time and the corrections will be updated in the next publication of the data.

• CMS will update data from the current and previous year at least once annually, in addition to the initial data publication followed the data submission.

• In cases where a dispute cannot be resolved, the latest, attested-to data submitted by the reporting entity will be published and identified as under dispute.
• Physicians can review and dispute records of payments or other transfers of value and physician ownership or investment interests submitted about them by reporting entities.

• Reporting entities submitted data for the period of August 1 – Dec. 31, 2013.

• Physicians will need to work directly with reporting entities to resolve disputes initiated.

• CMS will not mediate the dispute resolution process between a physician and reporting entity.

• In Open Payments system, users may perform certain actions for each record.
Review and Dispute Overview (Cont.)

• The review and resolution period for the program year 2013:
  – 45 days for review, dispute, and correction
  – 15 additional days (immediately following the 45 day period) for reporting entities to continue to make corrections

• Changes made to records during this period will be included in the Sept. 2014 data publication
• Records that remain under dispute at the end of this period will be identified as disputed in the Sept. 2014 data publication
• Review and resolution capabilities are open year-round
• Disputes initiated after the 45-day review and dispute period may not be included in the Sept. 2014 publication of data, but will be included in the next publication of data
How the dispute initiation and resolution timing affects the public display of data, providing that the dispute required correction to the data to be resolved.

Example:
If a physician disputes a record within 45-day initial review, dispute, and correction period (7.14.14 – 8.27.14) and if the dispute status of the record 9.11.14 is:
✓ Resolved then the corrected record is published as a non-disputed on 9.30.14
✓ Not resolved then the originally reported record is published as disputed in 9.30.14
• Any data that is timely disputed, if not corrected by the reporting entity, will be made public but will be identified as disputed.

• CMS will not mediate disputes between physicians and reporting entities.

• You may dispute or affirm any record that appears in your Open Payments view.

• Visit the “Dispute and Resolution” page of the Open Payments Website [https://go.cms.gov/openpayments](https://go.cms.gov/openpayments) for more information.
Welcome to the Open Payments System
Review and Dispute Landing Page

Open Payments (Sunshine Act)

Review and Dispute - John Doe - 2013

MLN Connects
a screenshot of the view record drilldown page that highlights hitting the back button to navigate
Review and Affirm Overview Process

2. Select Open Payments
3. Select “Review and Dispute” Tab
4. Select the Teaching Hospital or Physician and Program Year
5. View Records and Select Records to Affirm
6. Review Records Marked for Affirmation and select “Affirm Records”

Use the Open Payments User Guide and the Quick Reference Guide for on how to accept/reject a nomination.

***Step-by-step instructional webinar coming soon.***
Reminders for Reviewing and Affirming Records

- Make sure you have:
  - Registered in EIDM
  - Successfully registered in the Open Payments system
- Physicians or physician authorized representatives may affirm records
- Physician authorized representatives must hold the “Dispute Records” access level to affirm, review, and dispute records
- Authorized officials and authorized representatives for teaching hospitals have the same access levels and all may affirm records
- Records that have been affirmed can still be disputed at any time
Initiating Disputes Overview

- Physicians and teaching hospitals will have 45 days to initiate disputes for those disputes to be included in Sept. 2014 data publication.
- Once a dispute is initiated, the reporting entity will receive an email notification.
- The reporting entity may acknowledge the dispute in the Open Payments system.
- The physician or teaching hospital 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 screen in the Open Payments system.
Review and Dispute Record Statuses

- **Initiated** – The dispute has been initiated by the physician or teaching hospital
- **Acknowledged** – The dispute has been acknowledged by the reporting entity
- **Resolved No Change** – The reporting entity and physician or teaching hospital 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
- **Withdrawn** – The dispute has been withdrawn by the physician or teaching hospital
Review and Dispute Record Process

2. Select Open Payments
3. Select “Review and Dispute” Tab
4. Select Physician or Teaching Hospital and Program Year
5. View Records and Select Records to Dispute
6. Review Records Marked for Dispute, Enter Dispute Reason and Select “Send Dispute”

Use the Open Payments User Guide and the Quick Reference Guide for on how to accept/reject a nomination.

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Review and Dispute Record Process

2. Select Open Payments
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Resolving Dispute Overview

Reporting entities can resolve disputes in one of two ways:

1. The dispute can be resolved with **no changes** made to the disputed record
2. The dispute can be resolved **with updates** made to the disputed record
Resolving Dispute Overview (Cont.)

- CMS will not mediate disputes between physicians/teaching hospitals and reporting entities.
- Reporting entities, physicians, and teaching hospitals should work outside of the Open Payments system to resolve disputes.
- If a dispute is resolved by re-assigning a record to another physician or teaching hospital, the record will no longer appear in your view.
Withdrawing Dispute Overview

- Physicians and teaching hospitals can withdraw disputes
- A dispute can be withdrawn after it has been initiated or acknowledged
- The reporting entity will receive an email notification when a dispute has been withdrawn
Withdrawing Dispute Process

2. Select Open Payments
3. Select “Review and Dispute” Tab
4. Select Physician or Teaching Hospital and Program Year
5. View Records and Select Records to Withdraw
6. Review Records Marked for Withdrawal, and Select “Withdraw Disputes”

Use the Open Payments User Guide and the Quick Reference Guide for on how to accept/reject a nomination.

***Step-by-step instructional webinar coming soon.***
CMS Mobile Apps

Physician

Open Payments

Industry

Open Payments

Add Payment

View Payments

Read QR Code

Reports & Statistics

Personal Profile

Manage Vendors

Add Payment

View Payments

Read QR Code

Reports & Statistics

Select Vendor:

Select Form of Payment

Select Nature of Payment

Select a year to view sum of payments per vendor:

Please fill out the form below:

Select Vendor:

Create Vendor

Form of Payment or Transfer of Value:
Conclusion

• Unintended consequences
• Kinks along the way
• Step in the right direction

http://www.realityclarkcounty.com/2013/07/21/the-consequences-of-supporting-the-crc/

http://www.opensecrets.org/news/2011/03/cceo-3-16-2011/

http://www.banklawyersblog.com/.a/6a00d8341c652b53ef0120a5bc78f9970b-popup
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Questions?
Citations


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• http://www.duanemorris.com/alerts/research-related_payments_and_the_physician_payment_sunshine_act_4780.html


• http://www.policymed.com/2013/02/physician-payment-sunshine-act-final-rule-research.html