User Guide

OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY INTO INDUSTRY-PHYSICIAN FINANCIAL RELATIONSHIPS

July 2014

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PART I: INTRODUCTION

INTRODUCTION

Purpose of the Open Payments User Guide

This Open Payments User Guide includes definitions, descriptions, screenshots, tools, and tips designed to help applicable manufacturers, applicable group purchasing organizations (GPOs), physicians, and teaching hospitals better understand how to comply with Open Payments (the Sunshine Act), including how to operationalize the collecting and reporting of data.

As the Open Payments system develops, the User Guide will be updated accordingly. The User Guide consists of the following chapters:

- **Introduction to Open Payments**

- **Introduction to Reporting and Data Collection**

- **Applicable Manufacturer and Applicable Group Purchasing Organization (GPO) Registration**

- **Data Submission and Attestation**

- **Audits**

- **Non-Compliance and Penalties**

- **Physician and Teaching Hospital Registration**

- **Review and Dispute**

- **Public Data Publishing**

- **Additional Information and Resources**

Revision History

Version	Date Published	Description	Version Updates
1.0	August 2013	Initial Release	Chapters 1, 2, 3, & 4
2.0	June 2014	Update	Chapters 1, 2, 3, 4, & 7
3.0	July 2014	Update	Chapters 5, 8, & 9

Chapter 1: Introduction to Open Payments (the Sunshine Act)

This introduction chapter provides general information about the program, an overview of the Open Payments system, and an explanation of how to determine if an organization is required by Open Payments to report certain payments or other transfers of value to physicians and teaching hospitals, or certain physician ownership or investment interests.

Section 1.1: Program Overview

1.1a: What is the Affordable Care Act Section 6002?

Section 6002 of the Affordable Care Act [P.L. 110-148] amends Title XI of the Social Security Act to add Section 1128G, which mandates the creation of a program for (1) reporting payments and other transfers of value made to covered recipients and physician owners or investors, by manufacturers of drugs, devices, biologicals, or medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP); and (2) reporting ownership or investment interests held by physicians or their immediate family members in applicable manufacturers and applicable GPOs, as well as reporting payments or transfers of value made by these applicable manufacturers and applicable GPOs to these physicians.

This program establishes a system for annually reporting this data to the Centers for Medicare and Medicaid Services (CMS).

1.1b: What is the Purpose of Open Payments (the Sunshine Act)?

Open Payments is a national disclosure program that promotes transparency by publishing data on the financial relationships between the healthcare industry (applicable manufacturers and applicable GPOs; together referred to as reporting entities) and healthcare providers (physicians and teaching hospitals) on a publicly accessible website. This publically available website is designed to increase access to, and knowledge about, these relationships and provide the public with information to enable them to make informed decisions. The public can search, download, and evaluate the reported data.

Disclosure of the financial relationships between industry and healthcare providers is not intended to signify an inappropriate relationship, and Open Payments does nothing to prohibit such transactions. Collaborations among the medical product industry, physicians, and teaching hospitals contribute to the design and delivery of life-saving drugs, devices, biologicals, and medical supplies. However, these relationships may also influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care and may potentially lead to increased healthcare costs. While disclosure alone is not sufficient to differentiate between the beneficial financial relationships and those that may create conflicts of interests, transparency will shed light on the nature and extent of the relationships that exist and discourage development of inappropriate relationships.

1.1c: Who Participates in Open Payments (the Sunshine Act)?

Open Payments requires participation from certain manufacturers of drugs, devices, biologicals, or medical supplies covered under Title XVIII of the Social Security Act (Medicare), or a State plan under Title XIX (Medicaid) of XXI of the Social Security Act (CHIP) and certain GPOs.

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:

- Payments or other transfers of value made to physicians and teaching hospitals.

- Certain ownership or investment interests held by physician owners or investors, or their immediate family members.

Applicable GPOs are required to annually report to CMS:

- Payments or other transfers of value made to physicians.

- Certain ownership or investment interests held by physician owners or investors and their immediate family members.

While not required to report in the program, Open Payments encourages physicians and teaching hospitals to participate by tracking their financial relationships with applicable manufacturers and applicable GPOs and reviewing data reported about them in the Open Payments system to ensure the accuracy of the information.

Open Payments also encourages the general public and healthcare consumers to access, review, and use the data to make informed healthcare decisions.

1.1d: Key Deadlines for Open Payments Program Year 2013

For the Open Payments 2013 program year, applicable manufacturers and applicable GPOs were required to begin collecting data documenting their financial relationships with certain physicians and teaching hospitals beginning on August 1, 2013, and ending on December 31, 2013.

Open Payments registration and data submission **for applicable manufacturers and applicable GPOs** was conducted in a two-phased approach for this first reporting year:

- **Phase 1** (February 18 through March 31, 2014) included industry registration in CMS's Enterprise Portal (https://portal.cms.gov/), the gateway to CMS's Enterprise Identity Management system (EIDM), and submission of corporate profile information and aggregate information about 2013 payment or other transfer of value and ownership/investment interest data.

- **Phase 2** (early June through June 30, 2014) includes industry registration in the Open Payments system, submission of detailed information about 2013 payment or other transfer of value and ownership/investment interest data, and legal attestation to the accuracy of the data.

Open Payments registration **for physicians and teaching hospitals**, as well as review and dispute for all users, is also being conducted in a two-phased approach for this first reporting year:

- **Phase 1** (begins in early June 2014) includes physician and teaching hospital registration in CMS's Enterprise Portal (https://portal.cms.gov/), the gateway to EIDM.

- **Phase 2** (begins mid-July and extends for 45 days) includes physician and teaching hospital registration in the Open Payments system as well as review, dispute, and correction functionality for all users.

CMS will release the 2013 data publicly by September 30, 2014.

Section 1.2: Determining if an Entity is an Applicable Manufacturer or Applicable GPO

Open Payments requires certain entities that make payments or other transfers of value to physicians or teaching hospitals to report relevant data regarding the payment or other transfer of value to CMS.

To determine if a particular entity is required to report, follow these steps:

Step 1: Determine if the entity <u>operates in the United States</u> (including any territory, possession, or commonwealth of the United States). See the reference guide in **Figure 1.1.**

Step 2: Determine if the entity engages in <u>activities</u> of a Type 1 or Type 2 applicable manufacturer. See the reference guide in **Figure 1.1.**

Step 3: Determine if the entity's products are covered drugs, devices, biologicals, or medical supplies or <u>covered products</u>. See the reference guide in **Figure 1.1.**

Step 4: If the entity possesses the characteristics illustrated in Figure 1.1, **the entity is determined to be an applicable manufacturer in Open Payments**.

If the entity does not meet these characteristics, the entity is not determined to be an applicable manufacturer. Note: The entity still may be an applicable GPO in Open Payments.

Proceed to Step 5 to determine if the entity is an applicable GPO.

Step 5: Determine if the entity <u>operates in the United States</u> (includes any territory, possession, or commonwealth of the United States). See the reference guide in **Figure 1.2.**

Step 6: Determine if the entity engages in <u>activities</u> of an applicable GPO. See the reference guide in **Figure 1.2.**

Step 7: Determine if the entity's products are covered drugs, devices, biologicals, or medical supplies or <u>covered products.</u> See the reference guide in **Figure 1.2.**

Step 8:   If the entity possesses the characteristics illustrated in **Figure 1.2, the entity is determined to be an applicable GPO in Open Payments.**

If the entity does not possess the characteristics as illustrated in **Figure 1.2,** the entity is not determined to be an applicable GPO in Open Payments.

Figure 1.1 provides a reference guide for determining if a drug, device, biological, or medical supply manufacturer is an applicable manufacturer in accordance with Open Payments. **Figure 1.1** also outlines the characteristics for two types of applicable manufacturers.

Figure 1.1: Determining if an Entity Is an Applicable Manufacturer

Characteristic	Type 1 Manufacturer IF	Type 2 Manufacturer IF
Operate in US?	• Entity's physical location is within the United States and/or it conducts activities within the United States. This includes any territory, possession, or commonwealth of the United States.	• Same as Type 1 Manufacturer
Activities	• 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.	• Exists under common ownership with a Type 1 applicable manufacturer AND • Provides assistance or support to such an entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply.
Covered Products	• Reimbursed by Medicare, Medicaid, or Children's Health Insurance Program AND • If the product is a drug or biological, and it requires a prescription (or doctor's authorization) to administer OR • If the product is a device or medical supply, and it requires premarket approval or premarket notification by the FDA.	• Same as Type 1 Manufacturer

Figure 1.2 provides a reference guide for determining if a drug, device, biological, or medical supply purchasing entity is an applicable GPO in accordance with Open Payments. Figure 1.2 also outlines the characteristics of applicable GPOs.

Figure 1.2: Determining if an Entity Is an Applicable GPO

Characteristic	Group Purchasing Organization IF
Operate in US?	• Entity's physical location is within the United States and/or it conducts activities within the United States. This includes any territory, possession, or commonwealth of the United States.
Activities	• 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.
Covered products	• Reimbursed by Medicare, Medicaid, or Children's Health Insurance Program AND • If the product is a drug or biological, it requires a prescription (or doctor's authorization) to administer OR • If the product is a device or medical supply, it requires pre-market approval or pre-market notification by the FDA.

Section 1.3: Who Are Entities Reporting On

Applicable manufacturers and applicable GPOs are required to report payments or other transfers of value to covered recipients and physician owners/investors. Covered recipients in Open Payments include physicians (except for physicians who are bona fide employees of the reporting entity) and teaching hospitals. For the purposes of Open Payments, physicians are defined as doctors of medicine or osteopathy practicing medicine or surgery, doctors of dental medicine or dental surgery practicing dentistry, doctors of podiatric medicine, doctors of optometry, or chiropractors, all legally authorized to practice by their state.

A teaching hospital is any institution that received a payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs under 1886(d) (5) (B), 1886(h), or 1886(s) of the Social Security Act during the last calendar year for which such information is available.

Additionally, applicable manufacturers and applicable GPOs are required to report ownership or investment interests in the entity held by a physician (referred to as a physician owner or investor) or the physician's immediate family members, and report payments or transfers of value to these physicians holding ownership or investment interests. A physician's immediate family member is the physician's (1) spouse; (2) natural or adoptive parent, child, or sibling; (3) step-parent, step-child, step-brother, or step-sister; (4) father-, mother-, daughter-, son-, brother-, or sister-in-law; (5) grandparent or grandchild; or the (6) spouse of a grandparent or grandchild.

Section 1.4: Open Payments System Overview

The Open Payments system is the tool developed to support Open Payments. Users will interact with the system to perform a number of functions based on their role.

The Open Payments system will be available for applicable manufacturer and applicable GPO registration starting in June 2014. Registration for physicians and teaching hospitals will be available in July 2014. **Figure 1.3** provides a high-level timeline for the system release dates and the actions associated with each release for reporting year 2013.

Figure 1.3: High-Level Timeline for Open Payments

Phase	Date	Description
Data Collection	AUG 1 - DEC 31, 2013	Applicable manufacturers and applicable GPOs collect data about their financial relationships with physicians and teaching hospitals.
Phase 1 Industry Registration and Submission	FEB. 18 - MAR 31, 2014	Applicable manufacturers and applicable GPOs register in CMS's Enterprise Portal (the gateway to EIDM) and submit via email corporate profile information and aggregated 2013 data.
Phase 2 Industry Registration and Submission	EARLY JUN - JUN 30, 2014	Applicable manufacturers and applicable GPOs register in the Open Payments system, submit detailed 2013 data, and legally attest to the accuracy of the data.
Phase 1 Physician and Teaching Hospital Registration	EARLY JUN 2014	Physicians and teaching hospitals register in CMS's Enterprise Portal (the gateway to EIDM) and request access to the Open Payments system.
Phase 2 Physician and Teaching Hospital Registration	JULY-AUG 2014	Physicians and teaching hospitals register in the Open Payments system.
Review and Dispute	JULY-AUG 2014	Physicians and teaching hospitals review and dispute data in the Open Payments system. Applicable manufacturers and applicable GPOs correct data or dismiss disputes as appropriate.
Publication	FALL 2014	CMS posts the data on the public website.

1.4a: Open Payments Browser Requirements

The Open Payments system is a web-based application and should be run **only** on Internet Explorer, version 8 or higher.

1.4b: Functionalities within the Open Payments System

Users will perform functions within the Open Payments system based on what is required of them by the program and their specific user roles. Most of the functions required by Open Payments will require interaction with the Open Payments system.

Key functions of the Open Payments system users include the following:

- For applicable manufacturers/applicable GPOs: Register in the system, submit data into the system, verify the data, and attest to the accuracy of the data.

- For physicians/teaching hospitals: Register in the system, review the data supplied by applicable manufacturers and/or applicable GPOs, and dispute, if necessary, data upon review.

This Guide will cover functions of the system in detail in each chapter.

When working in the Open Payments system, it is important to remember to never use the navigation buttons on your browser toolbar. Only use the navigation buttons (Back buttons) within the Open Payments system itself.

1.4c: Setting Email Filters to Accept Open Payments Emails

The Open Payments system will transmit emails to communicate to users. Take precautions to ensure that these emails are not directed into your junk mail or spam folders. Open Payments notification emails will come from the address OpenPaymentsNotification@cms.hhs.gov.

1.4d: Accessibility Guidance

This section provides some basic guidance for keyboard and JAWS screen reader users. While not all screen reader users use JAWS and not all JAWS users have the same version, this guidance should be applicable to other screen readers and most versions of JAWS.

1.4d(1): "Skip to Main Content" Link

The "Skip to main content" link provides a shortcut to the main content of the page. Using the link allows a keyboard user to reach the core information on the page without having to tab through the global portal banner.

Screen reader users can use the link to jump their screen reader to the start of the portal content and skip the global banner area on each page. Activating the "Skip to main content" link brings the user to the beginning of the Open Payments content area on the page.

1.4d(2): Useful JAWS Keystrokes

The keystrokes given in Figure 1.4 all find the next occurrence of a particular element on a page. Using the Shift key at the same time will find the previous occurrence. These shortcuts allow a screen reader user to quickly jump their screen reader between the form fields on each page or explore the overall

structure of the page by jumping between the different headings on the page that denote the start of different content areas on the page.

Figure 1.4: Useful JAWS Keystrokes

Key	What it finds	Why this is useful
F	Form field	The F key allows users to move from form field to form field. The majority of pages in the Open Payments website is made of forms. The F key allows JAWS users to determine what fields are on the Open Payments form pages quickly.
H	Heading	The H key allows users to move from heading to heading. Headings define the structure of many pages. Moving between sections of an Open Payments page allows for a quick guide to page structure and a way to access sections easily.

Section 1.5: Additional Information and Resources

CMS will support Open Payments system users through a number of different methods. These include webinars, Frequently Asked Questions (FAQs), step-by-step instructions and instructional videos, technical support, and the Open Payments Help Desk (available by emailing openpayments@cms.hhs.gov or calling 1-855-326-8366, Monday through Friday, from 7:30 a.m. to 6:30 p.m. (CT), excluding Federal holidays).

1.5a: Open Payments Website

The Open Payments website (http://go.cms.gov/openpayments) is your primary resource for information about Open Payments. The website contains numerous resources aimed at preparing and informing users about Open Payments regulations as well as the system. These resources are meant to provide guidance and instruction so users can successfully navigate through the system and understand the components of Open Payments that apply to them. Check this website often for updated tools, resources, and important announcements pertaining to Open Payments.

1.5b: Open Payments Help Desk

CMS has established the Open Payments Help Desk to serve as a single point of contact for all Open Payments-related inquiries. The Help Desk provides answers to questions ranging from basic business and program questions to technical questions. The Help Desk can also offer guidance on Open Payments, actions users must take in the system, and technical support. You can submit inquiries to openpayments@cms.hhs.gov or call 1-855-326-8366, Monday through Friday, from 7:30 a.m. to 6:30 p.m. (CT), excluding Federal holidays.

1.5c: Open Payments Listserv

By registering for the Open Payments listserv, you will be signed up to receive periodic email notifications regarding program, system, and resource updates. This is a good way to keep informed on any updates, changes, or important messages from CMS. To sign up for the Open Payments listserv, please visit the Open Payments website (http://go.cms.gov/openpayments) and enter your email address at the bottom of the home page. You may see one of two displays to enter your email address,

depending on what website page you are on in the CMS site; on the Open Payments home page, you'll see this:

On other CMS websites, you'll see this:

Entering your email address will take you to a screen where you can select which listserv you want to subscribe to. At the top of the screen, your email address will be pre-populated after "Quick Subscribe for."

Under the section "Regulations and Guidance," select "Open Payments" and then the "Select" button at the bottom of the screen to join the mailing list.
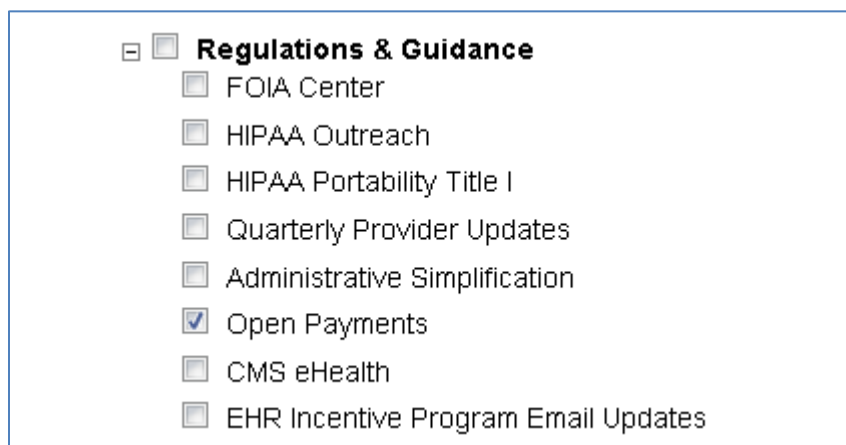
1.5d: Open Payments Mobile Application

CMS has created two mobile applications to help applicable manufacturers, applicable GPOs, and physicians keep track of payment and other transfer of value information. Application users can use these apps as a way to track payments and other transfers of value in real time on a mobile device as they occur throughout the year.

There is a separate app for industry and physicians:

- For applicable manufacturers and applicable GPOs: *Open Payments Mobile for Industry*

- For physicians: *Open Payments Mobile for Physicians*

These mobile apps do not interface with CMS systems or contractors in any way, and only serve as a mechanism to store data. CMS does not validate the accuracy of data stored in the app and is not responsible for protecting data stored in the app. These mobile apps are free and can be downloaded at the Google Play app store or iOS Apple app store by searching for "Open Payments." Additional information on the apps, including an FAQ for Open Payments Mobile, can be found on the Open Payments website (http://go.cms.gov/openpayments).

1.5e: Open Payments Webinars

CMS has conducted, and will continue to hold, a series of webinars to help industry, physicians, and teaching hospitals prepare for Open Payments. These webinars cover topics such as registration, data collection and submission, and the review and dispute process. Upcoming webinar dates and content will be posted on the Open Payments website and announced via the listserv prior to the scheduled webinar. At the conclusion of the webinar, the slides, transcript, and a recording of the session are made available for individuals who wish to view the session.

Visit the Events page (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Events.html) of the Open Payments website for more information.

PART II: REPORTING AND DATA COLLECTION

Reporting and Data Collection
For Industry

Chapter 2: Introduction to Reporting and Data Collection

This chapter provides information about data collection for entities required to report certain payments and other transfers of value in Open Payments.

Section 2.1: General Payments Reporting and Data Collection

This section on general payments reporting and data collection provides information about data collection for entities required to report certain general payments and other transfers of value in the Open Payments system. Five categories of information related to general payments made by applicable manufacturers and applicable GPOs to recipient physicians and teaching hospitals should be captured during data collection; these categories are shown in the bulleted list below.

Data is reported to the Open Payments system through bulk file uploads, using either extensible markup language (XML) or character-separated value (CSV) file formats, as well as through manual data entry through a graphic user interface. See Chapter 4 for details.

On the Data Submission and Attestation page of the Open Payments website, you can find the XML and CSV sample files that show how the data elements listed below will be reported to the Open Payments system.

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.

- **Recipient Demographic Information** identifies the recipient of the general payment or other transfer of value.

- **Associated Drug, Device, Biological, or Medical Supply Information** identifies the drug, device, biological, or medical supply that is related to the payment or other transfer of value.

- **Payment or Other Transfer of Value Information** specifies information regarding the general payment or other transfer of value.

- **General Record Information** captures other general information about the payment or other transfer of value.

A complete listing of metadata elements used for general payments data input into the Open Payments system can be found in the *Submission Data Mapping Document,* which is available on the Data Submission and Attestation page (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-

Attestation.html) of the Open Payments website. This extensive listing includes specific, detailed descriptions of the information that must be collected by reporting entities to document general payments.

Section 2.2: Research Payments Reporting and Data Collection

This section on research payments reporting and data collection provides information about data collection for entities required to report certain research-related payments and other transfers of value in the Open Payments system. Five categories of information related to research payments made by applicable manufacturers and applicable GPOs to recipient physicians and teaching hospitals should be captured during data collection; these categories are shown in the bulleted list below.

Data is reported to the Open Payments system through bulk file uploads, using either extensible markup language (XML) or character-separated value (CSV) file formats, as well as through manual data entry through a graphic user interface. See Chapter 4 for details.

On the Data Submission and Attestation page of the Open Payments website, you can find the XML and CSV sample files that show how the data elements listed below will be reported to the Open Payments system.

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.

- **Recipient Demographic Information** identifies the recipient of the research payments or other transfers of value.

- **Associated Drug, Device, Biological or Medical Supply Information** identifies the drug, device, biological or medical supply that is related to the payment or other transfer of value.

- **Payment or Other Transfer of Value Information** specifies information regarding the research payment or other transfer of value.

- **Research-related Information** captures specific information about payments or other transfers of value for research activities.

A complete listing of metadata elements used for research payments data input into the Open Payments system can be found in the *Submission Data Mapping Document*, which is available on the Data Submission and Attestation page (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html) of the Open Payments website. This extensive listing includes specific, detailed descriptions of the information that must be collected by reporting entities to document research payments.

Section 2.3: Physician Ownership/Investment Interest Reporting and Data Collection

This section on physician ownership/investment interest reporting and data collection provides information about data collection for reporting entities required to report physician ownership or investment interest in the Open Payments system.

Three categories of information related to ownership/investment interests held by physicians in applicable manufacturers and applicable GPOs should be captured during data collection; these categories are shown in the bulleted list below.

Data is reported to the Open Payments system through bulk file uploads, using either extensible markup language (XML) or character-separated value (CSV) file formats, as well as through manual data entry through a graphic user interface. See Chapter 4 for details.

On the Data Submission and Attestation page of the Open Payments website, you can find the XML and CSV sample files that show how the data elements listed below will be reported to the Open Payments system.

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.

- **Physician Demographic Information** identifies the recipient of the ownership or investment interest.

- **Ownership or Investment Information** captures information about the ownership or investment.

A complete listing of metadata elements used for ownership/investment interest data input into the Open Payments system can be found in the *Submission Data Mapping Document*, which is available on the Data Submission and Attestation page (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html) of the Open Payments website. This extensive listing includes specific, detailed descriptions of the information that must be collected by reporting entities to document physician ownership/investment interest.

PART III: APPLICABLE MANUFACTURERS AND APPLICABLE GROUP PURCHASING ORGANIZATIONS

Open Payments Registration
For Industry

Chapter 3: Applicable Manufacturer and Applicable GPO Registration

This chapter provides information on registering in CMS's Enterprise Identity Management system (EIDM) via the CMS Enterprise Portal (https://portal.cms.gov/), and registering in the Open Payments system. Registration in both systems is required for access to the Open Payments system. All applicable manufacturers and applicable GPOs that have made payments or other transfers of value to covered recipients and physician owners or investors during program years must complete registration for both systems (EIDM and Open Payments) prior to reporting payments or other transfers of value made to physicians and teaching hospitals. Note that registration is required for entities submitting data in a single report as well as entities submitting data as part of a consolidated report.

This chapter is divided into the following sections:

- **Overview of Registration**, which provides information on Phase 1 and 2 of the registration process. Phase 1 includes user registration in EIDM via the CMS Enterprise Portal, and Phase 2 includes registration in the Open Payments system.

- **Open Payments Users and User Roles**, which contains information on who is authorized to register in the Open Payments system and the user roles that must be filled by the Open Payments system users.

- **Registration and Access to the Open Payments System**, which contains instructions for registering, logging into the system, and managing the applicable manufacturer or applicable GPO registration and user roles.

- **Nominations**, which contains information on the process for nominating users to roles.

- **Vetting**, which contains information on the reporting entity vetting process and timeframes.

Section 3.1: Two-Phased Registration Process

Applicable manufacturers and applicable GPOs must register in the Open Payments system to submit, attest, correct, and view data.

Prior to registration in the Open Payments system, users must successfully register in EIDM to obtain login credentials. Once the user has registered in EIDM, they will be able to register in the Open Payments system.

3.1a: Registration Phase 1 – EIDM Registration

Open Payments registration and data submission for the 2013 program year will be completed in a two-phased approach. **Figure 3.1,** below, illustrates the two-phased approach used only for this first program year.

Phase 1, which ran from February 18 - March 31, 2014, required authorized officials to obtain EIDM credentials, request access to the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/), and submit corporate profile and aggregated information about their 2013 payment or other transfer of value and ownership/investment interest data. Instructions for registering in EIDM and obtaining access to the Open Payments system can be found in Section 3.2. Information on the data elements required for Phase 1 data submission can be found in Section 4.1.

Figure 3.1: Phased Applicable Manufacturer and Applicable GPO Registration and Data Submission Process

Phase 1

- Industry registers in EIDM and emails preliminary Open Payments data to CMS (corporate profile information and aggregate 2013 data)

Phase 2

- Industry completes entity and individual registration in the Open Payments system, submits detailed 2013 data, and attests to the accuracy of all data
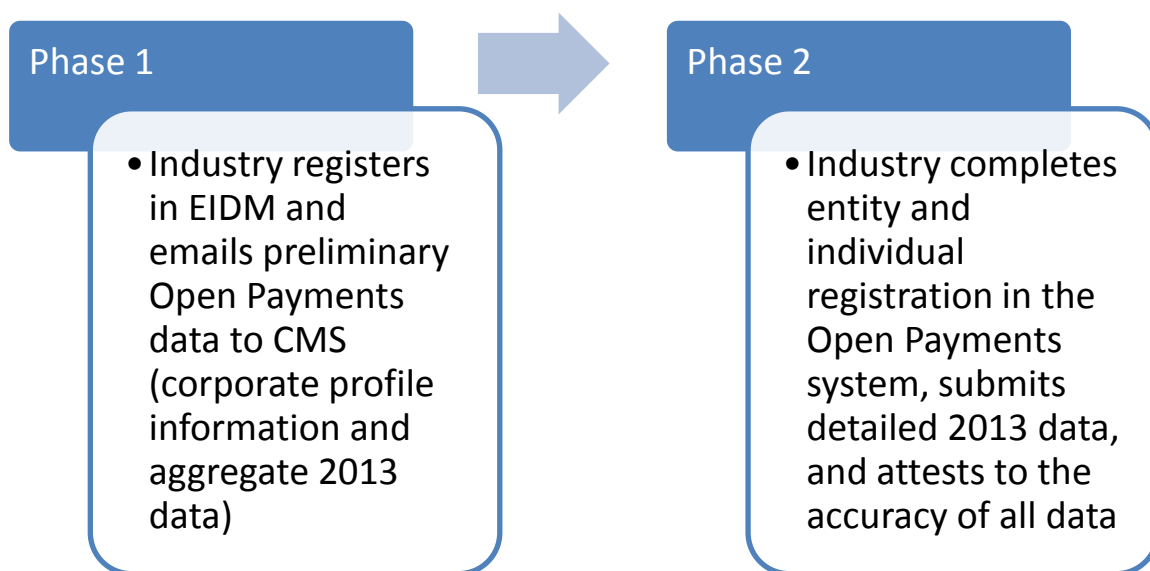
3.1b: Registration Phase 2 – Open Payments System

Phase 2 of Open Payments registration and data submission begins when the Open Payments system becomes available in early June, 2014. Once the Open Payments system goes live, the authorized official will register the reporting entity in the Open Payments system following the steps in Section 3.3. In Phase 2, some entity registration information will be pre-populated in the Open Payments system using information that was submitted during Phase 1. Note: In order to access Phase 1 pre-populated data for the reporting entity, the authorized official who registered in Phase 1 must be the first person to access the Open Payments system for the reporting entity, using the same EIDM ID established in Phase 1. The authorized official will need to review the information in the reporting entity's profile and confirm its accuracy. Entities that did not submit information in Phase 1 will not have any information pre-populated for them in the Open Payments system and will need to complete all of the required fields.

Section 3.2: Enterprise Identity Management (EIDM) Registration and Open Payments Access

Enterprise Identity Management (EIDM) is an identity management and services system that a) serves as an identity proofing tool to verify a person's identity, and b) provides users with access to various CMS applications. Registering in EIDM provides users with login credentials **required** for access to the Open Payments system. Users will be able to set up their own login credentials in the form of a user ID and password during the EIDM registration process. EIDM credentials allow login to the CMS Enterprise Portal and the ability to request access to various CMS applications, including the Open Payments system.

To begin the registration process, EIDM can be accessed via the CMS Enterprise Portal (https://portal.cms.gov/). A complete EIDM Operations Document (https://portal.cms.gov/wps/wcm/connect/6288dd9d-a7a3-4e69-87d4-3bea07cb1ade/EIDM_Authenticated_User_Operations_Document_2013.01.02_CR.pdf?MOD=AJPERES) and a list of EIDM FAQs (https://portal.cms.gov/wps/portal/unauthportal/faq) are available on the CMS website. Users who already have EIDM credentials can move ahead to Section 3.2b for instructions on how to request access to the Open Payments application.

EIDM will lock your user account if no activity is reported in the account for 60 or more days. When you login after 60 days, the system will display the "Unlock my Account" view. To unlock your account, enter your user ID and correctly answer all challenge questions. Then enter your new password in the input fields of "New Password" and "Confirm New Password" to unlock your account. If you are still unable to reactivate, contact the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366.

EIDM will automatically deactivate any user that has not logged in for 180 days or more. Once the user's account has been deactivated, the user will not be able to access CMS applications, including the Open Payments system. You can contact the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366 to reinstate your account after 180 days of inactivity.

Please note that system users who have addresses outside of the United States must contact the Open Payments Help Desk to register in EIDM.

3.2a: EIDM New User Registration

<u>Step 1</u>: Go to the CMS Enterprise Portal (https://portal.cms.gov) and select "New User Registration."
"New User Registration" is on the right side of the screen, inside the "Login to CMS Secure Portal" box.
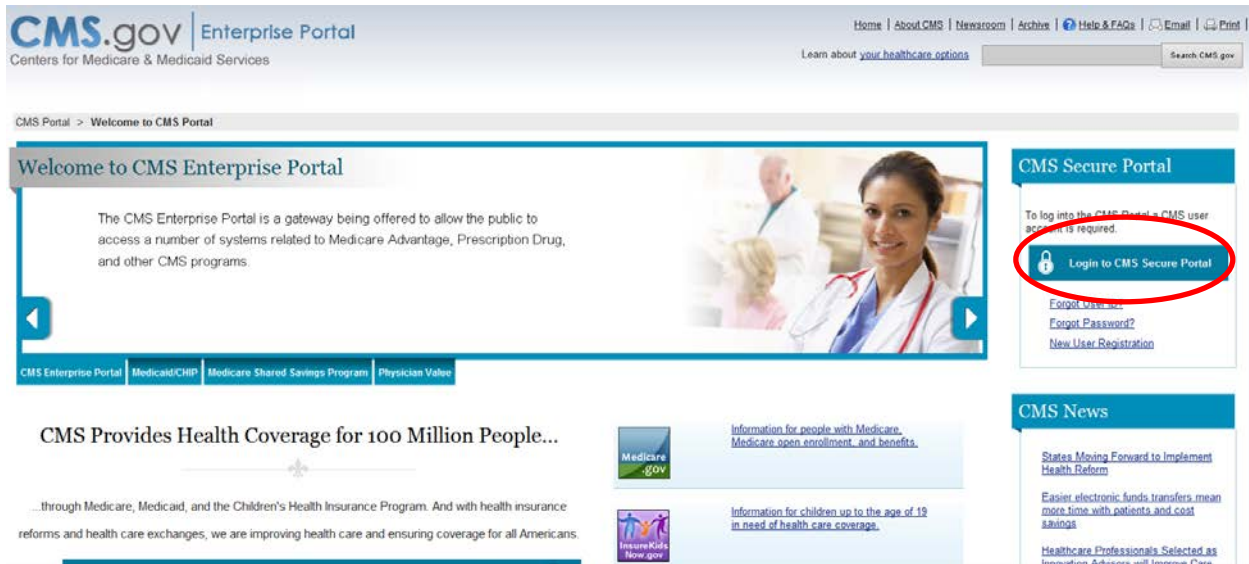
<u>Step 2</u>: Accept the Terms and Conditions of the CMS Enterprise Portal page and then select the "Next" button to continue.

Step 3: Enter your personal user information. Be sure to enter all information in all required fields. Filling in all fields will speed the processing of your registration. **Note: Pressing the "Cancel" button will cause you to lose all data entered.** Select the "Next" button when all information has been entered.

Data fields to be completed are the following:

- Name (First, Middle, Last, Suffix)

- Home Address, City, State, Zip

- Primary Phone Number

- Email Address

- Social Security Number (*Optional*)

- Date of Birth

Take care to enter your legal name, current home address, primary phone number, and email address correctly. EIDM collects personal information only to verify your identity with Experian, an external identity verification provider. If this information is not validated successfully and identity proofing fails, contact the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366.

Individuals with addresses outside of the United States may not be able to register successfully. Users with addresses outside of the United States should contact the Open Payments Help Desk for assistance with EIDM registration. Any additional EIDM issues should be directed to the Open Payments Help Desk at openpayments@cms.hhs.gov.

Step 4: Select an EIDM user name and password in accordance with the guidance provided below. You will also be asked to select three challenge questions and provide answers in the open text fields next to the question fields. Select "Next" when finished. **Note: Pressing the "Cancel" button will cause you to lose all data entered.**

- The CMS Portal User ID must:

  o Be a minimum of 8 and a maximum of 74 alphanumeric characters.

    ▪ Allowed special characters are dashes (-), underscores (_), apostrophes ('), at sign (@), and periods (.).

- The CMS Portal password must:

  o Be changed at least every 60 days;

  o Be a minimum of 8 and a maximum of 20 characters;

  o Be changed no more than once per day;

  o Contain at least one uppercase letter, one lowercase letter, and one number;

  o Not contain your User ID; and

  o Differ from your previous 6 passwords.

Once EIDM registration is completed, you will receive an email confirmation that contains your confirmed EIDM User ID. Select the OK button to take you to the CMS Portal Landing page.

Step 5: Request access to the Open Payments application. Proceed to Section 3.2b for instructions on how to request access to the application.

3.2b: Requesting Access to Open Payments with EIDM Credentials

Once you have EIDM credentials, you can request access to the Open Payments system through the Enterprise Portal (https://portal.cms.gov/) and EIDM.

Step 1: Select "Login to CMS Secure Portal."
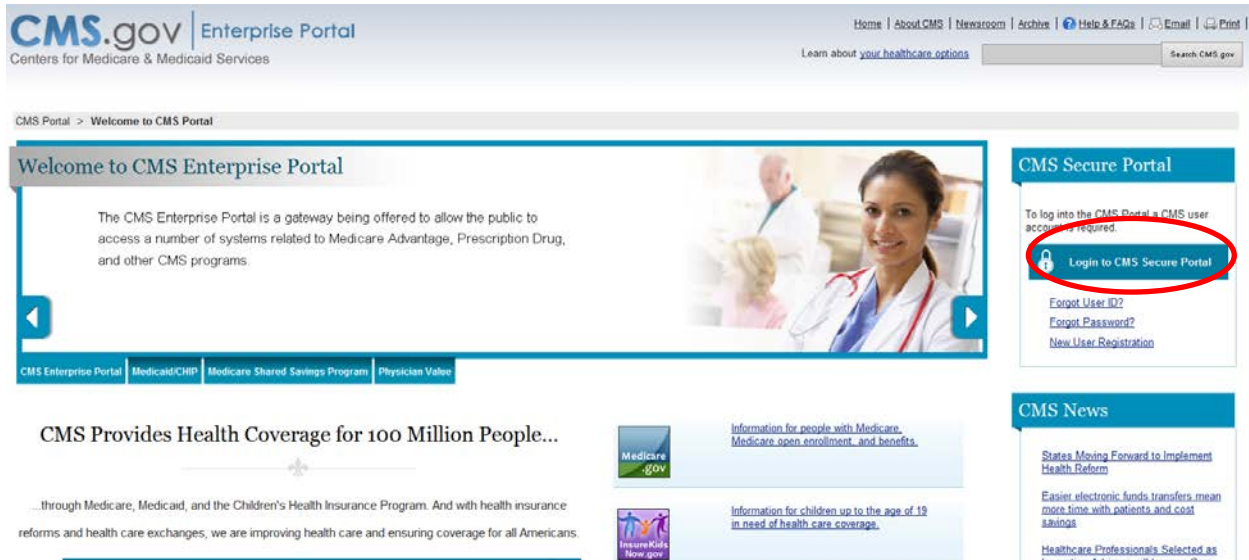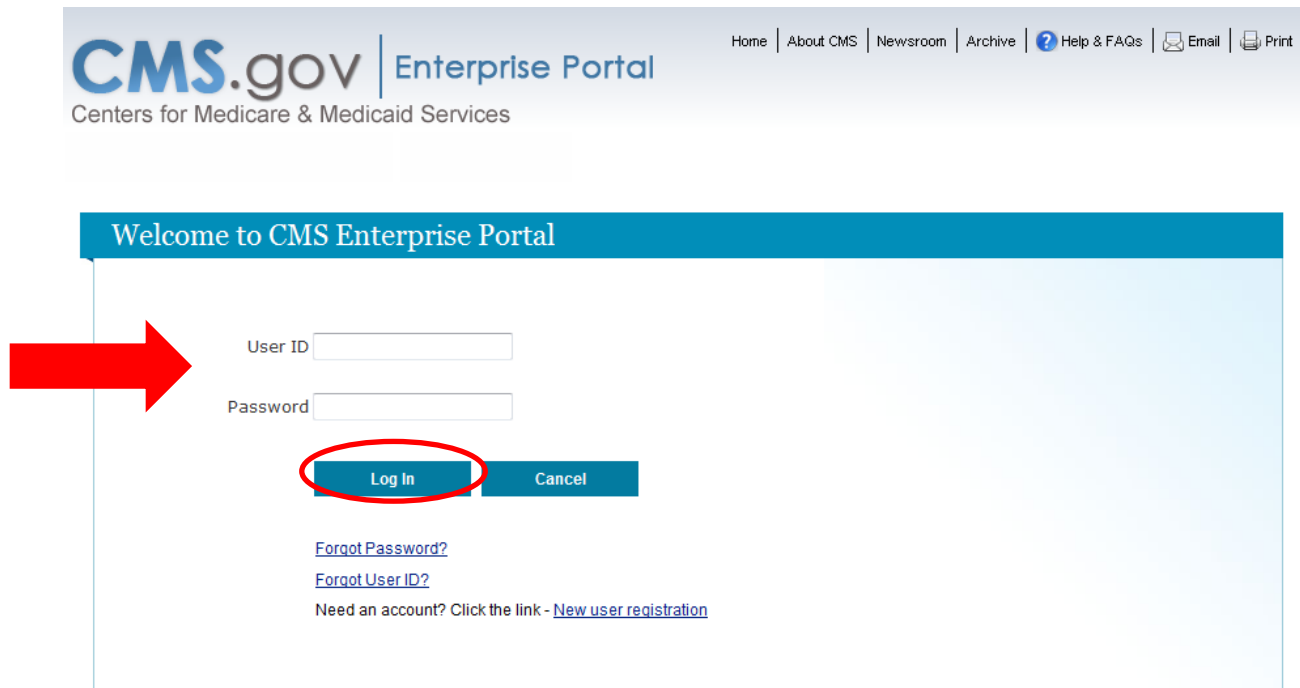
Step 2: Accept the Terms and Conditions of the CMS Enterprise Portal page.

Step 3: Once you have accepted the terms, you will be prompted to log in using your existing username and password.
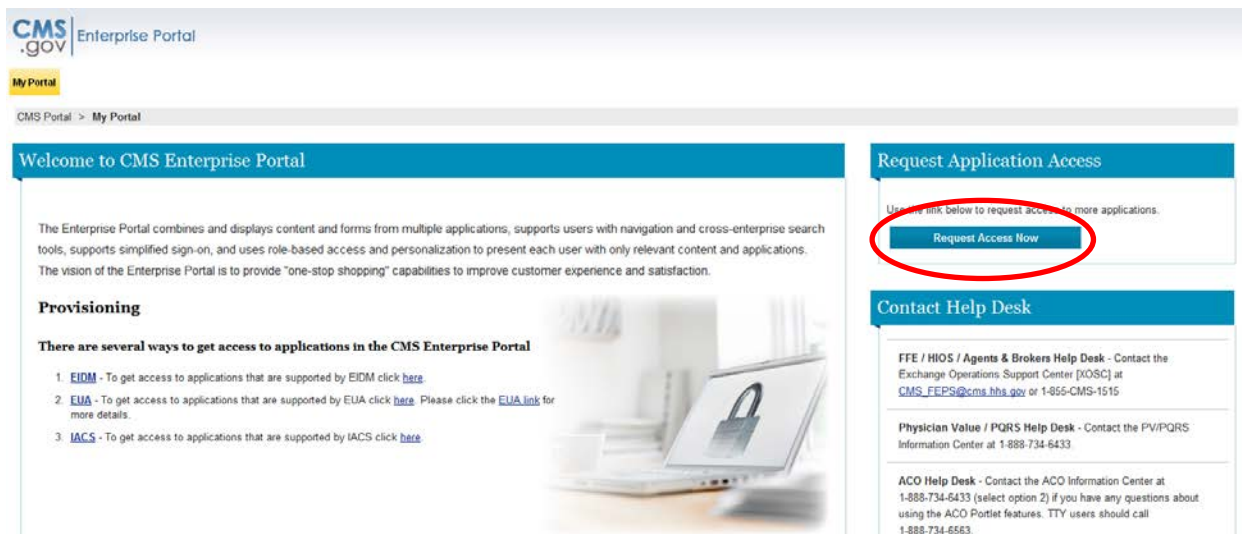
Step 4: Select on "Request Access Now."

Step 5: On the "My Access" page, select "Request New Application Access."
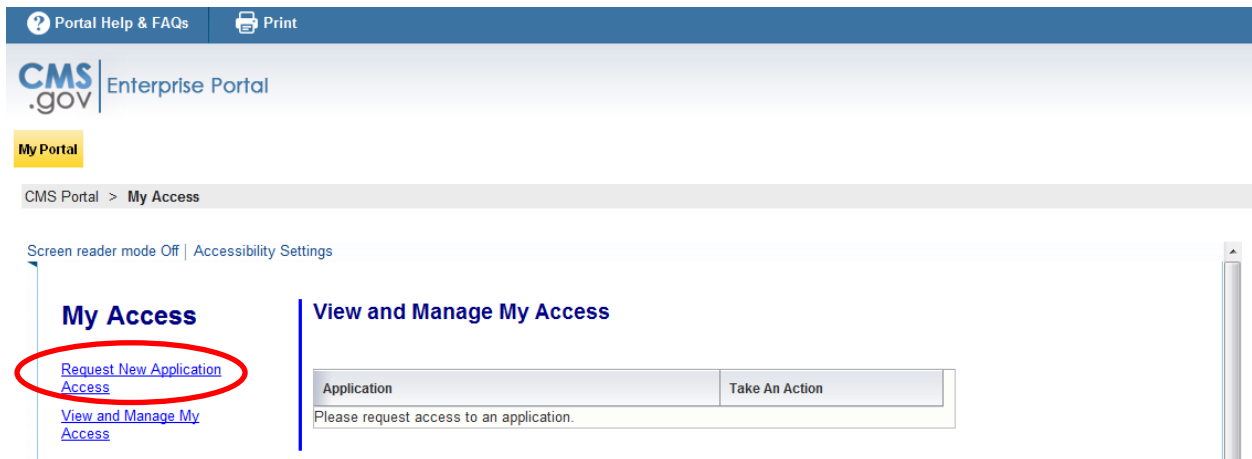
Step 6: Select Open Payments from the drop-down menu. You will be asked to select an EIDM user role. Select "Open Payments – Open Payments Application" from the "Application Description" drop-down menu. Select "Applicable Manufacturer, GPO, Physician, or Teaching Hospital" from the "Role" drop-down menu. Select the "Submit" button when complete. **Note: Pressing the "Cancel" button will cause you to lose your selected choices**.
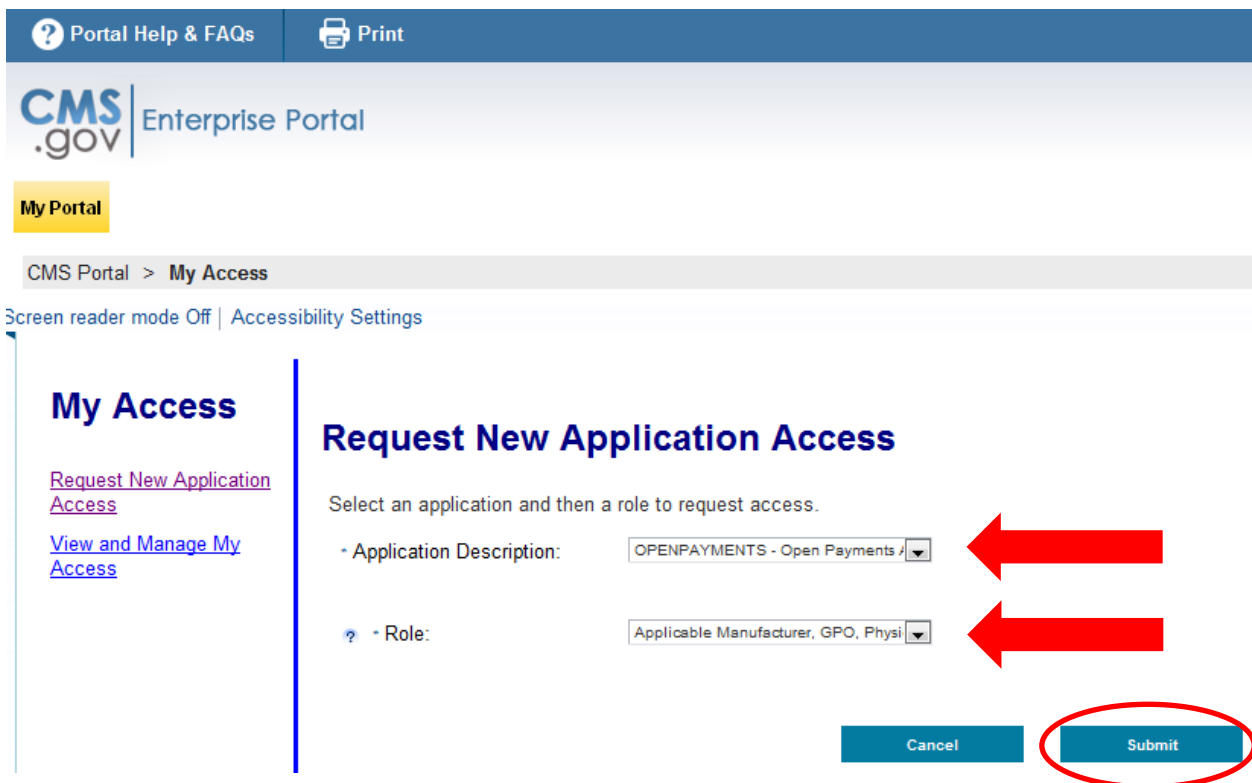
Step 7: Once you have requested access to the Open Payments application, you will then be asked to review the identity verification information. Select the "Next" button once you have reviewed the information.

Step 8: Accept the terms and conditions by selecting the checkbox, and select the "Next" button.

Step 9: Enter your information. **Note: Pressing the "Cancel" button will cause you to lose all data entered.**

Step 10: Verify your identity by answering the identity proofing questions. The identity proofing questions are created by Experian based upon the information you input during EIDM registration and Experian's databases. Experian also performs a soft credit inquiry to verify your identity. Soft credit inquiries are visible only to the user and only appear on credit reports produced by Experian. They are not visible to lenders. If you order a credit report from Experian, you will see an entry of inquiry by the Centers for Medicare and Medicaid Services with CMS's address and the date of request. **Identity proofing does not affect your credit score.** If you have questions about Experian's verification process, please refer to Experian Consumer Assistance (http://www.experian.com/help/).

Select the "Next" button when you have completed this screen.

Note: Pressing the "Cancel" button will cause you to lose all data entered.

Step 11: Once your identity has been verified, you will be brought to the Complete Set Up page. Select "Next" to continue.
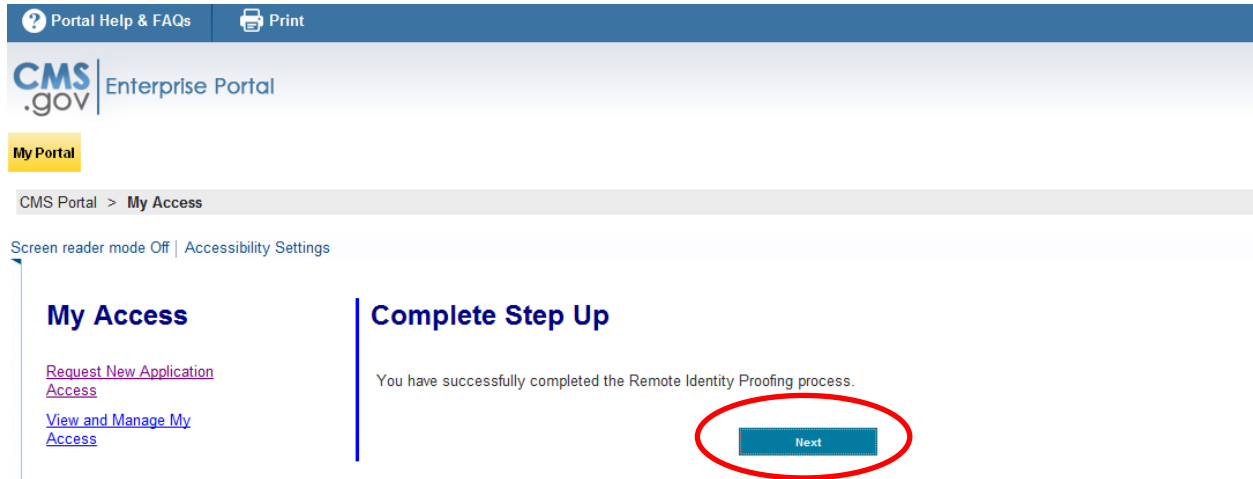
Step 12: Once you have requested access to the Open Payments application and successfully completed the Remote Identity Proofing process, you will receive an acknowledgement on the screen. Select "OK" to continue.
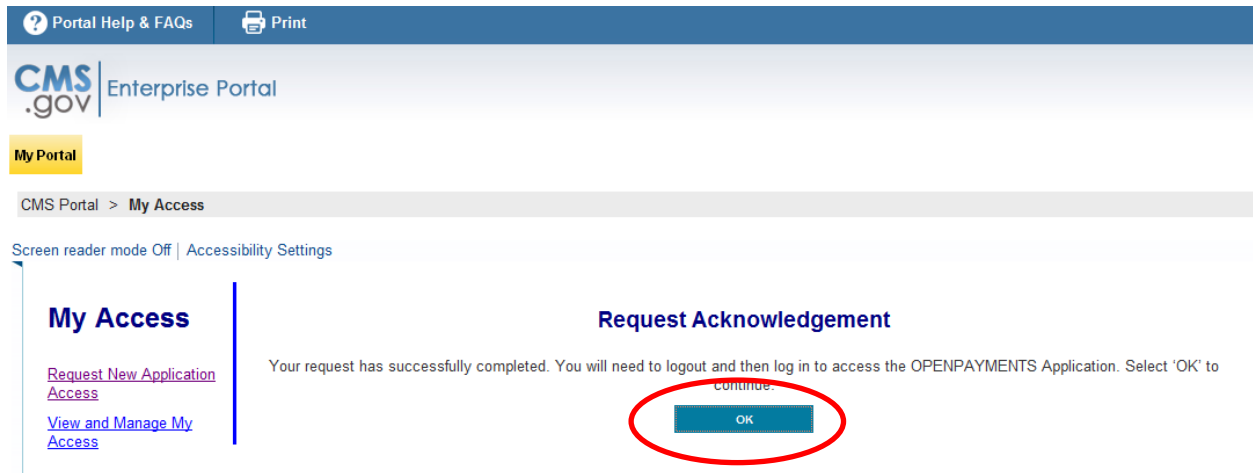
After you have been granted access to the Open Payments system, you will be able to view the application via the CMS Enterprise Portal. Access to the Open Payments application will be instantaneous, though after you register, you will need to log out of the Enterprise Portal and then log back in before the link to the Open Payments system will appear in the top menu bar.

Section 3.3 Registering Applicable Manufacturers and Applicable GPOs

Once your entity has decided who should fill the required user roles, you can begin Open Payments registration. During the registration, you will enter the required information for your reporting entity profile, user personal profile, and nominees for each user role. Reporting entity registration has five steps, as shown in **Figure 3.2.** Details on these steps are included later in this section.

Figure 3.2: Entity Registration

Step 1 Select entity type	Step 2 Create entity profile	Step 3 Create user profile	Step 4 Confirm user role	Step 5 Nominate additional users
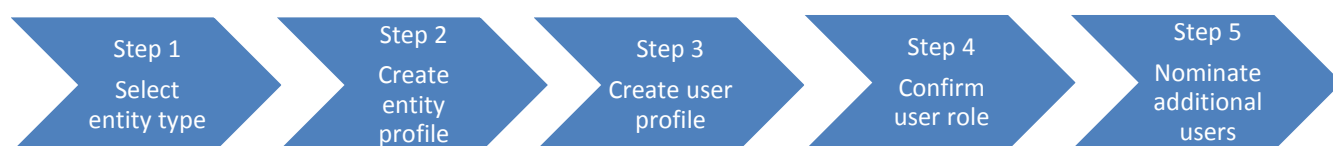
The authorized official is an officer with the entity who enters all required information to create the entity's profile. The authorized official should be highly placed within the entity, a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization or equivalent position (specific titles may vary depending on the management structure of the entity).

During registration, the authorized official must select the user role of officer for him- or herself to complete the registration process. The entire registration process takes approximately 30 minutes and must be completed in a single session. Users cannot save entries or complete the profile at a later time. Users will be able to edit, manage, or update a profile once it is created. Note that the system does not currently have an auto-save feature, and will time out after 15 minutes of inactivity.

Figure 3.3 and **Figure 3.4** detail which fields are required and which fields are optional when creating an entity and user profile. It is important to have this information on-hand prior to beginning the registration process.

Figure 3.3: Entity Profile Fields

Fields	Required	Optional
Reporting Entity Business Type	X	
Reporting Entity Legal Name	X	
Doing Business As (DBA) Name		X
Reporting Entity Business Address	X	
Reporting Entity Business Phone Number	X	
Reporting Entity Type of Ownership	X	
Taxpayer Identifier Number (TIN)/ Employer Identification Number (EIN)	X	
Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS)		X
Food and Drug Administrator (FDA) Establishment Identifier (FEI)		X
Uniform Resource Locator (URL) of Parent Company	X	
Consolidated Report Indicator (Y/N) (default N)	X	
Primary Point of Contact Name	X	
Primary Point of Contact Business Phone Number	X	
Primary Point of Contact Title at the Entity	X	
Primary Point of Contact Email Address	X	
Backup Point of Contact Name	X	
Backup Point of Contact Business Phone Number	X	
Backup Point of Contact Title at the Entity	X	
Backup Point of Contact Email Address	X	

Regarding the "Uniform Resource Locator (URL) of Parent Company," if the reporting entity does not have a URL, enter the value http://www.cms.gov.

Figure 3.4: User Profile Fields

Fields	Required	Optional
First Name	X	
Middle Name		X
Last Name	X	
Name Suffix		X
Job Title	X	
Business Address	X	
Business Phone Number	X	
Email Address	X	

After submitting both the entity and user profiles, Open Payments will vet the entity to ensure it is a valid entity. See Section 3.5 for information on vetting. Users cannot perform any functions in the Open Payments system until the entity has been successfully vetted and registered.

Important Notes:

Registration for both the entity and authorized official must be completed in one session.

The Open Payments system logs out all users after 15 minutes of inactivity.

Never use the navigation buttons on your browser toolbar. Only use the navigation buttons (Back buttons) within the Open Payments system itself.

3.3a: Registering a Reporting Entity (First-Time System Users)

Step 1: Log in to the CMS Enterprise Portal (https://portal.cms.gov/) using your EIDM user ID and password to access the Open Payments system. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.

Step 2: The on-screen text contains important information regarding creating the entity and individual profile. Read the on-screen text and select "Start Profile" at the bottom of the screen when you are ready to continue.

Step 3: Select the profile type "Applicable Manufacturer or Applicable GPO" and select "Continue."

Step 4: Once your entity type is selected, provide the entity's Taxpayer Identification Number (TIN/EIN). This will be the entity's Employer Identification Number (EIN), a nine-digit number used by the entity for tax reporting. The format for the TIN/EIN is XX-XXXXXXX. Enter the entity's TIN/EIN in the space provided and select "Lookup TIN/EIN."

Step 5: The system will perform a search and make sure no other entity with that TIN/EIN has already been registered.

If the TIN/EIN returns a match, your entity has already been registered. You may choose to proceed by nominating yourself for a role with that entity by selecting the entity name, or you may select "Cancel" to exit entity registration. See Section 3.4b(5) for instructions on how to complete the self-nomination process.

If no match is found for that TIN/EIN, you can proceed with registering that entity. Select the "Register your Entity on Open Payments" hyperlink to continue with entity registration.

Step 6: Enter the entity information. All required fields will be marked with an asterisk. Users will not be able to proceed with registration until all of the required fields have been entered. Make sure that when entering information into free-form text boxes, you restrict your use of special characters (i.e., non-alphanumeric characters) to those permitted by the system. For example, when entering the entity phone number and Taxpayer Identification Number (TIN/EIN), you must include the hyphen ("-") in the proper place within the field to pass field validation.

URL is also a required field. If the entity you are registering does not have a website, enter the generic URL of http://www.cms.gov into the field.

When you are done, select "Continue." Note: Pressing the "Cancel" button will cause you to lose all data entered.

Additional Information on the fields for entity registration:

- The **Consolidated Report Indicator** indicates whether or not the applicable manufacturer or applicable GPO intends to submit a consolidated report. Consolidated reporting allows the reporting entity to submit bulk data files across multiple registered entities. Applicable manufacturers or applicable GPOs should select yes if another applicable manufacturer or applicable GPO under

common ownership with the registering entity is submitting a report on its behalf. The option selected in the consolidated report indicator is a system indicator only and does not commit the user to submitting a consolidated report. See Section 4.7 for more on consolidated reporting.

- The **Entity Business Type** indicates the type of applicable manufacturer or applicable GPO registering in the Open Payments system. Entities may select whether the type is any of the following:

  o **Applicable manufacturer**

    If applicable manufacturer is selected, an entity must select one of the following business types:

    − applicable manufacturer-drugs/biologicals

    − applicable manufacturer-devices/medical supplies

    − applicable manufacturer-drugs/biologicals and devices/medical supplies

    − applicable manufacturer-physician-owned distributor

    − applicable manufacturer-hospital-owned distributor

    − applicable manufacturer-distributor/supplier (non-hospital, non-physician-owned)

  o **Applicable GPO**

    If GPO is selected, an entity must select one of the following business types:

    − GPO-drugs/biologicals

    − GPO-devices/medical supplies

    − GPO- drugs/biologicals and devices/medical supplies

    − GPO-physician-owned

    − GPO-hospital-owned

    − GPO-hospital and physician-owned

    − GPO-non-hospital, non-physician-owned

    − GPO-government-owned

Step 7: Enter the required information and select your user roles. For a description of user roles, see Section 3.4. When registering a new entity, you must select the role of officer for yourself. The system will not allow you to proceed if this role is not selected. You may also select the role of submitter and/or attester for yourself. When you are done, select "Continue." **Note: Pressing the "Back" button will cause you to lose all data entered.**

Step 8: You may nominate additional individuals to fulfill the officer, submitter, and attester roles at this step. If you do not wish to nominate additional individuals, select "Continue," but please note **that at least one individual must be identified for each of the three roles in the Open Payments system during initial entity registration.** If the registering authorized official will not be fulfilling all three user roles, that person must nominate at least one other individual to fill each of the remaining roles. The system will not allow you to proceed without at least one individual associated with each user role.

Step 9: To add a nominee, select "+ Add Nominee." The screen will expand to show additional fields that will need to be completed. Fill in the information for the individual being nominated. Once you are done, select the "Add Nominee" button at the bottom of the page. An entity can have up to ten users associated with it, up to five of which may hold the role of officer. **Note: Pressing the "Back" button will cause you to lose all data entered.**

The screen will display a summary of all of the individuals being nominated for user roles for this entity. Once all nominations have been completed, select "Continue."

Step 10: Review any pre-populated information for accuracy or enter your personal information as appropriate. All required fields will be marked with an asterisk. Users will not be able to proceed with registration until all of the required fields have been completed. Once your personal information has been entered, select "Continue." **Note: Pressing the "Back" button will cause you to lose all data entered.**

Step 11: Review the information entered for your entity and personal profile. Select "Back" to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Continue."

The following message will appear on-screen to confirm your entity and personal profile have been successfully created. An email notification with the entity registration ID is sent to the identified officer(s) and Point of Contact (POC).

After both the entity profile and officer profile are created, the Open Payments system vets the entity based on the information provided in the entity profile. A complete overview of the vetting process can be found in Section 3.5.

The officer will be notified via email whether the registration was successful or unsuccessful. If registration is successful, users can access the Open Payments system and begin performing their tasks. If the registration is unsuccessful for the entity, Open Payments will send an email notification to the officer(s) and point of contact stating the entity could not be successfully verified and registered. Contact the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance.

3.3b: Registering an Entity (Returning System Users)

If you already have access to the Open Payments system and wish to register a new entity with the system, follow these steps:

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). Select the "Manage Entities" tab from the menu bar on the Open Payments home page.

Step 2: Select "Register New Entity."

Step 3: Select the profile type "Applicable Manufacturer or Applicable GPO" and select "Continue."

Step 4: Once your entity type is selected, you will be asked to provide the entity Taxpayer Identification Number (TIN/EIN). Enter the entity TIN/EIN in the space provided and select "Lookup TIN/EIN."

Step 5: The system will perform a search and make sure no other reporting entity with that TIN/EIN has already been registered. If the TIN/EIN returns a match, your entity has already been registered. You may choose to proceed by nominating yourself for a role with that reporting entity by selecting the entity name, or you may select "Cancel" to exit entity registration. See Section 3.4b(5) for instructions on how to complete the self-nomination process.

If no match is found for that TIN/EIN, you can proceed with registering that entity. Select "Register your Entity on Open Payments" to continue with entity registration.

Step 6: Enter the entity information. All required fields will be marked with an asterisk. Users will not be able to proceed with registration unless all of the required fields have been completed. Make sure that when entering information into free-form text boxes, you restrict your use of *special characters* (i.e., non-alphanumeric characters) to those permitted by the system. For example, when entering the entity phone number and Taxpayer Identification Number (TIN/EIN), you must include the hyphen ("-") in the proper place within the field to pass field validation. URL is also a required field. If the entity you are registering does not have a website, enter the URL of http://www.cms.gov into the field. When you are done, select "Continue." **Note: Pressing the "Back" button will cause you to lose all data entered.**

Additional Information on the fields for entity registration:

• The **Consolidated Report Indicator** indicates whether or not the applicable manufacturer or applicable GPO intends to submit a consolidated report. Consolidated reporting allows the reporting entity to submit bulk data files across multiple registered entities. Applicable manufacturers or applicable GPOs should select yes if another applicable manufacturer or applicable GPO under common ownership with the registering entity is submitting a report on its behalf. The option selected in the consolidated report indicator is a system indicator only and does not commit the user to submitting a consolidated report. See Section 4.7 for more on consolidated reporting.

- The **Entity Business Type** indicates the type of applicable manufacturer or applicable GPO registering in Open Payments. Entities may select whether the type is any of the following:

  o **Applicable manufacturer**

  If applicable manufacturer is selected, an entity must select one of the following business types:

  − applicable manufacturer-drugs/biologicals

  − applicable manufacturer-devices/medical supplies

  − applicable manufacturer-drugs/biologicals and devices/medical supplies

  − applicable manufacturer-physician-owned distributor

  − applicable manufacturer-hospital-owned distributor

  − applicable manufacturer-distributor/supplier (non-hospital, non-physician-owned)

  o **Applicable GPO**

  If GPO is selected, an entity must select one of the following business types:

  − GPO-drugs/biologicals

  − GPO-devices/medical supplies

  − GPO- drugs/biologicals and devices/medical supplies

  − GPO-physician-owned

  − GPO-hospital-owned

  − GPO-hospital and physician-owned

  − GPO-non-hospital, non-physician-owned

  − GPO-government-owned

Step 7: Enter the required information and select your user roles. For a description of user roles, see Section 3.4. When registering a new entity, you must select the role of officer for yourself. The system will not allow you to proceed if this role is not selected. You may also select the role of submitter and/or attester for yourself. When you are done, select "Continue." **Note: Pressing the "Back" button will cause you to lose all data entered.**

Step 8: You may nominate additional individuals to fulfill the officer, submitter, and attester roles at this step. If you do not wish to nominate additional individuals, select "Continue," but please note **that at least one individual must be identified for each of the three roles in the Open Payments system during entity registration.** If the registering officer will not be fulfilling all three user roles, that person must nominate at least one other individual to fill each of the remaining roles. The system will not allow you to proceed without at least one individual associated with each user role.

Step 9: To add a nominee, select "+ Add Nominee." The screen will expand to show additional fields that will need to be completed. Fill in the information for the individual being nominated. Once you are done, select the "Add Nominee" button at the bottom of the page. An entity can have up to ten users associated with it, up to five of which may hold the role of officer. **Note: Pressing the "Back" button will cause you to lose all data entered.**

The screen will display a summary of all of the individuals being nominated for user roles for this entity. Once all nominations have been completed, select "Continue."

Step 10: Review the information entered for your entity and personal profile. Select "Back" to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Continue."

The following message will appear to confirm your entity and personal profile have been successfully created.

After both the entity profile and officer profile are created, the Open Payments system vets the entity based on the information provided in the entity profile. A complete overview of the vetting process can be found in Section 3.5.

The officer will be notified via email whether the registration was successful or unsuccessful. If registration is successful, users can access the Open Payments system and begin performing their tasks. If the registration is unsuccessful for the entity, Open Payments will send an email notification to the officer(s) and point of contact stating the entity could not be successfully verified and registered. Contact the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance.

3.3c: Registering an Entity with Phase 1 Submitted Data (First Time System Users)

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) using the EIDM username that was used in the submission of data for Phase 1. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.

Open Payments (Sunshine Act)

Welcome to the Open Payments System

Note: Our records indicate you have not registered with the Open Payments reporting application before. You must create your profile in order to use the System.

Create My Profile

Step 2: The on-screen text contains important information regarding creating the entity and individual profile. Read the on-screen text and select "Start Profile" at the bottom of the screen when you are ready to continue.

Open Payments (Sunshine Act)

Create Profile

Create Profile

① Select Profile Type
② Register Entity
③ Personal Information
④ Review and Submit Profile

↪ Access the Open Payments User Guide

Create Profile

To begin creating a profile and registering in the Open Payments system, you must identify your affiliation with an applicable manufacturer, applicable group purchasing organization (GPO), or teaching hospital, or identify as a physician or physician's authorized representative. During this process, you will also have the ability to nominate additional authorized users or representatives.

Note: When registering, it is important that you have all required information available, as registration must be completed in one session. Also note that your session will time out after 15 minutes of inactivity and all information inputted during that session will be lost.

The information needed to create your user profile or nominate additional authorized users or representatives includes:

Step 3: Select the profile type "Applicable Manufacturer or Applicable GPO" and select "Continue."

Step 4: Once your entity type is selected, select "I have a submitted Entity Profile via Phase 1 Data Submission" instead of providing the entity Taxpayer Identification Number (TIN/EIN).

Step 5: From those displayed on the screen, select the reporting entity that submitted data during Phase 1 data submission, and then select "Continue." Remember, Phase 1 data will only appear if the EIDM username used to access the system was the username associated with the Phase 1 data submission email.

Step 6: In some cases, data submitted during Phase 1 may be identified as containing data entry errors. As a result, the fields with errors will not contain pre-populated data on the "Register Entity" page. You will need to enter corrected data in the required fields prior to selecting "Continue." If no errors were found, review the information contained on the "Register Entity" page and select "Continue."

Step 7: Confirm the information displayed, enter your business telephone number, and select your role. For a description of user roles, see Section 3.4. Once complete, select "Continue."

Step 8: You may nominate additional individuals to fulfill the officer, submitter, and attester roles at this step. If you do not wish to nominate additional individuals, select "Continue," but please note **that at least one individual must be identified for each of the three roles in the Open Payments system during entity registration.** If the registering officer will not be fulfilling all three user roles, that person must nominate at least one other individual to fill each of the remaining roles. The system will not allow you to proceed without at least one individual associated with each user role.

Step 9: Review any prepopulated information for accuracy or enter your personal information as appropriate. All required fields will be marked with an asterisk. Users will not be able to proceed with registration unless all of the required fields have been completed. Once your personal information has been entered, select "Continue." **Note: Pressing the "Back" button will cause you to lose all data entered.**

Open Payments (Sunshine Act)

Enter Personal Information

Add the following personal and business information to your user profile. Also, review any pre-populated information for accuracy and correct any invalid information. Once completed, select the "Continue" button.

Note: Making changes here will not update your other CMS accounts such as Medicare, National Plan & Provider Enumeration System (NPPES), or EIDM.

A field with an asterisk (*) is required.

Create Profile

✓ Select Profile Type
✓ Register Entity
③ Personal Information
④ Review and Submit Profile

↱ Access the Open Payments User Guide
? Need help with the website? Contact Us by email

Your Name

*First Name:
Tom

*Last Name:
Smith

Middle Name:

Suffix (Jr., Sr., etc.):

Your Business Contact Information

Enter your business or entity information.

Note: The Business Telephone Number must be in the following format XXX-XXX-XXXX.

*Business Email Address:
tomsmith@yopmail.com

*Business Telephone Number:

*Job Title:
CEO

*Business Address, Line 1:
7500 Security Blvd.

Business Address, Line 2:

*City Name:
Baltimore

*State:
Maryland

*Zip Code:
21244

Cancel   Back   Continue

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Step 10: Review the information entered for your entity and personal profile. Select "Back" to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Continue."

Open Payments (Sunshine Act)

Review and Submit Profile

Review the information on this page to ensure it is correct. Select "Back" to navigate to the previous pages to correct any invalid information. Select "Continue" to submit your profile.

Create Profile

✔ Select Profile Type
✔ Register Entity
✔ Personal Information
④ Review and Submit Profile

▶ Access the Open Payments User Guide

? Need help with the website? Contact Us by email

Entity's Legal Name: ABCDE Medical

Reporting Entity Type: Applicable Manufacturer

Business Type: Applicable manufacturer-drugs/biological

Food & Drug Administration (FDA) Establishment Identifier:

Data Universal Numbering System (D-U-N-S®) Number):

URL of Parent Company: www.cms.gov

Business Address:

Country: United States

Business Address, Line 1: 7500 Security Blvd.

Business Address, Line 2:

City Name: Baltimore

State: Maryland

Zip Code: 21244

Business Telephone Number: 555-555-5555

Business Ownership Information

Type of Ownership: Corporation

Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 11-1111111

Doing Business As (DBA) Name: Rawls Enterprises, Inc.

Is this entity part of a consolidated report (e.g., where an entity is reporting on behalf of another entity)?

The following message will appear upon successful completion of the registration process.

After both the entity profile and officer profile are created, the Open Payments system vets the entity based on the information provided in the entity profile. A complete overview of the vetting process can be found in Section 3.5.

The officer will be notified via email whether the registration was successful or unsuccessful. If registration is successful, users can access the Open Payments system and begin performing their tasks. If the registration is unsuccessful for the entity, Open Payments will send an email notification to the officer(s) and point of contact stating the entity could not be successfully verified or registered. Contact the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance.

Section 3.4: Open Payments Users and User Roles

Users in the Open Payments system affiliated with applicable manufacturers and applicable GPOs must hold at least one of three user roles: officer, submitter, or attester. Each reporting entity must have at least one officer identified. The officer should be highly placed within the entity, a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization, or equivalent position (specific titles may vary depending on the management structure of the entity). These roles are discussed in detail below.

3.4a: Applicable Manufacturer and Applicable GPO User Roles

Entities must have individuals assigned to specific roles within the Open Payments system to perform specific functions. Each role has a specific function in the system. There can be a total of 10 users per entity, with no more than five of those users holding an officer role. Each user can hold multiple user roles. It is important that prior to registration your entity determines who is the appropriate individual to fill each of these roles and perform the required tasks.

There are three user roles for applicable manufacturers and applicable GPOs:

1. Officer: A person who will manage the applicable manufacturer or applicable GPO in the Open Payments system, and manage all user roles associated with the entity.

2. Submitter: A person who will submit data on payments, other transfers of value, and/or ownership and investment interests for the applicable manufacturer or applicable GPO. The submitter will also receive all notifications of disputed data.

3. Attester: A person who will attest to the accuracy of the data that has been submitted for the applicable manufacturer or applicable GPO.

The roles, responsibilities, and access levels for the roles are shown in **Figure 3.5,** below.

Figure 3.5: Open Payments User Role

User Roles	Functions	Requirements
Officer	• Manage the reporting entity's profile in the Open Payments system • Nominate (approve) other individuals for submitter, attester, and officer roles	• Must be an officer as designated by the applicable manufacturer or applicable GPO • If nominated, must either accept or reject the nomination
Submitter	• Submit data in the Open Payments system on behalf of the applicable manufacturer or applicable GPO • May edit payments or other transfers of value and ownership/investment interests submitted to the Open Payments system • Receives emails regarding data disputed by physicians and teaching hospitals	• Not required to be an officer of the applicable manufacturer or applicable GPO • If nominated, must either accept or reject the nomination

User Roles	Functions	Requirements
Attester	• Attest to accuracy of the data in the Open Payments system on behalf of the applicable manufacturer or applicable GPO	• Must be an officer of the applicable manufacturer or applicable GPO as required in the Open Payments final rule at 42 CFR 403.908(e) • If nominated, must either accept or reject the nomination

3.4b: Nominations

The nomination process allows the user to assign specific roles to individuals within the entity. Roles are associated with being able to perform certain tasks in the Open Payments system. Once an entity is successfully registered in the Open Payments system, users can begin nominating additional users to fill user roles. The officer must confirm **all** nominations before users can begin performing actions in the system. There are two ways that users can nominate individuals for a user role:

• An individual may nominate someone else for a role; or

• An individual may nominate him- or herself for a role ("self-nomination").

Entities may have third parties submit payments or other transfers of value on their behalf. In this case, the officer would nominate the third party to fulfill the submitter role. See Section 4.9 for more information on third party roles.

Additional guidelines on nominations:

- For the officer and attester roles, the individual must be an officer in the entity.

- The submitter is not required to be an officer within the entity. The submitter does not have to be an employee of the entity. See Section 4.9 for details on third-party submitters.

- An attester must meet the requirements outlined at 42 CFR 403.908(e), which require an attestation to be completed ". . . by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief."

3.4b (1): Nominating Individuals

Any user may nominate other individuals to user roles within the Open Payments system. The system will generate an email notification to the nominee once their nomination has been approved by an officer. Once an individual receives the nomination notification, that individual must access the Open Payments system via the CMS Enterprise Portal and either accept or reject the nomination.

If the nomination is accepted, the individual will be able to complete a user profile, gain access to the system, and perform the duties of their role. If they reject the nomination, the individual will not be able to perform the actions on that entity's behalf and the officer will receive an email notification of the rejection. Note that nominees will need to have EIDM credentials in order to access the Open Payments system and accept or reject their nominations.

During initial entity registration, the authorized official must nominate at least one user for each of the three roles (officer, submitter, and/or attester). One individual can hold multiple roles and entities may nominate up to 10 users total with no more than five individuals for the officer role. To nominate an individual for a role, the following information must be input into the Open Payments system about that individual:

- First name

- Last name

- Job title

- Business address

- Business phone

- Email address

Nominations can be done when registering a new entity, or after the entity profile has already been created. To nominate individuals during new entity registration, follow the process detailed below:

Step 1: Access the Open Payments system via the CMS Enterprise Portal and select the "Manage Entities" tab from the menu bar on the Open Payments home page.

Step 2: Select the reporting entity for which you will nominate an individual by clicking the entity's name.

Step 3: You will be taken to the "Entity Details" tab, which displays the profile details for the entity selected. Select the "Manage Roles" tab to continue with the nomination process.

Step 4: Select "Nominate New Role."

Step 5: Enter the required nominee information. Make sure that when entering information into free-form text boxes, the only special characters (i.e., non-alphanumeric characters) you use are those that are permitted by the system. Once you are done, select "Send Nomination." **Note: Pressing the "Cancel" button will cause you to lose all data entered.**

The on-screen message below will appear once you have completed the nomination.

The individual that has been nominated will receive an email notification that they have been nominated for a role in the Open Payments system. The email notifying the nominee of the nomination will contain a registration ID and a nomination ID. The individual will then access the system using those IDs and either accept or reject the nomination. Instructions for confirming nominations can be found in the next section.

3.4b (2): Accepting a Nomination (First Time System Users)

Users notified of their nomination for a role must access the Open Payments system via the CMS Enterprise Portal and either accept or reject their nomination. The user will use the registration ID and nomination ID received in the nomination email to complete their profile in the Open Payments system and will receive access to the functions for that specific role.

Figure 3.6: Accepting Nominations

Step 1: Access the Open Payments system via the CMS Enterprise Portal and select "Create My Profile".

Step 2: Select "Start Profile" at the bottom of the screen after reading the instructions on the Create Profile page.

Step 3: Select the "I have a Nomination ID and Registration ID" link on the Select Profile Type page.

Step 4: Enter the registration ID and nomination ID that you received in the nomination notification email and then select "Show Nomination."

Step 5: Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select "Cancel" and contact the reporting entity's authorized official.

Step 6: Review and confirm the entity information displayed and then select "Continue."

Open Payments (Sunshine Act)

Create Profile

- ✔ Select Profile Type
- ② Register Entity
- ✔ Search Nomination
    - Entity Information
    - Confirm Nomination
- ③ Personal Information
- ④ Review and Submit Profile

Access the Open Payments User Guide

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Confirm Entity

Below is the information for your selected entity. Review and confirm the entity identified below is correct. Select "Continue" button to begin creating your user profile.

Entity's Legal Name: EFGH Medical

Reporting Entity Type: Applicable Manufacturer

Business Type: Applicable manufacturer-drugs/biological

Food & Drug Administration (FDA) Establishment Identifier:

Data Universal Numbering System (D-U-N-S® Number):

URL of Parent Company: www.cms.gov

Business Address:

Country: United States

Business Address, Line 1:   7500 Security Blvd

Business Address, Line 2:

City Name: Baltimore   State: Maryland

Zip Code: 21244   Business Telephone Number: 555-555-5555

Business Ownership Information

Type of Ownership: Corporation

Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN):   65-9853149

Doing Business As (DBA) Name: EFGH Medical

Consolidated Report Type: I don't know whether my entity's data will be submitted in a consolidated report

Cancel   Back   Continue

Step 7: Select "I accept" for roles you accept and "I do not accept" for roles you do not accept. If you reject all roles for which you have been nominated, press "Continue" after selecting "I do not accept" for all roles. The system will ask you if you're sure you want to reject these roles. If you confirm your choice to reject the roles, you will exit the system and the nominator will receive an email that you rejected the nominations. The nominator will then be allowed to nominate other people for the roles.

If you accept one or all roles and select continue, you will continue the nomination confirmation process.

Step 8: Enter your personal information and select "Continue."

Open Payments (Sunshine Act)

Create Profile

✔ Select Profile Type

✔ Register Entity

③ Personal Information

④ Review and Submit Profile

↪ **Access** the Open Payments User Guide

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Enter Personal Information

Add the following personal and business information to your user profile. Also, review any pre-populated information for accuracy and correct any invalid information. Once completed, select the "Continue" button.

Note: Making changes here will not update your other CMS accounts such as Medicare, National Plan & Provider Enumeration System (NPPES), or EIDM.

A field with an asterisk **(*)** is required.

Your Name

*First Name:
Jane

*Last Name:
Doe

Middle Name:

Suffix (Jr., Sr., etc.):

Your Business Contact Information

Enter your business or entity information.

Note: The Business Telephone Number must be in the following format XXX-XXX-XXXX.

*Business Email Address:
submitter@yopmail.com

*Business Telephone Number:
555-555-5555

*Job Title:
CFO

*Business Address, Line 1:
7500 Security Blvd

Business Address, Line 2:

*City Name:
Baltimore

*State:
Maryland

*Zip Code:
21244

Cancel   Back   Continue

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Step 9: Now you'll be asked to review the information you've entered. To correct any errors, select "Back" on the bottom of the page to return to previous pages and make your corrections. If the information is correct, select "Continue."

The following message will appear on-screen to confirm your nomination has been successfully accepted.

3.4b (3): Accepting a Nomination (Returning System Users)

Step 1: Access the Open Payments system via the CMS Enterprise Portal and select the "My Profile" tab from the menu bar on the Open Payments home page.

Step 2: On the "My Roles and Nominations" tab, select "Accept a Role."

Step 3: Enter the registration ID and nomination ID provided in the email notification and select "Show Nomination." The entity and role information will be displayed on the screen. If this information is correct, select "Continue." If it is not correct, select "Cancel" and contact your reporting entity's authorized official.

Step 4: Review the entity information on the screen and select "Continue" to proceed with the nomination confirmation process. If any of the entity details are incorrect, contact the entity's authorized official.

Open Payments (Sunshine Act)

Home	Payments View, Edit, Report (Transfers of Value)	Manage Entities Register, Edit, Nominate Roles	My Profile Account, Roles, Notifications	Help

Create Profile

- ✔ Select Profile Type
- ② Register Entity
- ✔ Search Nomination
  - **Entity Information**
  - Confirm Nomination
- ③ Personal Information
- ④ Review and Submit Profile

➡ **Access** the Open Payments User Guide

? Need help with the website? **Contact Us** by email

Confirm Entity

Below is the information for your selected entity. Review and confirm the entity identified below is correct. Select "Continue" button to begin creating your user profile.

Entity's Legal Name: ABCDE Medical

Reporting Entity Type: Applicable Manufacturer

Business Type: Applicable manufacturer-drugs/biological

Food & Drug Administration (FDA) Establishment Identifier:

Data Universal Numbering System (D-U-N-S® Number):

URL of Parent Company: www.cms.gov

Business Address:

Country: United States

Business Address, Line 1:   7500 Security Blvd

Business Address, Line 2:

City Name: Baltimore   State: Maryland

Zip Code: 21244   Business Telephone Number: 555-555-5555

Business Ownership Information

Type of Ownership: Corporation

Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN):   94-3728192

Doing Business As (DBA) Name: ABCDE Medical

Consolidated Report Type: I don't know whether my entity's data will be submitted in a consolidated report

Cancel		Back	Continue

Step 5: Select "I accept" for roles you accept and "I do not accept" for roles you do not accept. If you reject all roles for which you have been nominated, press "Continue" after selecting "I do not accept" for all roles. The system will ask you if you're sure you want to reject these roles. If you confirm your choice to reject all roles, you will exit the system and the nominator will receive an email that you rejected the nominations. The nominator will then be allowed to nominate other people for the roles.

If you accept one or all roles and select "Continue", you will continue the nomination confirmation process.

Step 6: Review the entity information and personal profile. Select "Back" to go back and edit any personal information. If the entity information is not correct, select "Cancel" and contact your reporting entity's authorized official. If the information is correct, select "Continue."

The following message will appear on-screen to confirm your acceptance of one or more user roles.

3.4b (4): How to Reject a Nomination

To reject a nomination, access the Open Payments system via the CMS Enterprise Portal using the registration ID and nomination ID provided in the notification email and follow the steps below to reject the nomination.

1. Follow steps 1 through 4 outlined in Section 3.4b (2) for accepting a nomination.

2. During step 5, select "No I do not accept" and select "Continue."

Once you reject a nomination, you will be exited from the system and will be unable to perform any functions in Open Payments. The officer for that entity will receive an email notifying him or her of the rejection. The officer may nominate another individual for that role.

3.4b (5): Self-Nomination Overview

Self-nominations occur when a user nominates him or herself for a user role within the Open Payments system. The officer must approve this nomination before the nominee can perform any functions within the system. Users choosing to self-nominate in the system must also obtain EIDM credentials in order to access Open Payments. The following figure depicts the self-nomination process.

Figure 3.7 Self-Nomination Process

Obtain EIDM Credentials → Access Open Payments via Enterprise Portal → Find Entity using TIN/EIN → Select User Role → Complete User Profile

To self-nominate for a role in the Open Payments system, users must access the Open Payments system via the CMS Enterprise Portal, and use the reporting entity's TIN/EIN in order to find the entity in the Open Payments system. Once the user has submitted their nomination request, the officer for that reporting entity will receive an email notification asking to approve the nomination. If the officer approves the nomination, the nominee will receive an email notification and be granted access to the system. Sections 3.4b (6) and 3.4b (7) below provide the steps required to complete the self-nomination process.

3.4b (6): Self-Nomination with a Registered Entity (First Time System Users)

Step 1: Access the Open Payments system via the CMS Enterprise Portal. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" to begin the registration process.

Open Payments (Sunshine Act)

Welcome to the Open Payments System

Note: Our records indicate you have not registered with the Open Payments reporting application before. You must create your profile in order to use the System.

Create My Profile

Step 2: The on-screen text contains important information regarding creating the entity and individual profile. Read the on-screen text and select "Start Profile" at the bottom of the screen when you are ready to continue.

Step 3: Select the profile type "Applicable Manufacturer or Applicable GPO" and select "Continue."

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Step 4: Enter the entity TIN/EIN that you want to associate yourself with. The TIN must be nine digits, with a dash after the second digit. Select "Lookup TIN/EIN."

Step 5: Select the correct entity from the list displayed and select "Continue." Note that if no entity is found, the entity has not yet been registered in the Open Payments system. You may register the entity in Open Payments (if you are a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization (GPO)), or contact a Chief Executive Officer or similar officer within your organization to request that he or she register the entity in the Open Payments system.

Step 6: Review and confirm the entity information displayed on screen. If any of the entity information is incorrect, contact an authorized official in the officer role. Select "Continue" to proceed.

Step 7: Enter your personal information and select the roles for which you want to nominate yourself. Make sure that when entering information into free-form text boxes, the only special characters (i.e., non-alphanumeric characters) you use are those permitted by the system. Select "Continue" to proceed.

Step 8: On the "Enter Personal Information" screen, enter your personal information and business contact information. Required fields are marked with an asterisk. When entering a telephone number, be sure to place hyphens between the area code and prefix and the prefix and the last four digits. Once you have entered in all of the information, select "Continue."

Step 9: Review the information entered in your profile. Select "Back" to go back and edit any incorrect information. When the information is correct, select "Continue."

Open Payments (Sunshine Act)

Create Profile

✔ Select Profile Type

✔ Register Entity

✔ Personal Information

④ Review and Submit Profile

↪ **Access** the Open Payments User Guide

? Need help with the website? **Contact Us** by email

Review and Submit Profile

Review the information on this page to ensure it is correct. Select "Back" to navigate to the previous pages to correct any invalid information. Select "Continue" to submit your profile.

Entity's Legal Name: EFGH Medical

Reporting Entity Type: Applicable Manufacturer

Business Type: Applicable manufacturer-drugs/biological

Food & Drug Administration (FDA) Establishment Identifier:

Data Universal Numbering System (D-U-N-S® Number):

URL of Parent Company: www.cms.gov

Business Address:

Country: United States

Business Address, Line 1: 7500 Security Blvd

Business Address, Line 2:

City Name: Baltimore

State: Maryland

Zip Code: 21244

Business Telephone Number: 555-555-5555

Business Ownership Information

Type of Ownership: Corporation

Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 65-9853149

Doing Business As (DBA) Name: EFGH Medical

Is this entity part of a consolidated report (e.g., where an entity is reporting on behalf of another entity)?

I don't know whether my entity's data will be submitted in a consolidated report

Nominations:

Role:	First Name:	Last Name:	Middle Name:	Suffix (Jr., Sr., etc.):	Business Email Address:
SubmitterAttester	John	Doe			submitter@yopmail.com

Cancel   Back   Continue

The following on-screen message will appear to confirm your profile creation was successful.

3.4b (7): Additional Self-Nomination with a Registered Entity (Returning System Users)

Step 1: Access the Open Payments system via the CMS Enterprise Portal and select the "My Profile" tab from the menu bar.

Step 2: Select the "My Roles and Nominations" tab.

Step 3: Select "Request a Role."

Step 4: Enter the entity TIN/EIN and select "Lookup TIN/EIN." The TIN must be nine digits, with a dash after the second digit (XX-XXXXXXX). Select the entity with which you want to associate yourself. Note that if no entity is found, the entity has not yet been registered in the Open Payments system. You will either need to register this entity as the authorized official, or contact an officer within your organization to register the entity in the Open Payments system.

Step 5: Review and confirm the entity information displayed on screen. If any of the entity information is incorrect, contact the authorized official in the role of officer to update the entity profile information. Select "Continue" to proceed.

Step 6: Enter your personal information and select the roles you want to nominate yourself for. Make sure that when entering information into free-form text boxes, the only special characters (i.e., non-alphanumeric characters) you use are those permitted by the system. Select "Continue" to proceed.

Step 7: Review the information entered in your profile. Select "Back" to go back and edit any incorrect information. When the information is correct, select "Continue."

You will receive the following on-screen notification.

3.4b (8): Approving Nominations (Officers Only)

Step 1: Access the Open Payments system via the CMS Enterprise Portal and select the "Manage Entities" tab from the menu bar on the Open Payments home page.

Step 2: You will see a list of all of the reporting entities you are associated with. Select the entity for which you will be confirming the nominations.

Step 3: You will be taken to the "Entity Details" tab, which displays the profile details for the entity selected. Select the "Manage Roles" tab to continue with the nomination approval process.

Step 4: View the nominations waiting for approval. To approve the nominations with no changes, select "Approve" next to the name and role. The status will change directly on screen from "Requested" to "Approved." If you need to modify the nomination, select "Modify."

You may modify the nomination prior to approval. This can be done by overriding the information submitted directly on the screen. You may modify the roles the user has requested by checking or unchecking each user role box accordingly. Once you have modified the nomination, select "Submit."

The following on-screen confirmation message will appear. The nomination status has now changed to "Nomination Approved."

Section 3.5: Vetting

Vetting is the process of verifying an applicable manufacturer's or applicable GPO's corporate identity. This is done to ensure that the applicable manufacturer or applicable GPO is a valid reporting entity. All applicable manufacturers and applicable GPOs registering in the Open Payments system will be vetted. Vetting occurs once the authorized official has completed his or her profile and submitted his or her registration in the Open Payments system. **Note that entity registration is not considered complete until the vetting process has been successfully completed.**

3.5a: Entity Vetting

Vetting of an applicable manufacturer or applicable GPO is an automated process. The automated vetting process will typically require little action from the user in order to complete it. Once the authorized official submits the entity and user profile, the vetting process begins. The process will attempt to vet the entity using the information provided in the entity profile.

If the vetting fails, the authorized official will be notified via email and have the opportunity to correct the information and resubmit the entity for vetting. The authorized official will have three attempts to successfully complete the automated vetting process for the entity. If the vetting fails three times, the authorized official will need to contact the Open Payments Help Desk to receive a "Conditionally Approved" status in order to gain access to the Open Payments system. "Conditionally Approved" status is given on a discretionary basis by the Open Payments Help Desk. This status will allow the authorized official and additional users to perform tasks within the system to remain compliant with the program, though it will be noted that the entity could not be successfully vetted.

If the authorized official believes all of the information provided in the entity profile is correct and the entity should have been successfully vetted, the authorized official can contact the Open Payments Help Desk at any time during the vetting process for assistance at openpayments@cms.hhs.gov or 1-855-326-8366.

Note: If the Open Payments Help Desk does <u>not</u> assign the entity the "Conditionally Approved" status, the entity vetting status will remain as "Failed Vetting" in the Open Payments system and users associated with the reporting entity will not be able to perform any action in the system.

3.5b: Vetting Timeframe

The automatic vetting process normally takes a short time. Nevertheless, the process could take longer, depending on the information provided by the user and the number of entities undergoing vetting at the same time. CMS encourages authorized officials to register and begin the vetting process as early as possible to allow sufficient time for vetting to be completed.

Data Submission and Attestation

Chapter 4: Data Submission and Attestation

This chapter on data submission and attestation provides detailed information on how applicable manufacturers and applicable GPOs are able to submit payments or other transfers of value, and ownership or investment interest information, to the Open Payments system. The Open Payments system provides two data entry and submission options: (1) bulk data entry via XML or CSV files, or ZIP file that contains XML or CSV file uploads for both individual and consolidated reports, and (2) manual data entry via a Graphic User Interface (GUI).

This chapter is divided into the following sections:

- **Data Submission Phases 1 and 2,** contains information on the two phases of data submission for the Open Payments system in program year 2013.

- **Instructions, Sample Files, and Data Mapping**, contains information on the types and locations of data submission resources.

- **Bulk File Upload** contains information and instructions for the preparation and upload of XML or CSV files (or ZIP files containing XML or CSV files) for submission through the Open Payments system.

- **Manual Data Entry Using the Graphic User Interface** contains information about submitting information to the Open Payments system through a graphical user interface.

- **Final Submission of Payments** contains information about the final data submission process after all records are uploaded and ready for submission.

- **Third Party Data Submitters** contains information about the use of third parties by entities to submit data to the Open Payments system.

- **Consolidated Reporting** contains information about entities under common ownership having their data collectively submitted by one entity in the group in consolidated reports.

- **Data Submission Errors** contains information about how to understand error reporting and how to correct errors in submitted records.

- **Attestation and Assumptions** contains information about the attestation to the accuracy of data submitted to Open Payments.

Figure 4.1 provides an overview of the data and submission attestation process for the 2013 program year.

Figure 4.1: The Four Steps of Data Submission and Attestation

Note: Applicable manufacturers and applicable GPOs must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the entity's compliance for five years from the date of publication. Data reporting is complete only after electronic attestation is received for the program year.

Section 4.1: Data Submission Phase 1

Data submission for program year 2013 was split into two phases. During Phase 1, which ended on March 31, 2014, authorized officials completed EIDM registration and requested access to the Open Payments system, and also sent an email to CMS with a CSV file that contained corporate profile information and aggregate 2013 data. Data elements requested in the CSV file are listed in **Figure 4.2**. The authorized official must have obtained their EIDM credentials prior to submitting any email information. See Section 3.2 for instructions on how to obtain EIDM credentials.

After the authorized official received his or her EIDM credentials, the official was able to delegate another individual within their entity to complete Phase 1 of data submission. **Regardless of who sent the Phase 1 email, the email submission must have contained the EIDM user name of the authorized official who will register the entity in the Open Payments system when it becomes available.** The EIDM credentials must be for an entity's Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer who can legally represent the organization. The authorized official's EIDM user name will be used to match the email submission to the appropriate entity in the system once the system is available.

Authorized officials representing multiple entities within the Open Payments system were required to send a separate data submission email for each entity. Each of these emails contained its own unique CSV file that contained only a single entity's corporate information and aggregate data. Emails and/or CSV files that referenced multiple entities were rejected.

Figure 4.2: Required Content for Email Submission/CSV File

Entity Information	Payment Information

1. **Authorized official's EIDM user name**
 	
 2. **Registering entity legal name**
 	
 3. **Doing business as (DBA) name**
 	
 4. **Registering entity business type**
 	
 5. **Website address/uniform resource locator (URL) of parent company**
 	
 6. **Registering entity business address**
 	
 7. **Registering entity business telephone number**
 	
 8. **Consolidated report indicator (Y/N)**
	1. Aggregate information representing the first look at the applicable manufacturer's or applicable GPO's 2013 payment report:
	
	 a. Category 1: Research Payments Aggregate Data:
	
	    i. Total aggregate amount (in dollars) of payments or other transfers of value the applicable manufacturer or applicable GPO has provided to Covered Recipients of physician owners/investors during the reporting period.
	
	    ii. Total number of payments or other transfers of value made.
	
	    iii. Total number of covered recipients (unique/non-duplicate) or physician owners/investors that were recipients of the payments or other transfers of value during the reporting period.
	
	 b. Category 2: Non Research Payments Aggregate Data:
	
	    i. Total aggregate amount (in dollars) of payments or other transfers of value the applicable manufacturer or applicable GPO has provided to Covered Recipients of physician owners/investors during the reporting period.
	
	    ii. Total number of payments or other transfers of value made.
	
	    iii. Total number of covered recipients (unique/non-duplicate) or physician owners/investors that were recipients of the payments or other transfers of value during the reporting period.
	
	 c. Ownership or Investment Interests Aggregate Data:
	
	    i. Total number of physician owners/investors

Phase 1 emails were sent to CMS with the CSV file attached. Once the authorized official or other designee submitted the email, he or she received an email confirmation. No additional action needed to be taken until the Open Payments system became available in June 2014.

A Phase 1 Data Submission Instructions document can be found on the Open Payments website's Data Submission and Attestation (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html) page.

Section 4.2: Data Submission Phase 2

Phase 2 of the data submission process requires reporting entities to submit detailed information regarding payments or transfers of value made during the 2013 program year, and attest to the accuracy of the data. Reporting entities will submit data either through bulk file upload or manual data entry. Both submission options are covered later in this chapter. Note that only individuals holding the role of submitter may submit the data in the Open Payments system and only individuals holding the role of attester may attest to the data.

Beginning in early June, 2014, applicable manufacturers and applicable GPOs may start Phase 2 data submission, which will be completed in two steps.

Step 1: Early June through June 30, 2014. Authorized officials of applicable manufacturers and applicable GPOs are required to:

- Complete Open Payments system registration for themselves and their reporting entity;

- Confirm the accuracy of the reporting entity profile data submitted for Phase 1; and

- Delegate roles and responsibilities by nominating system users to fill specific user roles.

During this period, system users in the role of submitter should:

- Perform test file uploads and submit data files to validate the file structure and contents of the file (for more detail on this process, review the Phase 2 Instructions document (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Phase-2-Instructions-Document-%5bMay-2014%5d.pdf)); and

- Use the error report produced by the Open Payments system to fix any data errors in submitted files.

Once the data files have been successfully uploaded and validated at this step, move on to Step 2.

Step 2: June 9 through June 30, 2014. The Open Payments system will also allow:

- Submitters to perform final data submission; and

- Attesters to attest to the accuracy of their submitted detailed 2013 payment or other transfer of value data, or ownership/investment interest data.

All Phase 2 activities (Steps 1 and 2) must be completed by June 30, 2014. Review the Phase 2 Instructions document for a detailed guide to Phase 2 timing and activities. This document is available

on the Program Registration and Data Submission and Attestation pages of the Open Payments website (http://go.cms.gov/openpayments) .

For program year 2013, CMS will not enforce penalties for reporting non-compliance until after the close of Phase 2 registration and data submission.

This phased approach to Open Payments registration and data submission is for the 2013 program year **only** (data collected between August 1, 2013 and December 31, 2013).

Section 4.3: Instructions, Sample Files, and Data Mapping

Chapter 2 of this Guide presents detailed descriptions of the information that must be collected for reporting by reporting entities.

This section provides details on how to submit that collected data through bulk upload. The XSD file (XML Schema Definition), and XML and CSV sample files, plus a bulk data submission instruction document are available on the Open Payments Data Submission and Attestation page (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html). The schema and sample files define the exact format and layout of the files accepted in the Open Payments system. The instructions document explains how to use the XSD (XML Schema Definition) document and sample files, as well as a mapping of each data field in the sample files to the data elements. Please refer to the Submission Data Mapping Document to see the mapping of each data element (previously included in the Submission File Specifications) to the appropriate XML and CSV field names. These documents provide users with all of the information needed for the purposes of Open Payments and data formatting and submission.

Using the Submission Data Mapping Document, the correct data element in the XML and CSV sample file can be populated with the entity's data. To map the data elements in the mapping document to the XML/CSV sample files, follow these steps:

1. Download the Submission Data Mapping Document from the Open Payments website. The data element name identified in column B can be used to map to the field name used in the XML and CSV sample files.

2. If an XML file is being submitted, map the data element name listed in the Data Element Name column to XSD Element Name column.

3. If a CSV file is being submitted, map the data element name listed in the Data Element Name column to CSV Element Name column.

4.3a: Creating CSV and XML Files

CSV and XML file formats are the only two file formats accepted by the Open Payments system for bulk file upload (or ZIP files that contain XML or CSV files). The selected file type must be prepared and formatted properly for successful submission. Check with your entity's IT department if you are unsure which file format to use. For more detailed information, you can refer to the "Phase 2 CSV and XML Tutorial: Preparing Files for Data Submission" webinar (https://event.webcasts.com/starthere.jsp?ei=1033506) on the Open Payments website.

Bulk data files may not exceed 250MB in size. If the data in your file exceeds that limit, you can split the data into more than one data file. Note that the Open Payments system also accepts CSV or XML data files that have been compressed into a ZIP file if the file is under 250MB after compression.

There are no system limitations to the number of data lines or rows that can be included in a file. The Submission Data Mapping Document can be used to reference the data elements, data element descriptions, and expected size/format/name.

4.3b: CSV Files

There are many applications that can be used to prepare CSV files. Two applications covered in the Phase 2 CSV and XML Tutorial: Preparing Your Files for Data Submission, are Excel and Open Office.

When creating CSV files using Excel on a Windows-based computer, you must first update the computer's regional settings to display "pipe" as the field delimiter instead of "comma." You can find the regional settings in your computer's Control Panel under *Region and Language -> Additional Settings -> List Separator*. Once this is complete, you can then create the pipe by holding down the shift key and pressing backslash (i.e., "\"). Please note that this "regional setting" change is not necessary when using Open Office.

When using Excel on a Windows-based computer, load an applicable CSV sample file downloaded from the Open Payments website. Next, enter required data within the columns, "auto-fit" the columns to make all data visible to ensure the data is entered correctly, and save the file. Be sure to save the file in the file format of "CSV" (Excel default is either ".XLS" or ".XLSX").

When using Open Office on either a Macintosh or Windows-based computer, first open the sample file downloaded from the Open Payments website. When the Text Import window opens, one of the options you will see is "Separators." Ensure that the button for "Other" is checked and press the "shift" and "\" keys to create the pipe as the separator in the "Other" field. Once this is done, enter required data within the columns, Ensure all data has been entered correctly and save the file. You must save the file as a CSV file.

Whether you are using Excel or Open Office, it is important to perform the following final checks before submitting your file:

- Open the CSV file in a text editor (Notepad for Windows, Text Editor for Macintosh) and confirm that the rows are delimited with pipes; and

- Ensure that rows of data are not contained within quotation marks to avoid the data being rejected by the system.

4.3c: XML Files

When creating XML files, use the Open Payments XSD document with a programming application such as integrated development environments. Acceptable programming applications are available on the internet, but if you are not familiar with creating XML files, you should contact your reporting entity's IT department for assistance.

The Submission Data Mapping Document can be used to reference the data elements, data element descriptions, and expected size/format/name of each XSD element. Refer to both the Submission Data Mapping Document and XSD (XML Schema Definition) document for all XML formatting questions. You must save the file with the suffix ".XML", and the file name cannot exceed 50 characters.

Section 4.4: Bulk File Upload

The Open Payments system allows applicable manufacturers and applicable GPOs to submit payment or other transfers of value, and ownership or investment interest information via bulk file uploads. Files can be submitted as an individual entity submitting a single report or as a consolidated report on behalf of multiple entities (see Section 4.7 for information on Consolidated Reporting). There are two types of file formats that can be used for bulk data upload into the Open Payments system: XML or CSV (or ZIP file containing one of these file types). The files listed below can be downloaded from the Open Payments Data Submission and Attestation page (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html).

1. XML

Payments.xsd is the XSD (XML Schema Definition) document available for download for XML file validation. Use the XSD document for all three reporting categories. The reporting entity should download the XML Schema Definition document plus the sample XML file(s) for the type of payments being submitted.

- General Sample File XML – To be used for general payment submissions

- Research Sample File XML – To be used for research payment submissions

- Owner/Investor Sample File XML – To be used for ownership/investment information submissions.

2. CSV

There are three CSV sample files available for download for submitting Open Payments data. These sample files correspond to the three reporting categories.

- General Sample File CSV – To be used for general payment submissions

- Research Sample File CSV – To be used for research payment submissions

- Owner/Investor Sample File CSV – To be used for ownership/investment information submissions.

Please refer to the Bulk Data Upload Instructions on the Open Payments website for directions on how to prepare and upload each file type.

Note: Applicable manufacturers and applicable GPOs can submit test submissions to test the format validity of the files being uploaded. This function is provided solely for the purposes of ensuring submission files follow the correct submission format. Test data is not retained in the system and is not included in the data submission. Submission of a test file will be covered in the appropriate steps below.

4.4a: Bulk File Upload Instructions

Step 1: Access the Open Payments system via the CMS Enterprise Portal and select the "Payments" tab.

Step 2: You will be brought to the "Payments Overview Page." Select the "Bulk File Upload (CSV or XML)" option to begin the bulk upload process. Complete the "Upload Files Page." Select the payment category for the type of file being submitted: General, research, or ownership/investment interest. Then select the entity for which you will be uploading the files and the program year of the data. Browse and select the file that is to be uploaded.

You may only submit one file at a time. If you have multiple files to upload, repeat the bulk upload process for each file.

Step 3: After you have entered this information, you may select from two buttons: "Submit as Test File" or "Submit File to Open Payments."

Files submitted as test files are not uploaded for reporting purposes or kept on the system. The system instead checks the file for the following:

- The file is in a valid CSV, XML, or zip file format;

- The file is smaller than 250 MB;

- The file header is present; and

- The file template and payment category, which you selected at upload, match.

The Open Payments system will display test results on the screen. To upload the file for reporting, select the "Submit File to Open Payments" button. The file will first undergo the same checks as a test submission. The file will then undergo file validation, where the system will check that the information contained in the file adheres to the size and character restrictions given in the Submission Data Mapping Document, available on the Data Submission and Attestation page of the Open Payments website (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html).

You will receive an email that will provide you with the overall results of the validation, as well as general instructions on how to correct records that failed validation. Records that fail validation must be corrected before the final submission process. See Section 4.10 for details on record correction and resubmission.

Take note that the data has only been uploaded to the system; it has not yet been submitted as final into the Open Payments system. Performing bulk file upload only uploads the file and checks each record to ensure that it adheres to a valid data format. Final data submission can only take place once all records are error free and in "Ready for Submission" status. See Section 4.6 for details on final submission.

Open Payments (Sunshine Act)

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Upload Payments

To submit your payment file follow the steps identified below. Prior to uploading your payment file, ensure that the file is in a valid file format (.csv, .xml, or .zip) and conforms to the file specifications. If needed, you may download the latest Open Payments submissions sample files available on the right side of the page.

1 – Select the appropriate payment category, entity, and program year for which your payments apply.

2 – Select the "Browse" button to locate and select your file.

Once the file is selected, you have the option to submit as a test file or directly to the Open Payments system. Note that submitting your file as a test will verify that the file is correctly formatted, but the records will not be saved in the Open Payments system for review. Submitting as a test file is an optional step. If you select the "Submit File to Open Payments" button, in addition to validating the file format, the records within the file will be submitted for validation and will be viewable within the Open Payments system.

When you upload a payment file, you must first identify the payment category. You can upload more than one file, but no file can be larger than 250 MB.

Your file has been successfully uploaded.

* Payment Category:

General Payments

* Entity:

ABCDE Pharmaceuticals

* Program Year:

2013

* File:

C:\Users\jjdoyle\Desktop\ReSub_opani   Browse...

Must be a valid .csv, .xml, or .zip file. Maximum of 250MB per file.

Submit as Test File

Submit File to Open Payments

Access the Open Payments User Guide

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Download the Reporting Templates

The most recent versions of the reporting template files are below.

XML Templates

Open Payments Research Template.xml

Open Payments General Template.xml

Open Payments OwnerInvestor Template.xml

CSV Templates

Open Payments Research Template.csv

Open Payments General Template.csv

Open Payments OwnerInvestor Template.csv

Download All Templates

Open Payments Templates

Cancel

Section 4.5: Manual Entry Using the Graphic User Interface

The Open Payments system provides the ability to enter information regarding individual payments or other transfers of value through an online interface. The Submission Data Mapping Document, available on the Data Submission and Attestation page of the Open Payments website, (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html) provides guidance and descriptions on each of the fields that will be entered during the manual data entry process. It is suggested that submitters have this document available during manual entry to refer to for questions related to the data fields and descriptions.

4.5a: Manual Entry of General Payments

To enter general payments data manually, follow these steps:

Step 1: Access the Open Payments system via the CMS Enterprise Portal and select the "Payments" tab from the home page.

Step 2: Select "Manual Data Entry" from the Payments Overview page. On the "Enter Records Manually" page, use the drop-down menus to select the Payment Category, Entity Name, Program Year, and enter in the Home System Payment ID (if applicable). The Home System Payment ID refers to the identifier associated with the payment transaction in the applicable manufacturer or applicable GPO home system. Select "Continue" to proceed.

Step 3: Select the covered recipient type: physician or teaching hospital.

Step 4: The next few screens will differ depending on the covered recipient type selected. For teaching hospitals, enter information as requested on the screen below. Required fields are marked with asterisks. For a list of all teaching hospitals, refer to the Teaching Hospital page on the Open Payments website (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Teaching-Hospitals.html). The name entered in the "Teaching Hospital Name" field should match the name listed in the teaching hospital list.

For physicians, enter information as requested on the screen below. Required fields are marked with asterisks. Please note that physician license numbers entered into the Open Payments system cannot contain special characters (i.e., non-alphanumeric characters) and any special characters in the license number should be ignored. For a list of the available physician taxonomy codes, refer to the Medicare Provider/Supplier to the Healthcare Provider Taxonomy list in Appendix C. Specialty codes that are not on the taxonomy code list may not be entered.

Step 5: Enter product information. Select the product indicator for covered, non-covered, none, or combination. "Covered" is to be used when reporting only payments or other transfers of value related to covered drugs, biologicals, devices, or medical supplies. "Non-covered" is to be used when reporting payments or other transfers of value related to only non-covered drugs, biologicals, devices, or medical supplies. "None" is to be used when the reported payment was not made in relation to a drug, biological, device, or medical supply. "Combination" is to be used when reporting payments or other transfers of value related to a combination of both covered and non-covered drugs, biologicals, devices, or medical supplies.

Then enter National Drug Codes (NDCs) for up to five covered drugs or biologicals to be included in this record. NDCs are unique identifiers with ten alphanumeric characters and made up of three segments. These segments can be separated by dashes, though they do not have to be. As a result, the NDC must be in one of the following formats to be accepted by the Open Payments system:

- 12B45678A0

- 12B4-5678-A0

- 12B45-678-A0

- 12B45-678A-0

NDCs entered that do not match one of these four formats will not be accepted. NDCs can be found on the U.S. Food and Drug Administration's website at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm.

Enter the names of the drugs or biologicals associated with those NDCs in the table on the bottom left of the screen. If you are submitting information for covered devices or medical supplies, provide their names in the fields on the bottom right of the screen.

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Enter Payments Manually

✔ Recipient Demographic Information

② Associated Drug, Device, Biological, or Medical Supply Information

③ Transfer of Value (Payment) Information

④ General Record Information

⑤ Review and Submit

➦ **Access** the Open Payments User Guide

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Associated Drug, Device, Biological, or Medical Supply Information

Select the product indicator from the dropdown menu and then enter the applicable information for the associated drug, device, biological, or medical supply. If "Covered" or "Combination" is selected from the dropdown menu, you must enter either the name of the associated drug or biological, or the name of the associated covered device or medical supply. Optionally, you may enter the National Drug Code (NDC) of the associated covered drug or biological. When done, click the "Continue" button.

A field with an asterisk (*) is required.

* Product Indicator:

Covered ▾

National Drug Code of Associated Covered Drug or Biological:

1. 3698727262
2. 3698727263
3.
4.
5.

* Required: Enter the name of the associated drug or biological, or name of the associated covered device or medical supply.

Name of Associated Drug or Biological:

1. Advil
2. Bayer
3.
4.
5.

-OR-

Name of Associated Covered Device or Medical Supply:

1.
2.
3.
4.
5.

Cancel Back Continue

Step 6: Enter payment information in the required fields: total amount of payment, date of payment (which for program year 2013 must fall between August 1 and December 31, 2013), the number of payments included in the total amount, the form of payment or other transfer of value, and the nature of payment or other transfer of value. Note that only positive dollar values are allowed when reporting payment amounts. Negative dollar values are not permitted. Select "Continue."

Step 7a: Enter general record information for teaching hospitals. The "Contextual Information" box is a free-form text field where you can enter any information you deem helpful or appropriate regarding the payment or other transfer of value. The text field has a limit of 500 characters. If the "Delay in Publication of Research Payment" field is set to request a delay in publication, the Contextual Information box must include the name of the relevant research study.

Step 7b: Enter general record information for physicians. The "Contextual Information" box is a free-form text field where you can enter any information you deem helpful or appropriate regarding the payment or other transfer of value. The text field has a limit of 500 characters. If the "Delay in Publication of Research Payment" field is set to request a delay in publication, the Contextual Information box must include the name of the relevant research study.

Step 8: Review the payment information entered in the previous screens. Select "Back" to go back and edit information. Select "Save Record" to continue.

A confirmation message will be displayed on-screen to confirm that the record of the payment or other transfer of value has been saved and is being processed.

See Section 4.6, "Final Submission of Data," for the next steps.

4.5b: Manual Entry of Research Payments

To enter research payment data manually, follow these steps:

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Payments" tab from the home page.

Step 2: Select "Manual Data Entry" from the Payments Overview page. On the "Enter Records Manually" page, use the drop-down menus to select the Payment Category, Entity Name, Program Year, and enter in the Home System Payment ID (if applicable). The Home System Payment ID refers to the identifier associated with the payment transaction in the applicable manufacturer or applicable GPO home system. Select "Continue" to proceed.

Step 3: Select the recipient type: covered recipient physician, covered recipient teaching hospital, non-covered recipient entity, or non-covered recipient individual.

Step 4a: For covered recipient teaching hospitals, enter information as requested on the screen below. Required fields are marked with asterisks. For a list of all teaching hospitals, refer to the Teaching Hospital page on the Open Payments website (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Teaching-Hospitals.html). The name entered in the "Teaching Hospital Name" field should match the name listed in the teaching hospital list.

Step 4b: For covered recipient physicians, enter information as requested on the screen below. Required fields are marked with asterisks. Please note that physician license numbers entered into the Open Payments system cannot contain special characters (i.e., non-alphanumeric characters) and any special characters in the license number should be ignored. For a list of the available physician taxonomy codes, refer to the Medicare Provider/Supplier to the Healthcare Provider Taxonomy list in Appendix C. Specialty codes that are not on the taxonomy code list may not be entered.

Step 4c: For non-covered recipient entities, enter information as requested on the screen below. Required fields are marked with asterisks.

Step 4d: For non-covered recipient individuals, make the appropriate selection from the drop-down on the "Recipient Demographic Information" page and select "Continue."

Step 5: Enter product information. Select the product indicator for covered, non-covered, none, or combination. "Covered" is to be used when reporting only payments or other transfers of value related to covered drugs, biologicals, devices, or medical supplies. "Non-covered" is to be used when reporting payments or other transfers of value related to only non-covered drugs, biologicals, devices, or medical supplies. "None" is to be used when the reported payment was not made in relation to a drug, biological, device, or medical supply. "Combination" is to be used when reporting payments or other transfers of value related to a combination of both covered and non-covered drugs, biologicals, devices, or medical supplies.

Then enter National Drug Codes (NDCs) for up to five covered drugs or biologicals to be included in this record. NDCs are unique identifiers with ten alphanumeric characters and made up of three segments. These segments can be separated by dashes, though they do not have to be. As a result, the NDC must be in one of the following formats to be accepted by the Open Payments system:

- 12B45678A0

- 12B4-5678-A0

- 12B45-678-A0

- 12B45-678A-0

NDCs entered that do not match one of these four formats will not be accepted. NDCs can be found on the U.S. Food and Drug Administration's website at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm.

Enter the names of the drugs or biologicals associated with those NDCs in the table on the bottom left of the screen. If you are submitting information for covered devices or medical supplies, provide their names in the fields on the bottom right of the screen.

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Enter Payments Manually

✔ Recipient Demographic Information

② Associated Drug, Device, Biological, or Medical Supply Information

③ Transfer of Value (Payment) Information

④ Review and Submit

↪ **Access** the Open Payments User Guide

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Associated Drug, Devices, Biological, or Medical Supply Information

Select the product indicator from the dropdown menu and then enter the applicable information for the associated drug, device, biological, or medical supply. If "Covered" or "Combination" is selected from the dropdown menu, you must enter either the name of the associated drug or biological, or the name of the associated covered device or medical supply. Optionally, you may enter the National Drug Code (NDC) of the associated covered drug or biological. When done, click the "Continue" button.

A field with an asterisk **(*)** is required.

*Product indicator:

Covered ▾

NDC of Associated Covered Drug or Biological:

1. 6975482154669
2. 2534856747777
3.
4.
5.

*Required: Enter the name of the associated drug or biological, or name of the associated covered device or medical supply.

Name of Associated Drug or Biological:

1. Ranitidine
2. Bayer
3.
4.
5.

-OR-

Name of Associated Covered Device or Medical Supply:

1.
2.
3.
4.
5.

Cancel   Back   Continue

Step 6: Enter payment information in the required fields: total amount of payment, date of payment (which for program year 2013 must fall between August 1 and December 31, 2013), the number of payments included in the total amount, the form of payment or other transfer of value, and the nature of payment or other transfer of value. Note that only positive dollar values are allowed when reporting payment amounts. Negative dollar values are not permitted.

If you wish to request a delay in public reporting of that payment, you can request a delay in the "Delay in Publication of Research Payment Indicator" drop-down menu near the bottom of the screen.

The "Contextual Information" box is a free-form text field where you can enter any information you deem helpful or appropriate regarding the payment or other transfer of value. The text field has a limit of 500 characters. If the "Delay in Publication of Research Payment" field is set to request a delay in publication, the Contextual Information box must include the name of the relevant research study. Select "Continue."

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Enter Payments Manually

✓ Recipient Demographic Information

✓ Associated Drug, Device, Biological, or Medical Supply Information

③ Transfer of Value (Payment) Information

④ Review and Submit

➦ **Access** the Open Payments User Guide

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Research Payment or Other Transfer of Value Information

Enter the required payment or transfer of value information. Dollar amounts are to be entered in the following format and must not exceed 12 digits:[#####.##]. Note: Date of Payment must be entered in the following format yyyymmdd. When done, click the "Continue" button.

A field with an asterisk (*) is required.

Applicable Manufacturer or Applicable GPO Making Payment Name: ABCDE Pharmaceuticals

Applicable Manufacturer or Applicable GPO Making Payment Registration ID: 100000009054

* Total Amount of Research Payment: $
5000

* Date of Payment:
20131112

* Form of Payment or Transfer of Value:
Cash or cash equivalent ▾

Expenditure Category: Enter the percent for each of the following expenditure categories

Professional Salary Support

Medical Research Writing or Publication

Patient Care

Non-patient Care

Overhead

Other

* Pre-clinical Research Indicator:
No ▾

* Delay in Publication of Research Payment Indicator:
No Delay Requested ▾

* Name of Study:
Test Study

Context of Research:

Note: ClinicalTrials.Gov Identifier should be 11 character alphanumeric, first 3 characters alpha.

ClinicalTrials.Gov Identifier:

Note: Format of URL must start with http://www. or https://www. or www.

Research Information Link:

* Principal Investigator Covered Recipient Physician Indicator:
No ▾

Cancel   Back   **Continue to Review**

Step 7: Review the payment information entered in the previous screens. Select "Back" to go back and edit information. Select "Save Record" to continue.

A confirmation message will be displayed on-screen to confirm that the record of the payment or other transfer of value has been saved and is being processed.

See Section 4.6, "Final Submission of Data," for the next steps.

4.5c: Manual Entry of Ownership/Investment Interest Payments

To enter data ownership/investment interest payments manually, follow these steps:

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Payments" tab from the home page.

Step 2: Select "Manual Data Entry" from the Payments Overview page. On the "Enter Records Manually" page, use the drop-down menus to select the Payment Category, Entity Name, Program Year, and enter in the Home System Payment ID (if applicable). The Home System Payment ID refers to the identifier associated with the payment transaction in the applicable manufacturer or applicable GPO home system. Select "Continue" to proceed.

Step 3: Enter the Physician Demographic Information seen on the screen below. Required fields are marked with asterisks. For a list of the available physician taxonomy codes, refer to the Medicare Provider/Supplier to the Healthcare Provider Taxonomy list in Appendix C. Specialty codes that are not on the taxonomy code list may not be entered.

Step 4: Enter the ownership or investment information. Required fields are marked with asterisks. The "Terms of Interest" field must contain a description of any applicable terms of the ownership or investment interest. When reporting the terms of an ownership or investment interest, applicable manufacturers and applicable GPOs should report the type of ownership or investment interest, including but not limited to stock, stock options, partnership shares, loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion of that property or revenue. The field is a free-form text field, with a 500-character maximum.

Step 5: Review the ownership or investment information entered in the previous screens. Select "Back" to go back and edit information. Select "Save Record" to continue.

A confirmation message will be displayed on-screen to confirm the payment has been saved and is being processed.

See Section 4.6, "Final Submission of Data," for the next steps.

Section 4.6: Final Submission of Data

Final submission of data occurs after data has been uploaded and each record is error free. For program year 2013, final submission takes place between June 9 and 30, 2014. During this period, submitters will perform final data submission, which consists of ensuring that the data passes a series of checks to match the reported data to appropriate physicians or teaching hospitals.

4.6a: Final Submission of Data

To perform final submission of data, follow these steps.

Step 1: On the "Payments Overview Page" select the "Payments" tab. Select the entity from the drop-down list for which the payments were just uploaded and select "Show Summary." Once the summary displays, select "Review Records."

Step 2: On the "Review Records" page, you'll see a summary of all records that have been submitted for that entity. The three payment types will be in separate boxes. In each box is a series of statuses and the number of records currently in that status for the entity. Again, please note that these numbers are for all records submitted for the entity to date. The statuses are the following:

- **Ready for submission:** These records are ready to be submitted for attestation.

- **System processing:** These records are being processed by the system for field validation checks.

- **Ready for attestation:** These records have passed field validation and data matching, and are ready for attestation.

- **Failed validation:** These records did not pass field validation checks.

- **Unmatched:** These records did not pass data matching checks. See Section 4.8 for information on data matching.

- **Returned to submitter:** These records were returned by the attester as containing errors and requiring correction.

- **Attested:** These records have been attested to as accurate by the attester.

- **Matching in progress:** These records are undergoing data matching. See Section 4.8 for information on data matching.

- **Total payments:** This is the total number of records in the Open Payments system for that entity and payment type.

Correct the records as necessary to get them to "Ready for Submission" status. See Section 4.10 for information on correcting record errors.

Once all records are in "Ready for Submission" status, select "Final Submission" to proceed. Note that for program year 2013, the final submission can only be performed between June 9 and 30, 2014.

NOTE: After selecting "Final Submission," all submitted records go through the data matching process, which matches each record to a valid physician or teaching hospital. See Section 4.8 for details on data matching. After data matching is successfully completed through corrections or overriding of unmatched status (see Section 4.8), attestation can begin. See Section 4.11 for instructions on how to complete the attestation process.

Open Payments (Sunshine Act)

Home	**Payments** View, Edit, Report (Transfers of Value)	**Manage Entities** Register, Edit, Nominate Roles	**My Profile** Account, Roles, Notifications	Help

ABCDE Medical 2013 - Review Records

Below are the records reported by the entity and categorized by 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 an 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.

Back to Payments Overview

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Help with this Page

Record Status Definitions

What do I do if payments failed validation?

How do I begin final submission?

How do I begin attestation?

Program Year: 2013

Research Payments   View All

Status	Record Count	Action Required
Ready for Submission	0	Final Submission
System Processing	0	No Action
Ready for Attestation	0	Attest
Failed Validation	0	Correction
Unmatched	0	Correction or Override
Return to Submitter	0	Correction or Override
Attested	0	No Action
Matching in Progress	0	No Action
Total Payments	0	

General Payments   View All

Status	Record Count	Action Required
Ready for Submission	1	Final Submission
System Processing	0	No Action
Ready for Attestation	0	Attest
Failed Validation	0	Correction
Unmatched	0	Correction or Override
Return to Submitter	0	Correction or Override
Attested	0	No Action
Matching in Progress	1	No Action
Total Payments	2	

Ownership or Investment Interest Category Records   View All

Status	Record Count	Action Required
Ready for Submission	0	Final Submission
System Processing	0	No Action
Ready for Attestation	0	Attest
Failed Validation	0	Correction
Unmatched	1	Correction or Override
Return to Submitter	0	Correction or Override
Attested	0	No Action
Matching in Progress	1	No Action
Total Payments	2	

Step 2a: Selecting the "View All" next to a payment category will bring up this screen, which provides details on specific records.

Step 3: Select "Final Submission." The screen that appears will allow you to review summary details of your submission. If those details are correct, select "Submit as Final Submission."

Section 4.7: Consolidated Reporting

Consolidated reporting allows one entity in a related group to submit and attest to data on behalf of all its entities in that group. It is up to the discretion of each entity to decide if they would like to submit and attest to a consolidated report, or if each entity in the related group should submit and attest to their own data. This functionality allows the reporting entity to submit and attest to bulk data files across multiple registered entities. Consolidated reports are permitted when multiple applicable manufacturers or applicable GPOs held under common ownership combine their respective submissions into a single "consolidated report" for each type of transaction (general, research, or ownership or investment interest), and attest to the accuracy of the consolidated report.

Nevertheless, each individual entity contributing to that report is required to register in the Open Payments system separately. Also, the entities in the consolidated report will not have their payment or transfers of value information reported together; their information will be listed separately.

Each payment record made by a consolidated reporting entity is listed under each individual entity within the Open Payments system and is not represented under the entity making the submission on behalf of the consolidated group. And, attestation should be completed by the same individual for all entities included in the consolidated report, which is why the attester for the reporting entity must hold

the attester role for all other entities included in the consolidated report, as described below. Note that the attester does not need to hold an officer position (e.g., Chief Executive Officer, Chief Financial Officer, other "officer" position) within all of the entities included in the consolidated report, only within the reporting entity.

The following pre-conditions must be met in order to successfully upload a consolidated report:

- All entities must be registered in the Open Payments system and be successfully vetted OR in "Conditionally Approved" status;

- The entity names and registration IDs in the file must match exactly those provided during Open Payments registration;

- The submitter of the reporting entity must hold the submitter role in all other entities included in the consolidated report;

- The attester of the reporting entity must hold the attester role in all other entities included in the consolidated report (Note that the attester does not need to hold an officer position, such as Chief Executive Officer or Chief Financial Officer, within all of the entities included in the consolidated report, only within the reporting entity);

- The consolidated Indicator field in file must be set to Y.

If the above conditions are not met, then the system will display those records under the reporting entity along with a failed status.

Consolidated reporting in Open Payments categorizes entities into two types: the reporting entity submitting and attesting to the consolidated report, and the entity(ies) included in the consolidated report. They are defined as follows:

- Reporting Entity: This is the entity that reports the payments or other transfers of value, or ownership/investment interest in the Open Payments system for all related entities for the program year, and attests to the accuracy of the data on the behalf of the other entity(ies) in the consolidated report.

- Entity(ies) in Consolidated Report: This is an entity in the consolidated report that made payments or other transfers of value, or had physician owners/investors during the program year.

Consolidated reporting must be performed by bulk file upload.

Example: Entity A made a consolidated report submission for itself, Entity B, and Entity C. Entities A, B, and C are all registered within the Open Payments system. The submitter must have the role of submitter for all three entities, A, B, and C. Similarly, the attester must have the role of attester for all three entities, A, B, and C. Once the submission is accepted in the Open Payments system, the payment records for Entity B and Entity C would be listed under those individual entities, and will not be listed under Entity A. Because the attester for Entity A holds the role of attester for Entities B and C, he/she can attest to the accuracy of the data submitted for those entities.

Section 4.8: Data Matching

After the submitter has made the final data submission, the data goes through a matching process to ensure the payments or other transfers of value reported are consistently attributed to the correct physicians and teaching hospitals. After the matching process is complete, the Open Payments system sends an email to submitters alerting them to the success or failure of their submission.

If the system is unable to match some or all of the reported transactions, the records result in "Unmatched" record status. Also, upon the attester's review of the reported transactions, the attester may choose to return some or all of the records back to the submitter for correction. An email notification is sent to the authorized user in the submitter role in both scenarios.

The submitter(s) can then override the record statuses of "Unmatched," and "Returned To Submitter." Overriding the status of records signifies that the submitted record(s) were reviewed and determined to be accurate to the best of the submitter's knowledge. Once the data in the record statuses of "Unmatched" and "Returned To Submitter" are manually overridden, the submitter can proceed with the submission.

Data matching may take from minutes to days, depending upon the size of the files and the number of submissions being processed simultaneously. Attestation of data may be done only after data matching has been successfully completed for each record. Submitters have the opportunity to make corrections to the data or proceed with the submission as entered if some of the records were not matched.

Section 4.9: Third Party Data Submitters

Applicable manufacturers and applicable GPOs may choose to have their data prepared and submitted by a third party organization. Third party organizations may format, prepare, and submit data on behalf of a reporting entity. The role of submitter is the only role third party companies can fulfill within Open Payments.

For a third party to submit payments on behalf of an entity, the entity must identify a specific individual within the third party organization to fulfill the submitter role. **A specific individual within the third party must be identified as the submitter, not simply the third party entity itself.**

Third party submitters may be associated with multiple reporting entities. In such a case, each reporting entity must have an individual within the third party assigned to the submitter role. Third party submitters will follow the same process outlined earlier in Chapter 4 of this guide for validating and submitting data.

Section 4.10: Data Submission Errors

During the data submission process, records may be uploaded unsuccessfully. Users will have an opportunity to review the unsuccessful records, correct any issues, and resubmit them through the system. For manual entries, users will be notified on screen in real-time if there are any data entry errors. For bulk uploads, users will receive an email notifying them of errors.

To avoid data submission errors, confirm all data entered for each line item prior to submitting the record(s). If any portion of the submitted file has failed validation, the user can log back into the Open

Payments system to view the error report which contains a list of error codes for each record. All records that have generated an error will appear in this report.

Users must access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) to access the error file generated from their file submission. Submitters will be able to view the error file, correct the individual records accordingly, and resubmit.

To find the error records for your submission, access the Open Payments system and select the Payments tab on the toolbar. This will bring up a "Show Entity" menu. Select the entity whose records you wish to review, then select "Show Summary."

A summary of submissions will appear. Select "View Records" from the summary to go to the "Review Records" page. This screenshot shows an example of what you will see when you access the Review Records page in the system after your data has been uploaded. The File IDs are on the left, the Record Status values are on the right.

You will be able to search for records that were not uploaded successfully by filtering for records in a "Failed Validation" status.

To access the error report for a given record, click on the record's File ID, which will take you to the File Properties page.

On the File Properties page, you will see a hyperlink at the bottom of the page that will allow you to download the error report associated with this file. All errors within that file will be included in the error report.

When downloading the error report file, you will be asked to select a format for viewing the error report. The screenshot below shows a sample error report opened as a CSV file. You may also open error reports using Notepad or another application.

The codes listed in the "Error Message ID" column are error codes. A complete list of error codes and their meanings is available on the CMS Open Payments website as the Open Payments Error Code File document (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html#Error Code File). Cross-reference the code in the "Error Message ID" field with the Open Payments Error Code File document to determine what the error is, as well as how to address the error.

Records with no errors do not need to be resubmitted. You must correct and resubmit the record(s) that failed validation. To resubmit the record(s), you may go through one of the following methods:

- If using the manual entry data submission option, open the record using the edit button, make your updates, then select submit.

- If using the bulk data submission option, fix the incorrect data in the bulk data file and then indicate in each resubmitted record that it is a resubmission. To do so, set the Resubmission Indicator in the record to "Y" and enter the original Record ID in the "Resubmitted Payment Record ID" field. The "Resubmitted Payment Record ID" field must be filled in with the original Record ID for the system to accept the record as a resubmission.

- If the changes are extensive, you may also delete your entire original data file submission and replace it with a new submission. The attester will need to re-attest to the accuracy of all re-

submitted data. Records that are deleted will no longer appear in the views of either the reporting entity or the covered recipient.

- If a resubmitted record changes the covered recipient, the original covered recipient will no longer see the record in his or her profile. Only the new covered recipient will see it.

Resubmissions cannot extend past the stated submission deadline (for program year 2013, that is June 30, 2014). Resubmissions past the stated submission deadline will be considered late submissions and will not be included in the publication of data in September 2014.

Note that if records are resubmitted, all records submitted for that reporting year will require re-attestation.

Section 4.11: Attestation and Assumptions

Data attestation is how entities affirm and certify that the information being submitted on behalf of the entity is accurate and correct. Only individuals with the designated role of attester may attest to the accuracy of the data in the Open Payments system. After the data is submitted and the data matching process is completed, the attester will be able to attest to the accuracy, completeness, and timeliness of the data. This applies to all re-submissions as well.

An attester can only attest to records that have been successfully submitted and validated for that program year. Additionally, the attester may decline to attest and request that some or all of the data submitted be returned to the submitter for corrections and review. The attester can select one or more records to return to submitter and then select the "Return to Submitter" button. The submitter must perform the corrective actions requested by the attester or indicate that no action is required, then re-submit the payment record(s) for attestation. If an attestation is made after the deadline for that respective program year, the system will flag the report as late.

The attester will also have the option of submitting an assumptions statement during the attestation process. Assumptions explain the reasonable assumptions made, and methodologies used, when reporting payments or other transfers of value, or ownership or investment interests. Assumptions will be made via a free-form text field during the attestation process. Users can choose to write free-form text, or cut and paste text from another document. Assumptions cannot be longer than 4,000 characters (including spaces). Note that the only special characters allowed by the system in free-form text boxes are listed in Appendix A. This information can be edited later.

Note that if you do not add any assumptions during the initial attestation, you will not be able to add them after attestation has been completed for that program year. If your assumptions statement has not been finalized at the time of attestation, you may add in placeholder text such as "Assumptions statement to be added" to allow you to update this field at a later time.

Users who knowingly submit to the Open Payments system any misrepresentation or any false, incomplete, or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties in accordance with the Open Payments system disclaimer and Title 18 U.S.C Section 1030.

Below you will find the attestation statements presented in the Open Payments system. Applicable manufacturers and applicable GPOs will be required to confirm the attestation statements prepopulated by the Open Payments system by selecting the checkboxes next to each of the applicable statements. The user must, at a minimum, select the first two checkboxes to proceed with the attestation process.

1. I am attesting that I am a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization with the authority to attest to the information submitted to the Open Payments system.

2. I am attesting that the information reported is timely, accurate, and complete to the best of my knowledge and belief.

3. I am attesting that my entity is only reporting payments or other transfers of value associated with covered drugs, devices, biologicals, or medical supplies based on one or more of the reasons listed below.

    If yes to statement 3 above, indicate the reason by selecting at least one of the following reporting limitation statements:

    a. My entity's gross revenue from covered drugs, devices, biologicals or medical supplies constituted less than 10 percent of gross revenue during the fiscal year preceding the reporting year.

    b. My entity is under common ownership, as defined by 42 CFR 403.902, with an applicable manufacturer and provides assistance or support to an applicable manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological, or medical supply. Therefore, my entity is only required to report payments or other transfers of value associated with covered drugs, devices, biologicals or medical supplies which my entity provided assistance and support to an applicable manufacturer.

    c. My entity has a separate operating division that does not manufacture any covered drugs, devices, biological, or medical supplies. Therefore, my entity is only required to report payments or other transfer of value to covered recipients related to the activities of these separating operating divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply.

    d. The only covered drug, device, biological or medical supply manufactured by my entity is pursuant to a written agreement to manufacture a covered drug, device, biological, or medical supply for another entity. My entity does not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and is not involved in the sale, marketing, or distribution of the covered drug, device, biological or medical supply. Therefore, my entity is only required to report payments or other

transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

    e.   My entity only manufactures covered drugs, devices, biologicals, or medical supplies.

4. I am attesting that my entity is requesting a delay in publication for one or more payments or other transfers of value.

   If yes to statement 4 above, indicate one or more of the reasons listed below.

       a. The payment or other transfer of value is related to research or development of a new drug, device, biological, or medical supply.

       b. The payment or other transfer of value is related to research or development of a new application of an existing drug, device, biological, or medical supply.

       c. The payment or other transfer of value is related to clinical investigations regarding a new drug, device, biological, or medical supply.

5. I am attesting that my entity is submitting a consolidated report because it is under common ownership, as defined by 42 CFR 403.902, with a separate entity or entities that are also applicable manufacturers.

4.11a: Attesting to Data in the Open Payments System

The following instructions show the step-by-step screens for the attestation process. Remember that all records must be in "Ready for Attestation" status to take these steps.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). Select the "Payments" tab on the Open Payments system home page.

Open Payments (Sunshine Act)

Home	**Payments** View, Edit, Report (Transfers of Value)	**Manage Entities** Register, Edit, Nominate Roles	**My Profile** Account, Roles, Notifications	Help

Payments Overview

A field with an asterisk (*) is required.

Applicable manufacturers or applicable group purchasing organizations (GPOs) must submit payments or other transfers of value, or ownership or investment interests in the Open Payments system. There are two methods for data submissions:

- Bulk File Upload (CSV or XML)
- Manual Data Entry

Note: If using the manual data entry option, you may only enter one record can be entered at a time.

Select one of the links above to submit your data to the Open Payments system. Note that to submit and edit data in the system, the user must have a role of "submitter" for the affiliated applicable manufacturer or applicable GPO.

Once the data submission is made, the user in the role of "submitter" and/or "attester" can review all of the payments or other transfers of value, or ownership or investment interests under each payment category by selecting the applicable manufacturer or applicable GPO name under "Show Entity" and clicking on the "Show Summary" button. In the search results table, you can view or edit the payments or other transfers of value by selecting the applicable program year hyperlink or by selecting the "View Records" button. There will be no payments or other transfers of value, or ownership or investment interests to view if the entity has not submitted any data to the Open Payments system. Payment category types include research, general, and ownership or investment interests.

Data for current and past payments (transfers of value) are available as they are submitted.

* Show Entity: [ABCDE Medical ▼]   **Show Summary**

Sidebar

↪ **Access** the Open Payments User Guide

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Download the Reporting Templates

The most recent versions of the reporting template files are below.

XML Templates

- Open Payments Research Template.xml
- Open Payments General Template.xml
- Open Payments OwnerInvestor Template.xml

CSV Templates

- Open Payments Research Template.csv
- Open Payments General Template.csv
- Open Payments OwnerInvestor Template.csv

Download All Templates

- Open Payments Templates

Step 2: Select the entity from the "Show Entity" drop-down list and then select "Show Summary." Once the summary appears, select "Review Records."

Step 3: Select "Begin Attestation of All Records."

Step 4: Review the payment information on screen. Select "Go to View Records" to view the detailed records being attested. Select "Next" when you are ready to continue with the attestation process.

Step 5: Next, the option to add assumptions associated with these records is presented. Select "No" if no assumptions will be added. Select "Yes" if assumptions will be added. If you select "Yes," a free-form text field will appear. Type or paste your assumptions into this text field, which has a 4,000-character limit. Special characters that can be used in the text field are limited to those listed in Appendix A. This text field can be edited later. If assumptions are not added at this point, they cannot be added later. When you are done, select "Next." Both options are displayed below.

Open Payments (Sunshine Act)

Home	Payments View, Edit, Report (Transfers of Value)	Manage Entities Register, Edit, Nominate Roles	My Profile Account, Roles, Notifications	Help

Attest

✔ Confirm Payments

② Add Assumptions

③ Agree to Attestations

④ Review and Attest

↪ **Access** the Open Payments User Guide

❓ Need help with the website?
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Add Assumptions

An asterisk (*) indicates a required field.

2013 Program Year:

ABCDE Medical

Applicable manufacturers and applicable GPOs may submit assumptions, which explain the reasonable assumptions made and the methodologies used when reporting payments or other transfers of value, or ownership or investment interests. By default, the assumptions statement applies to all payments (transfers of value) being attested to. Learn more about submitting assumptions in the Open Payments User Guide.

Note: Assumptions for an entity can only be entered and edited by a user with an attester role. Assumptions entered during the initial attestation can be updated and additional assumptions can be entered at any time, but doing so will require re-attestation. If no assumptions were entered during initial attestation, the user will not be able to add assumptions later.

* Do you wish to include assumptions with this attestation?

○ Yes, include an assumptions statement

○ No, do not include an assumptions statement (you can add this later if necessary, but only up to the submission deadline for the program year)

Assumptions

Enter your assumptions in the data entry box below. Note: You may enter up to 4,000 characters. Special characters allowed in the assumptions box are limited to apostrophes ('), single quotes ('), dots (.), ampersands (&), hyphens (-), and commas (,).

[text entry box]

Cancel		Back	Next

Step 6: Read and agree to the attestations on the next screen. You **must** agree to Attestation Statements 1 and 2 in order to complete the attestation process. Attestation statements 3 - 5 should be reviewed and selected only if they apply to your entity and the payments being attested to. The text of these statements is given earlier in this section. Once the appropriate attestations have been chosen, select "Continue."

Step 7: Review the information entered on the previous pages. If the information is correct, select "Attest" to complete attestation.

You will be brought back to the Review Records page. The record(s) attested to will appear in the "Attested" column. The Open Payments system will send an email to the attester notifying them of the success of the attestation, which concludes the data submission process.

NOTE: In the event of data submitted as a consolidated report, each individual entity within the consolidated report must attest to the accuracy of its own data.

Review and Dispute
For Industry

Chapter 5: Review and Dispute for Applicable Manufacturers and Applicable GPOs

This chapter provides information on the Review and Dispute process for applicable manufacturers and applicable GPOs. When an applicable manufacturer or applicable GPO has submitted records regarding payments, other transfers of value, or physician ownership or investment interests to Open Payments, the associated physician or teaching hospital will have an opportunity to review the data that was submitted about them. If a physician or teaching hospital finds discrepancies with the submitted data, they can initiate a dispute.

This chapter is divided into the following sections:

- **Overview of Review and Dispute**, which provides information on the review and dispute process within the Open Payments system.

- **Acknowledging Disputes and Resolving Disputes with No Change**, which provides information on how applicable manufacturers and applicable GPOs can acknowledge and resolve disputes initiated by physicians and teaching hospitals. The "resolved, no change" action should only be taken when dispute resolution does not require a change to the data by the reporting entity.

- **Correction and Resolution of Disputed Data**, which provides information on the correction and resolution of disputed data process for applicable manufacturers and applicable GPOs.

The review and dispute period will start at least 60 days before the information is to be published for that program year. Physicians and teaching hospitals will work directly with reporting entities to resolve disputes outside of the Open Payments system.

If a dispute is not resolved before the end of the 60-day period, the latest, attested-to data submitted by the applicable manufacturer or applicable GPO will be published in the next data publication and identified as being under dispute.

Reviews and disputes can occur outside of this 60-day period; the review and dispute process is open year-round. If the applicable manufacturer or applicable GPO cannot resolve the dispute with the physician or teaching hospital within those 60 days, all parties should continue to seek a resolution.

The process is outlined in Figure 5.1, below.

Figure 5.1: Review, Dispute, and Correction Process

During	What Happens During Review?	What Happens During Dispute?	What Happens During Corrections?
Day 1-45	• Applicable manufacturers, applicable GPOs, physicians and teaching hospitals review their data before it is made public.	• Physicians and teaching hospitals can dispute information reported about them or their institutions. • Disputes initiated during this 45-day period that are not resolved by the end of the period will be reflected in the public data as under dispute. • CMS will not mediate any dispute.	• Applicable manufacturers and applicable GPOs should work with the disputing physician or teaching hospital to correct disputed data. • Applicable manufacturers or applicable GPOs must submit a revised report to make the corrections and re-attest to the updated data.
> 45 Days	• Applicable manufacturers and applicable GPOs seek to resolve disputes received from physicians or teaching hospitals. • Physicians and teaching hospitals may continue to review the data.	• Physicians and teaching hospitals may continue to initiate disputes during this period, but resolutions may not be reflected in publicly displayed data.	• Applicable manufacturers and applicable GPOs should work with physicians and teaching hospitals to make corrections. • Corrections made to disputes may not be included in the next publication of data. • Applicable manufacturers and applicable GPOs must send CMS a revised report to make the appropriate corrections and re-attest to the updated data.

There is a 45-day period for physicians and teaching hospitals to review, dispute, and work with the reporting entity to resolve the disputed records. Immediately following that initial 45 days is an additional 15-day correction period for reporting entities to work with physicians and teaching hospitals on dispute resolution.

Disputes initiated within the initial 45-day review and dispute period, and resolved by the end of the additional 15-day correction period, will be published and identified as non-disputed in the initial public posting of data. Disputes initiated or resolved after the 60-day period will not be published in the initial publication of data. Those disputes and any related data changes will be published in the next

publication of data, which may be a refresh publication of the program year data or the publication of the next program year's data. In the publication, the data will be associated with the program year of the data, not the date of its publication.

To change data, applicable manufacturers and applicable GPOs must submit to CMS a revised report that contains the appropriate corrections, and the revised report must be re-attested to by the applicable manufacturer or applicable GPO to be fully submitted. Note that the Final Rule does not require CMS to display the data as disputed if the dispute is not resolved during this period.

Figure 5.2 below explains how the dispute initiation and resolution timing affects the public display status of the data:

Figure 5.2: Dispute Initiation, Resolution, and Public Display of Program Year 2013 Data

Timing of Dispute Initiation	Dispute Resolution Status Within 45-Day Initial Period or 15-Day Correction Period	Public Display Status
Within 45-day review, dispute & correction period	Resolved	Data, with any revisions from resolution, will be published as non-disputed in September 2014
	Not resolved	Data published as disputed in September 2014
After 45-day review, dispute & correction period and prior to the review, dispute & correction period before the next data refresh or publication	Resolved	Data published as non-disputed in both September 2014 and the subsequent data publication related to the 2013 program year data Any revisions to data due to resolution will appear in subsequent data publications
	Not resolved	Data published as non-disputed in September 2014 and as disputed in the subsequent data publication related to 2013 program year

Records in the Review and Dispute process will have one of the following statuses:

- **Initiated:** indicates that a physician or teaching hospital has initiated a dispute against a record submitted by an applicable manufacturer or applicable GPO.

- **Acknowledged:** indicates that an applicable manufacturer or applicable GPO has received and acknowledged a dispute initiated against them by a physician or teaching hospital. Acknowledging a dispute will trigger a notification to the initiating physician or teaching hospital letting them know their dispute has been received.

- **Resolved, No Change**: indicates that either the applicable manufacturer or applicable GPO does not agree with a dispute initiated by a physician or teaching hospital or the applicable manufacturer or applicable GPO has discussed the dispute with the initiating physician or teaching hospital and it was determined that no change in the data was necessary. The physician or teaching hospital who initiated the dispute can initiate a new dispute if they disagree with the "resolved, no change" status.

- **Withdrawn**: indicates that a physician or teaching hospital has withdrawn a dispute they initiated against a record submitted by an applicable manufacturer or applicable GPO.

- **Resolved:** indicates that disputed data was corrected and then resubmitted and re-attested to by the applicable manufacturer or applicable GPO.

Emails transmitted to applicable manufacturers, applicable GPOs, physicians, and teaching hospitals from the Open Payments system for review and dispute will not contain contact information. For example, an email notifying a reporting entity of a dispute from a physician will contain only the information needed to locate the record in the Open Payments system. You can view a sample notification email for each review and dispute action in Appendix D. Contact information can be obtained only by opening the record within the Open Payments system itself.

Section 5.1: Acknowledging Disputes and Resolving Disputes with No Change

Applicable manufacturers and applicable GPOs will be given the opportunity to acknowledge and resolve disputes initiated by physicians and teaching hospitals. When a dispute is acknowledged or set to a "resolved, no change" status, the covered recipient will receive an email notification. The five steps of the process are given in Figure 5.3 below.

Figure 5.3: Acknowledging Disputes and Resolving Disputes with No Change Process

Log in to Open Payments and Select Review and Dispute	Select Reporting Entity and Program Year	View Records Listed for Covered Recipient	[If Acknowledging] Review Selected Records and Acknowledge	[If Resolved, No Change] Review Selected Records and Resolve

Section 5.1a: Acknowledging a Dispute

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select "Review and Dispute."

Open Payments (Sunshine Act)

Manufacturer or Group Purchasing Organization Switch User Type

Home	Records View, Edit, Report	Review and Dispute View, Respond, Resolve	Manage Entities Register, Edit, Nominate Roles	My Profile Account, Roles, Nominations	Help

Welcome to the Open Payments System

You can manage your user profile and perform user role functions associated with your profile.

Access the Open Payments User Guide

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Contact Us by email

Step 2: Select the reporting entity and appropriate program year for which you wish to view disputes. When finished, select "Show Disputes."

Step 3: On the "Review and Dispute" page, you will see a list of all disputes initiated by physicians and teaching hospitals. If you wish, you may filter the records by entering the Dispute ID, the Record ID, Home System Payment ID, File ID, Date of Publication, Physician First Name, Physician Last Name, Teaching Hospital Name, or Review and Dispute Status. You do not need to filter the results in order to proceed. Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Step 4: To view details about a disputed record, scroll to the right of the table using the bottom scroll bar and select "View" under the "Action" column.

Step 5: Select the disputed record(s) you wish to acknowledge. Once you have selected the appropriate record(s), select "Acknowledge Dispute." You may only acknowledge disputes with a review and dispute status of "Initiated." Review and dispute statuses can be seen by scrolling to the right.

Step 6: Review the disputed record information as displayed on the "Acknowledge Dispute" page. When finished, select "Acknowledge."

The following confirmation message will be displayed on the screen. An email notification will be sent to the covered recipient informing them that their dispute has been acknowledged.

Section 5.1b: Resolved, No Change Disputes

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Review and Dispute" tab on the menu bar.

Step 2: Select the physician or teaching hospital and the appropriate program year that you wish to review disputes. When finished, select "Show Disputes."

Step 3: On the "Review and Dispute" page, you will see a list of all disputes regarding the payments or other transfers of value you reported initiated by the identified physicians and teaching hospitals. If you wish, you may filter the records by entering the Dispute ID, the Record ID, Home System Payment ID, File ID, Date of Publication, Physician First Name, Physician Last Name, Teaching Hospital Name, or Review and Dispute Status. You do not need to filter the results in order to proceed. To view details about a disputed record, scroll to the right of the table using the bottom scroll bar and select "View." Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Step 4: Review the information on the Record page. When finished, select "Back."

Step 6: Select the dispute record(s) you wish to resolve with no changes. Once you have selected the appropriate record(s), select "Resolved, No Change." You may only resolve disputes with no changes that has a review and dispute status of "Initiated" or "Acknowledged."

Step 7: Review the disputed record information as displayed on the "Resolved No Change" page. You must enter the reason the dispute has been resolved with no changes needed to the data in the text box in order to proceed. The text box can contain up to 4,000 characters, including spaces. Special characters allowed in the box are limited to apostrophes or single quotes ('), periods (.), ampersands (&), hyphens (-), and commas (,).

Note: As mentioned, you must provide a reason why the records are being resolved without change in the "Reason for dispute resolution with no change to the data" text box. If you have different reasons

for each of the records being resolved, you may resolve one or more record(s) at a time with a common dispute factor, and enter the relevant reason for the resolution. The contents of the "Reason for dispute resolution with no change to the data" box will be sent in an email to the physician or teaching hospital. If multiple disputes are resolved without changes at the same time across different covered recipients, the same "Reason for dispute resolution with no change to the data" text will be sent to all of the covered recipients included in the dispute. When finished, select "Resolved No Change."

The following confirmation message will be displayed on the screen. An email notification will be sent to the covered recipient physician or teaching hospital informing them that their dispute has been resolved

with no changes made to the data. The covered recipient may initiate a new dispute for the same record if the dispute has not been resolved to their satisfaction.

Section 5.2: Correction and Resolution of Submitted Payment Data

Once an applicable manufacturer or applicable GPO has received a dispute initiated by a physician or teaching hospital, the applicable manufacturer or applicable GPO may work with the physician or teaching hospital to correct the disputed data. The applicable manufacturer or applicable GPO will submit the corrected record; they must then attest to the newly submitted data. When submitting corrected data via bulk file upload, you will need to include the Record ID for the record(s) in the resubmission. If you are correcting data via the graphic user interface, you will need to locate the record(s) in the Open Payments system and change them using the edit function. See Section 5.2a below for more information.

After resubmission and re-attestation is complete, the covered recipient will receive an email notification instructing them on next steps. The five steps of the correction and resolution process are given in Figure 5.4 below.

Figure 5.4: Correction and Resolution Process
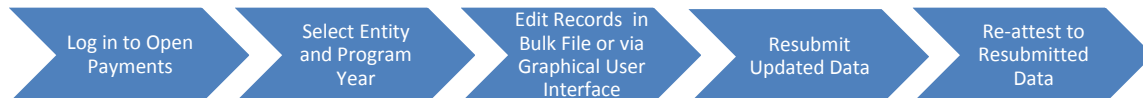
Section 5.2a: Edit Information and Resubmit Record

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Review and Dispute" tab on the menu bar.

Step 2: Select the entity name and the appropriate program year from the drop-down menus. When finished, select "Show Disputes." This will show you a list of all disputes for the selected entity.

Step 3: On the "Review and Dispute" page, scroll down until you see the table that contains all disputed records. Filter the "Review and Dispute Status" to "Acknowledged" and/or "Initiated," and select "Search." You can only update and/or correct record(s) with a review and dispute status of "Initiated" or "Acknowledged." Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Step 4: To manually edit a record, scroll to the right and select "Edit" under the "Action" column and edit the appropriate fields. For detailed instructions on how to manually edit a record, and to correct records via bulk file resubmission, see Section 4.10. The dispute history of a record that has been updated will show versions of the record prior to the resubmission as having a status of "inactive."

Section 5.2b: Resubmission and Re-attestation

Reporting entities can resolve disputes in one of two ways, either by resolving the dispute with no changes (described in Section 5.1b) or by correcting the record. Entities submitting corrected data must

resubmit and re-attest to the corrected data for the updates to be included in the public posting. Once re-attestation is complete, the records will be automatically placed in a review and dispute status of "Resolved." No further action is needed from the reporting entity.

To resubmit the record(s), you may go through one of the following methods:

- When using the manual entry data submission option, open the record using the edit button, make your updates, then select "Submit," or

- When using the bulk data submission option, fix the incorrect data in the bulk data file. Then indicate that it is a resubmission. To do so, set the Resubmission Indicator in the record to "Y" and enter the original Record ID in the "Resubmitted Payment Record ID" field for each record in the file. The "Resubmitted Payment Record ID" field must be filled in with the original Record ID for the system to accept the record as a resubmission.

It is strongly recommended that you do not delete your entire original data file submission and replace it with a new submission. If a file is deleted and replaced after the reporting deadline, the Open Payments system will treat the file as newly arriving late records rather than corrections. The new records will not be included in the current publication cycle and will be identified in review and dispute as for a future publication.

The attester will need to re-attest to the accuracy of all re-submitted data. An attester can only attest to records that have been successfully submitted and validated. Additionally, the attester may decline to attest and request that some or all of the data submitted be returned to the submitter for corrections and review. The attester can select one or more records to return to the submitter and then select the "Return to Submitter" button. The submitter must perform the corrective actions requested by the attester or indicate that no action is required, then re-submit the payment record(s) for attestation.

For detailed instructions on submitting data, see Section 4.6. For more detailed instructions on attestation of data, see Section 4.11.

Audits

Chapter 6: Audits

Coming Soon

Non-Compliance and Penalties

Chapter 7: Non-Compliance and Penalties

Coming Soon

PART IV: PHYSICIANS AND TEACHING HOSPITALS

Open Payments Registration
For Physicians and Teaching Hospitals

Chapter 8: Physician and Teaching Hospital Registration

This chapter provides information for physician and teaching hospital registration in CMS's Enterprise Identity Management system (EIDM) and the Open Payments system. Both registrations are required to obtain access to the Open Payments system. All physicians and teaching hospitals who wish to view data reported about them must complete both registrations prior to accessing the system.

This chapter is divided into the following sections:

- **Overview of Registration**, which provides information on Phase 1 and 2 of the Registration process. Phase 1 includes user registration in EIDM, and Phase 2 includes user registration in the Open Payments system.

- **Open Payments Users** and **User Roles**, which contains information on who is authorized to register in the Open Payments system and the user roles that must be filled by the Open Payments system users.

- **Registration and Access to the Open Payments System**, which contains instructions for registering, logging into the system, and managing physician and teaching hospital registration and user roles.

Section 8.1: Two-Phased Registration Process

Physicians and teaching hospitals must register in the Open Payments system in order to view, review and/or dispute data submitted about them. **Note: Physicians and teaching hospitals are not required to register but are encouraged to do so in order to view information reported about them prior to CMS's publication of the data.**

Prior to registration in the Open Payments system, users must register in EIDM to obtain login credentials. Users will not be able to access the Open Payments system without first completing successful EIDM registration. Once the user has registered in EIDM, he or she will be able to register in the Open Payments system.

8.1a: Registration Phase 1 – EIDM Registration

Open Payments registration for the 2013 program year will be completed in a two-phased approach. **Figure 8.1** below, illustrates the two-phased approach to physician and teaching hospital registration used only for this first program year. During Phase 1, physicians and authorized officials of teaching

hospitals may obtain EIDM credentials and request access to the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov).

Note: Physicians with addresses outside of the United States who wish to register with EIDM must begin by contacting the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366. When emailing, the subject line of the message should read "Foreign Address Credential Request – Attestation Letter."

Instructions for registering in EIDM and obtaining access to the Open Payments system can be found in Section 8.2.

Figure 8.1: Phased Registration Process for Physicians and Teaching Hospitals

Phase 1

- Physicians and teaching hospitals register in EIDM and request access to the Open Payments system

Phase 2

- Physicians and teaching hospitals register in the Open Payments system, review, and dispute data
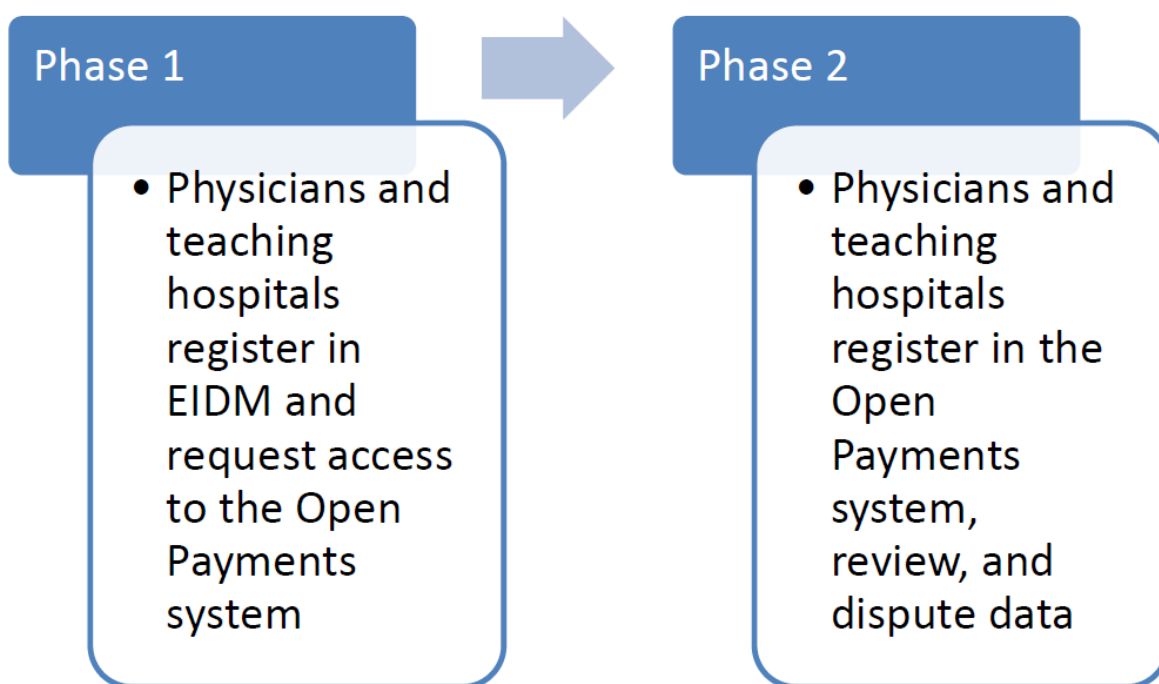
8.1b: Registration Phase 2 – Open Payments System

Phase 2 of Open Payments physician and teaching hospital registration begins when the Open Payments system becomes available to physicians and teaching hospitals in July 2014. During this phase, physicians and teaching hospitals that have already registered in EIDM and requested access to the Open Payments system may register in the Open Payments system, and may then review and dispute information reported about them.

Section 8.2: Enterprise Identity Management (EIDM) Registration and Open Payments Access

Enterprise Identity Management (EIDM) is an identity management and services system that a) serves as an identity proofing tool to verify a person's identity, and b) provides users with access to various CMS applications. Registering in EIDM provides users with login credentials **required** for access to the Open

Payments system. Users will be able to set up their own log in credentials in the form of a user ID and password during the EIDM registration process. EIDM credentials allow login to the CMS Enterprise Portal and the ability to request access to various CMS applications, including the Open Payments system.

EIDM can be accessed and the registration process begun on the CMS Enterprise Portal (https://portal.cms.gov). A complete EIDM Operations Document and a list of EIDM FAQs are available on the CMS website (http://go.cms.gov). Users who already have EIDM credentials can move ahead to request access to the Open Payments application.

EIDM will lock your user account if you do not log in to your account for 60 or more days. When you log in after 60 days, the system will display the "Unlock my Account" view. To unlock your account, enter your user ID and correctly answer all challenge questions. Then enter your new password in the input fields of "New Password" and "Confirm New Password" to unlock your account. If you are still unable to reactivate your account, contact the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366.

EIDM will automatically deactivate any user that has not logged in for 180 days or more. Once the user's account has been disabled, the user will not be able to access the CMS application(s). You can contact the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366 to reactivate your account after 180 days of inactivity.

Please note that system users who have addresses outside of the United States must contact the Open Payments Help Desk at openpayments@cms.hhs.gov to register in EIDM.

For assistance registering in CMS's Enterprise Portal, you can view the instructional presentation on steps to complete EIDM registration on the CMS Open Payments website (http://go.cms.gov/openpayments) on the Program Registration page. Here you will find complete step-by-step instructions on how to register with EIDM and request access to the Open Payments system.

Section 8.3: Registering in the Open Payments System

Once the physician or teaching hospital has decided who should fill the required user roles, that individual can begin Open Payments registration. The authorized representative user role is not required for physicians or teaching hospitals. This role also can be filled after registration. During the registration, the selected individual will enter the required information for their physician or teaching hospital profile, user personal profile, and nominees for each user role. Details on these steps are included later in this section.

A physician must register him- or herself, and the authorized official must register a teaching hospital in the Open Payments system. The authorized official may nominate other users and modify existing user roles, approve or deny nominations made by others, approve or deny requests for user roles made by others, including self-nominations, as well as review and dispute records. The physician may perform these same actions, as well as modify his or her physician profile.

In order to complete registration for teaching hospitals, you must hold the authorized official role to complete registration. If you incorrectly register a teaching hospital, you will need to contact the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366. The incorrectly registered teaching hospital will go into deactivated status until the authorized official goes back into the system and registers the correct teaching hospital.

For physicians, an authorized representative can be designated to take certain actions on behalf of the physician. The person selected as an authorized representative can be another physician, an office manager, or a practice manager. The registering physician can assign access levels for their authorized representative within the Open Payments system. A physician cannot be his or her own authorized representative. The physician can only have one physician authorized representative. See Section 9.4 for more detailed information on physician authorized representative access levels.

Physicians must undergo a vetting process to be fully registered in the Open Payments system. See Section 8.3c for more on physician vetting.

For teaching hospitals, authorized officials are responsible for approving all nominations and modifying user roles. The teaching hospital authorized representatives will be granted certain permissions to access/review data, initiate a dispute on behalf of the teaching hospital, and make/approve nominations by an authorized official. Teaching hospitals can have up to 10 active authorized users. There can be a maximum of five authorized official(s) per teaching hospital.

Teaching hospitals must be selected from a prepopulated list in the Open Payments system. This list is maintained by CMS. As such, teaching hospitals will not go through any vetting and will be approved immediately in the Open Payments system. The teaching hospital will be given a status of "vetted." However, no additional vetting will occur.

The entire registration process takes approximately 30 minutes and must be completed in a single session; users cannot save entries or complete the profile at a later time. Users will be able to edit, manage, or update a profile once it is created. **Note: The system times out after 15 minutes of inactivity, and it does not have an auto-save feature. If the system times out, your updates will not be saved.**

Physician registration has five steps, as shown in Figure 8.2 below. Details on these steps are included later in this document.

Figure 8.2: Physician Registration Process
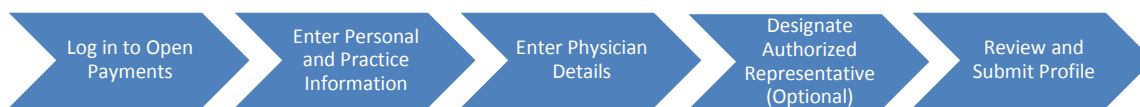
Figures 8.3 and 8.4 detail the fields which are required and which fields are optional when creating physician and user profiles. It is important to have this information on-hand prior to beginning the registration process.

Figure 8.3: Required and Optional Fields for Physician Profiles

Fields	Required	Optional
Practice Name		X
Practice Business Address	X	
Physician Primary Type	X	
Physician National Provider Identifier (NPI)**		X
Drug Enforcement Administration (DEA) Number**		X
Primary Specialty Code	X	
License State (at least 1)	X	
License Number (at least 1)	X	

**The National Provider Identifier (NPI) and Drug Enforcement Administration (DEA) Number must be entered if you have them. If you do not have these identifiers, you can still proceed with registration.

When registering in Open Payments, physicians must enter all of the state license numbers they hold, as well as their NPI number (if they have one). This is because records submitted to Open Payments are associated with physician license numbers and NPI. If a physician does not provide all of this identifying information, he or she will not be able to see all records identifying him or her. For example, a physician who has an NPI and holds licenses in both Michigan and Ohio, yet provides only the Michigan license number and no NPI in her profile, would not be able to see any records in Open Payments that identify her by her Ohio license number or NPI.

Figure 8.4: Required and Optional Fields for Individual User Profiles

Fields	Required	Optional
First Name	X	
Middle Name		X
Last Name	X	

Fields	Required	Optional
Name Suffix		X
Job Title (for Physician)		X
Job Title (for Authorized Representative)	X	
Business Address	X	
Business Phone Number	X	
Business Email Address	X	

Teaching hospital registration has five steps, as shown in Figure 8.5 below. Details on these steps are included later in this document.

Figure 8.5: Teaching Hospital Registration Process
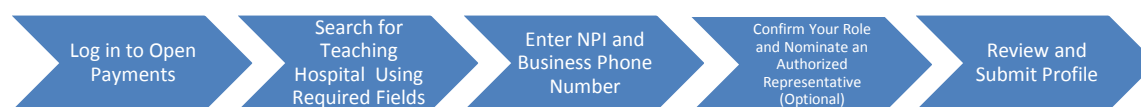
Figures 8.6 and 8.7 detail which fields are required and which fields are optional when creating teaching hospital and user profiles. It is important to have this information on-hand prior to beginning the registration process.

Figure 8.6: Required and Optional Fields for Teaching Hospital Profiles

Fields	Required	Optional
State Where Teaching Hospital is Located	X	
Teaching Hospital Name	X	
Teaching Hospital Address	X	
Taxpayer Identification Number (TIN)/Employer Identification Number (EIN)	X	

Fields	Required	Optional
Teaching Hospital National Provider Identifier (NPI)	X	
Teaching Hospital Business Phone Number	X	

Figure 8.7: Required and Optional Fields for Individual User Profiles

Fields	Required	Optional
First Name	X	
Middle Name		X
Last Name	X	
Name Suffix		X
Job Title	X	
Business Address	X	
Business Phone Number	X	
Business Email Address	X	

Important Notes:

Registration must be completed in one session.

The Open Payments system logs out all users after 15 minutes of inactivity.

Never use the navigation buttons on your browser toolbar. Only use the navigation buttons (Back buttons) within the Open Payments system itself.

If you do not know your ten-digit NPI number, you can find it on the NPI Registry, located at https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do.

If you cannot find your DEA number, contact the DEA Office of Diversion Control. Their website is https://www.deadiversion.usdoj.gov.

You can view a sample notification email for registration activities in Appendix D.

8.3a: Registering a Physician (First Time User)

If you are registering a physician and are a first-time user in the Open Payments system, follow the steps below.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.

Open Payments (Sunshine Act)

Welcome to the Open Payments System

Note: Our records indicate you have not registered with the Open Payments reporting application before. You must create your profile in order to use the System.

Create My Profile

Step 2: The on-screen text contains important information regarding creating the physician and individual profile. Read the on-screen text and select "Start Profile" at the bottom of the screen when you are ready to continue.

Open Payments (Sunshine Act)

Create Profile

Create Profile

① Select Profile Type
② Register Entity
③ Personal Information
④ Review and Submit Profile

Access the Open Payments User Guide

To begin creating a profile and registering in the Open Payments system, you must identify your affiliation with an applicable manufacturer, applicable group purchasing organization (GPO), or teaching hospital, or identify as a physician or physician's authorized representative. During this process, you will also have the ability to nominate additional authorized users or representatives.

Note: When registering, it is important that you have all required information available, as registration must be completed in one session. Also note that your session will time out after 15 minutes of inactivity and all information inputted during that session will be lost.

The information needed to create your user profile or nominate additional authorized users or representatives includes:

Step 3: Select the profile type "Physician" and select "Continue."

Step 4: Enter the physician's personal information. All required fields will be marked with an asterisk. Users will not be able to proceed with registration until all of the required fields have been entered. A frequent reason for the system not recognizing information is the incorrect use of special characters (i.e., non-alphanumeric characters). Make sure that when entering information into free-form text fields, you restrict your use of special characters to those permitted by the system. Telephone numbers must include dashes (-) and email addresses must include the at symbol (@) and period (.) Special characters allowed in name fields are given in Appendix A.

When you are done, select "Continue." **Note: Pressing the "Cancel" button will cause you to lose all data entered**.

Step 5: Enter the physician details. All required fields will be marked with an asterisk. Users will not be able to proceed with registration until all of the required fields have been entered.

Refer to the taxonomy code list in Appendix C for a complete listing of the available taxonomy codes. Specialty codes that are not on the taxonomy code list may not be entered.

To add your licensing information, select "Add License" and enter the state in which the license is held, and the license number. You are required to enter at least one license. The license number field accepts only letters and numbers. Any other characters, such as periods or hyphens, should not be entered. When you are done, select "Add." If the physician has licenses in more than one state, enter in the first

state and license number and then select "Add License." Repeat until all of the physician's state licenses have been added. You can enter up to five licenses. When you are finished, select "Continue."

Step 6: Physicians may choose to nominate the individual to serve as their authorized representative within the Open Payments system. By default, "Designate an Authorized Representative" will be selected. To designate an authorized representative, enter the required information. You will also be asked to select the access level for the authorized representative. A summary of the access levels are listed on the screen. Refer to Section 9.4 for more information on each access level. When you are finished, select "Continue."

If you choose not to designate an authorized representative at this time, select "Not Now" and then select "Continue." You do not need to designate an authorized representative during initial registration and may do so at a later time. For instructions on how to nominate an authorized representative after registration is complete, see Section 9.4d (1).

Note: A physician cannot be his or her own authorized representative. Please enter another individual's name, email address, phone number, and/or business address for the physician's authorized representative.

Open Payments (Sunshine Act)

Create Profile

✔ Select Profile Type

✔ Personal Information

Physician Details >

④ Authorized Representative

⑤ Review and Submit Profile

? **Need help with the website?** Contact Us by email.

↱ **Access** the Open Payments User Guide

Physician: Authorized Representative

A field with an asterisk (*) is required.

A physician may designate the authorized representative to take certain actions on his or her behalf in the Open Payments system. This person can be another physician, an office manager, a practice manager, or another person the physician would like to designate to interface with the Open Payments system on his or her behalf.

The nominated authorized representative will receive an email stating the he or she has been nominated for the role. The nominated authorized representative must accept this role in the Open Payments system to become an authorized representative. If the nominee does not accept the role, the physician may nominate another person.

Nominate the Authorized Representative in the Open Payments System

Nominations can be made now or later, and can be completed by updating the physician's profile. The nominee will have 10 business days to accept or reject the role. Open Payments will render the nomination inactive if the nominee does not respond within 10 business days.

Please note that an authorized representative nominee must register in the Enterprise Identity Management (EIDM) to obtain credentials before he or she can register and accept his or her role in the Open Payments system. If the nominee accepts the role, he or she will then be prompted to create an individual profile in the Open Payments system.

* **Designate an authorized representative?**

⦿ Designate an authorized representative

◯ Not now

Authorized Representative

Enter the name, business email, job title, and business telephone number of the nominated authorized representative.

* Authorized Representative's First Name:	Middle Name:
Jane	

* Authorized Representative's Last Name:	Suffix (Jr., Sr., etc.):
Doe	

* Business Email Address:	* Business Telephone Number:
physicianrep@yopmail.com	555-555-5555
	XXX-XXX-XXXX

* **Job Title:**

Office Manager

Authorized Representative's Business Address

Enter the nominated authorized representative's business address information below. Enter the primary business address if the authorized representative has multiple business addresses.

* **Business Address, Line 1:**

7500 Security Blvd

Business Address, Line 2:

* City Name:	* State:	* Zip Code:	
Baltimore	Maryland ▾	21244	
		XXXXX	XXXX

Nominated Authorized Representative's Access Level

By default, your authorized representative can read any information in the physician's profile in the Open Payments system. Select any additional level(s) of access to be granted to the authorized representative below. The access level will determine the actions the authorized representative can take on behalf of the physician in the Open Payments system. Regardless of the access level assigned to an authorized representative, authorized representatives cannot edit access levels.

* **Access Level:**

☑ **Read** - Default access level. Able to see physician profile and records information.

☑ **Modify Profile** - Able to edit or enter the physician's My Profile information (NPI, license, specialties, etc.).

☑ **Dispute Records** - Able to comment on information submitted about payments or other transfers of value, ownership, and investment interests with the submitter (applicable manufacturer or GPO). Also able to dispute reported payments or other transfers of value, ownership, and investment interests.

Cancel   Back   Continue

215

Step 7: Review the information entered. Select "Back" to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Submit."

The following message will appear on-screen to confirm your profile has been successfully created. If you have chosen to delegate someone to be an authorized representative, an email notification with a nomination ID will be sent to that individual.

8.3b: Registering as a Physician for a User with Another Role (Returning User)

If you are registering a physician and you already have an account in the Open Payments system, follow the steps below.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). Select the "My Profile" tab from the menu bar on the Open Payments home page.

Step 2: Select "My Profile Details." Review your profile information displayed on the page. To make any corrections, select "Update Profile." Any corrections made here will update your information for any profile you have in the Open Payments system. To proceed as registering as a physician, select "Register as a Physician." **Note: Changes made here will not automatically update your profile information in your other CMS accounts.**

Step 3: Select the profile type, when finished select "Continue."

Step 4: Enter the physician's personal information. All required fields will be marked with an asterisk. Users will not be able to proceed with registration until all of the required fields have been entered. A frequent contributor to the system not recognizing information is the incorrect use of special characters (i.e., non-alphanumeric characters). Make sure that when entering information into free-form text fields, you restrict your use of special characters to those permitted by the system. Telephone numbers must include dashes (-) and email addresses must include the at symbol (@) and period (.). Special characters allowed in name fields are given in Appendix A.

When you are done, select "Continue." **Note: Pressing the "Cancel" button will cause you to lose all data entered.**

Step 5: Enter the physician details. All required fields will be marked with an asterisk. Users will not be able to proceed with registration until all of the required fields have been entered.

Refer to the taxonomy code list in Appendix C for a complete listing of the available taxonomy codes. Specialty codes that are not on the taxonomy code list may not be entered.

In the state licensing section, the license number field accepts only letters and numbers. Any other characters, such as periods or hyphens, should not be entered. If the physician has licenses in more than one state, enter in the first state and license number and then select "Add License." Repeat until all of the physician's state licenses are added, you can enter up to five licenses.

Once you've added all of the required physician details, select "Continue."

Step 6: Next, you may nominate the individual you would like to be your authorized representative within the Open Payments system. By default, "Designate an Authorized Representative" will be selected. Enter the required information. You will also be asked to select the access level for the authorized representative. When you are finished, select "Continue." See Section 9.4a for more detailed information on physician authorized representative access levels.

If you choose not to designate an authorized representative at this time, select "Not Now" and then select "Continue." You can complete this step at a later time by updating your physician profile within the "My Profile" tab.

Note: A physician cannot be his or her own authorized representative. Please enter another individual's name, email address, phone number, and/or business address for the physician's authorized representative.

Step 7: Review the information entered. Select "Back" to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Submit."

The following message will appear on-screen to confirm your profile has been successfully created. If you chose to delegate someone to be an authorized representative, an email notification will be sent to that individual.

8.3c: Physician Vetting

Vetting is the process of verifying a physician's identity. This is done to ensure that the physician is a valid covered recipient and to aid in the matching of submitted payments to the corresponding physicians. All physicians registering in the Open Payments system will be vetted. Vetting occurs once the authorized official has completed his or her profile and submitted his or her registration in the Open Payments system. **Note: Physician registration is not considered complete until the vetting process has been successfully completed.**

The vetting process will typically require little action from the user in order to complete it. Once the physician submits the physician and user profile, the vetting process begins. The process will attempt to vet the physician using the information provided in the physician profile, so it is important for the physician to provide as much information as possible to aid in the vetting process. Particularly important are the NPI, DEA number, and the state license information. The Open Payments system will match physician information against multiple data sources.

If the vetting fails, the physician will have the opportunity to correct the information in his or her profile and resubmit the profile for vetting. The physician may update his or her profile as many times as necessary to successfully complete vetting.

Physicians must ensure to enter valid license information. If incorrect license information is entered, the physician would not be able to review records submitted for that state license. Physicians can perform actions only on record(s) associated with the state license that was entered and verified to be accurate.

If the physician does not successfully pass vetting despite all of the information provided in the physician profile is correct to the best of his or her knowledge, or the physician requires assistance with successfully vetting their profile, the physician can contact the Open Payments Help Desk (openpayments@cms.hhs.gov) or call 1-855-326-8366.

The automatic vetting process normally takes a short time. Nevertheless, the process could take longer, depending on the information provided by the user and the number of physicians undergoing vetting at

the same time. CMS encourages physicians to register and begin the vetting process as early as possible to allow sufficient time for vetting to be completed.

Please note that if a physician profile is modified, the profile will undergo vetting again.

8.3d: Registering a Teaching Hospital (First Time User)

If you are a first-time user registering a teaching hospital in the Open Payments system, follow the steps below.

Note: You must be an authorized official for the teaching hospital in order to complete registration.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.
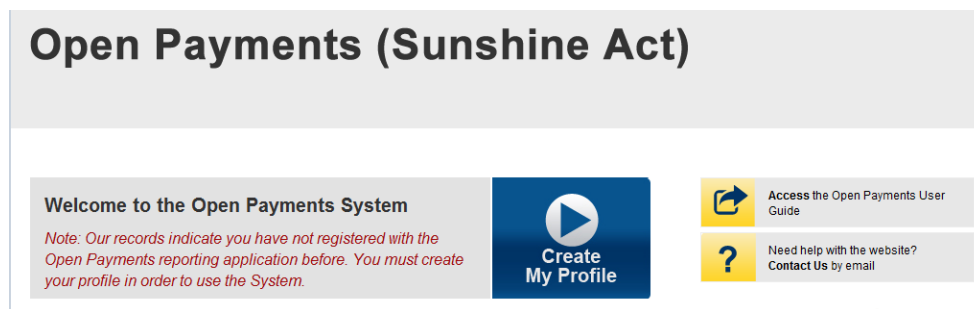
Step 2: The on-screen text contains important information regarding creating the individual profile. Read the on-screen text and select "Start Profile" at the bottom of the screen when you are ready to continue.

Step 3: Select the profile type, when finished select "Continue."

Step 4: Search for the teaching hospital by selecting the appropriate state, teaching hospital legal name, teaching hospital business address, and Taxpayer Identification Number (TIN) from the drop-downs and select "Search."

Teaching hospitals are pre-populated into the Open Payments system based on the 2014 Open Payments Cycle: Teaching Hospital List. Teaching hospitals not on this list will not have payments or transfers of value reported about them.

Step 5: Review the information displayed on the screen. Select "Continue" if the information displayed is the teaching hospital you wish to register. If this is not the correct teaching hospital, select "Back" to return to the previous page and re-enter the information.

Step 6: Review the information displayed on the screen. Enter the teaching hospital ten-digit National Provider Identifier (NPI) and the business phone number. When complete, select "Continue."

Step 7: Review the information generated by the system related to your role. You must select the role of "Authorized Official" to proceed with registration. First name, last name, email address, and business phone will be pre-populated with information from your EIDM profile. Edit these fields as necessary. All required fields will be marked with an asterisk. Users will not be able to proceed with registration until all of the required fields have been entered. When complete, select "Continue."

Step 8: You may choose to nominate additional users to fill the authorized official or authorized representative roles. To do so, select "Add Nominee" to nominate an additional individual(s).

Step 8a: Enter the required information and select either "Authorized Official" or "Authorized Representative." When complete, select "Add Nominee."

Repeat the process until you have entered all of the individuals you wish to nominate. A teaching hospital may have up to 10 active roles, five of which can be authorized officials. Each nominated individual will receive an email notifying them of their nomination. The nominee must confirm or reject the role within 10 business days. For more information on the different user roles, see Section 9.4.

Nominations do not have to be made during initial registration. You can nominate individuals later by updating your teaching hospital profile within the "My Profile" tab. If you choose not to add nominees at this time, select "Continue."

If you entered any nominees, you will see the nominee information displayed on the screen. Confirm the information and when complete select "Continue."

Open Payments (Sunshine Act)

2 Teaching Hospital: Nominate Roles

A field with an asterisk (*) is required.

The Teaching Hospitals can have up to 10 active authorized users in the role of authorized official or authorized representative. There can be a maximum of 5 authorized official(s) per teaching hospital. These users will be allowed to perform certain actions on behalf of the teaching hospital in the Open Payments system.

Each nominated authorized representative will receive an email notifying them of their nomination to serve as a representative for a teaching hospital. The nominee must confirm the role or reject the nomination. If the nominee accepts the role, he or she will be prompted to create an individual profile in the Open Payments system. If the nominee does not accept the role, another person may be nominated.

Note: Nominees must register in Enterprise Identity Management (EIDM) to obtain login credentials prior to accepting or rejecting the role in the Open Payments system.

Add Nominee

Nominations can be made now or later, by selecting "Add Nominee." You will be asked to provide the nominee's personal and contact information. A summary of the actions associated with each user role is referenced below.

The nominee will have 10 business days to accept or reject the role. After 10 business days, the nomination will be deactivated.

User Role Description:

- **Authorized Official:** Responsible for registering the teaching hospital in the Open Payments system. Authorized officials may nominate other users, or modify existing user roles. They are also responsible for approving/denying nominations made by others, and approving/denying requests for user roles made by others.
- **Authorized Representative:** Granted permission by the teaching hospital's authorized official to access/review data, initiate a dispute on behalf of the teaching hospital and make/approve nominations for other users.

Role:	Name:	Business Email:	Business Phone Number:	View
Authorized Official	John Doe	teachinghospital@yopmail.com	555-555-5555	
Authorized Official	Jane Doe	teachingrep@yopmail.com	555-555-5555	Delete

+ Add Nominee

Cancel   Back   Continue

Step 9: Enter your personal information. When finished, select "Continue."

Step 10: Review your profile information on the "Review and Submit Profile" page. Select "Back" to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Continue."

The following message will appear on-screen to confirm your profile has been successfully created. If you chose to nominate additional roles, an email notification is sent to the individuals nominated that will instruct them on their next steps.

8.3e: Registering a Teaching Hospital (Returning User)

If you are a returning user registering an additional teaching hospital in the Open Payments system, follow the steps below.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). Select the "Manage Teaching Hospitals" tab and then select "Register New Teaching Hospital."

Step 2: Search for the teaching hospital by selecting the appropriate state, teaching hospital legal name, teaching hospital business address, and Taxpayer Identification Number (TIN) from the drop-downs and select "Search."

Teaching hospitals are pre-populated into the Open Payments system based on the 2014 Open Payments Cycle: Teaching Hospital list. Teaching hospitals not on this list will not have payments or transfers of value reported about them.

Step 3: Review the information displayed on the screen, select "Continue" if the information displayed is the teaching hospital you wish to register. If this is not the correct teaching hospital, select "Back" to return to the previous page and re-enter the information. **Note: You must be an authorized official for the teaching hospital in order to complete registration.**

Step 4: Review the information displayed on the screen. Enter the teaching hospital's ten-digit National Provider Identifier (NPI) and the business phone number. When complete, select "Continue."

Step 5: Review the information generated by the system related to your role. You must select the role of "Authorized Official" to proceed with registration. First name, last name, email address, and business phone should be pre-populated with information from your EIDM profile. Edit these fields as necessary. All required fields will be marked with an asterisk. Users will not be able to proceed with registration until all of the required fields have been entered. When complete, select "Continue."

Step 6: You may choose to nominate additional users to fill the authorized official or authorized representative roles. To do so, select "Add Nominee" to nominate an additional individual(s).

Step 6a: Enter the required information and select either "Authorized Official" or "Authorized Representative." When complete, select "Add Nominee." A teaching hospital may have up to 10 active roles, five of which can be authorized officials. Each nominated individual will receive an email notifying them of their nomination. The nominee must confirm or reject the role within 10 business days.

Nominations do not have to occur during initial registration. You can nominate additional roles at a later time by updating your teaching hospital profile within the "My Profile" tab. If you choose not to add nominees at this time, select "Continue."

You will then see the additional nominee information displayed on the screen. Confirm the information and when complete select "Continue."

Step 7: Review your profile information on the "Review and Submit Profile" page. Select "Back" to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Continue."

The following message will appear on-screen to confirm your profile has been successfully created. If you chose to nominate additional roles, an email notification will be sent to the individuals nominated that will instruct them on their next steps.

8.3f: Using the Switch User Functionality

The Open Payments system allows individuals to hold multiple user roles based on their affiliations with multiple entities. Users can switch between the applicable manufacturer/applicable GPO, physician and teaching hospital user types through a "Switch User Type" functionality. Once a user has successfully registered within the Open Payments system under any user type (reporting entity, physician, or teaching hospital), the "Switch User Type" functionality will become available.

This functionality can be used when an individual holds multiple user roles across multiple user types, allowing them to access the profiles they hold under different user types. The screens will be similar for each user type, though the actions available will change depending on which user type you are operating under at that time.

All users have access to the "Switch User Type" functionality, as users who have only a single user type can use the functionality to request roles for and/or register as another user type.

Follow these steps to switch between user types or request a role as another user type in the Open Payments system:

Step 1: At the top of the page, select "Switch User Type."
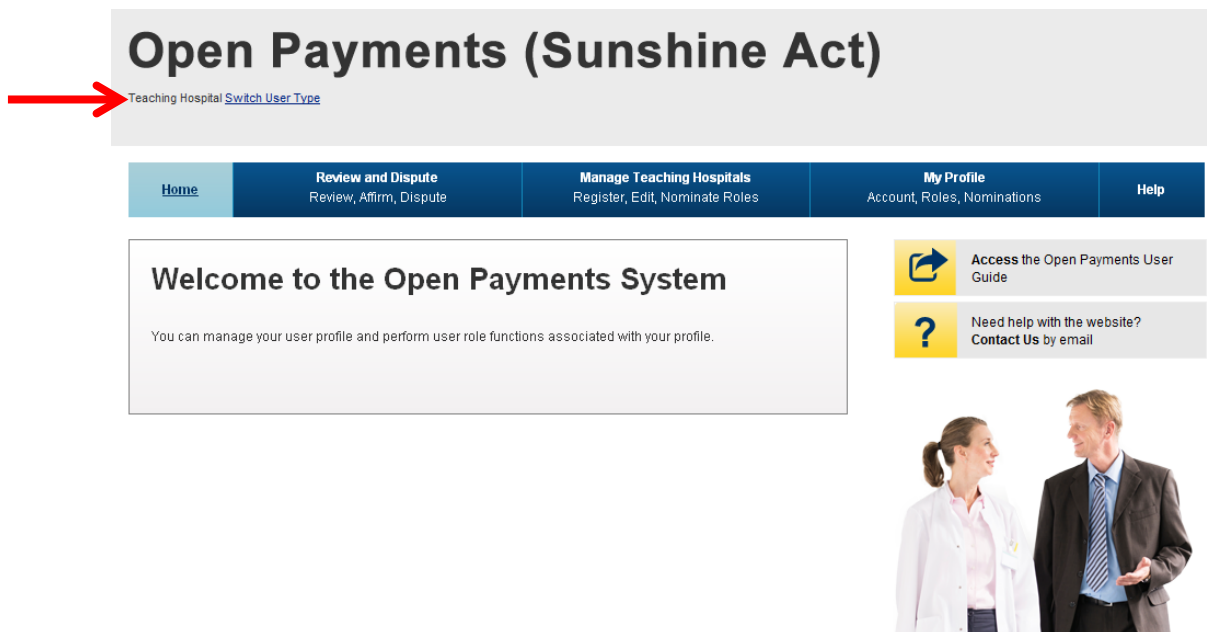
Step 2: Select the user type to which you would like to switch, or which user type you would like to request a role for. When finished, select "Switch." If you decide you do not want to change user types, or you selected "Switch User Type" by accident, select "Cancel and Go Back."

Step 3: If you are not currently assigned a role for the selected user type, you will be prompted to create a profile.

Step 3a: If you are currently assigned a role for the selected user type, you will be able to view your profile information for that user type.

The profile type will be displayed at the top of the screen.

You may switch between user types at any time. **To perform system actions such as registration and nominations, data submission, and review and dispute for the user type that is displayed, refer to the corresponding section of this User Guide.**

Section 8.4: Open Payments Users and User Roles

There are two user roles available for individuals associated with physicians or teaching hospitals: authorized officials or authorized representatives.

8.4a: Physician and Teaching Hospital User Roles

A physician may nominate **one authorized representative** within the Open Payments system during initial registration. This person can be another physician, an office manager, a practice manager, or another person the physician would like to designate to interface with the Open Payments system on his or her behalf.

The physician will designate the level of access for the authorized representative and more than one level can be granted. The different levels of access that can be granted to the authorized representative are:

1. **Read:** Default access level. Able to see physician profile and records information.

2. **Modify Profile:** Able to edit or enter the physician's My Profile information (NPI, license, specialties, etc.).

3. **Dispute Records:** Able to dispute reported payments, other transfers of value, or physician ownership and investment interests.

Figure 8.8: Physician User Roles and User Role Functions

User Role	Function
Physician	• Registers him- or herself in the system • Nominates an authorized representative • Has full access to review and dispute records

Authorized Representative	• Allowed activities depend upon access levels granted by physician:
	
	  — Read-only: (default) Able to see a physician's profile and records information
	
	  — Modify Profile: Able to edit or enter a physician's "My Profile" information (NPI, license, specialties, etc.)
	
	  — Dispute Records: Able to dispute records related to the physician submitted by reporting entities
	
	• Access levels are separate; having "dispute records" access does not automatically include "modify profile" access, or vice versa
	
	• Must be nominated by the physician

Teaching hospitals can have up to 10 active users, and they may hold the roles of **authorized official** or **authorized representative**.

The authorized representative can be a physician, an office manager, a practice manager, or any person the teaching hospital would like to designate. There can be a maximum of five authorized official(s) per teaching hospital.

The user roles applicable for teaching hospitals are given in Figure 8.9 below.

Figure 8.9: Teaching Hospital User Roles and User Role Functions

User Role	Function
Authorized Official	• Registers the teaching hospital in the Open Payments system • Modifies the teaching hospital's profile in the Open Payments system • Nominates other users and modifies existing user roles • Approves/denies nominations made by others, and approves/denies requests for user roles made by others, including self-nominations • Reviews and disputes records associated with the teaching hospital
Authorized Representative	• Reviews and disputes records associated with the teaching hospital • Nominates other individuals for user roles with teaching hospital • Nominations must be confirmed by an authorized official

To nominate an individual for any role, the following information must be input into the Open Payments system about that individual:

- First name;

- Last name;

- Business phone;

- Business address; and

- Email address.

8.4b: Updating a Physician Profile as an Authorized Representative

For a physician's authorized representative who holds the level of access of "Modify Profile" to edit their physician's profile, follow these steps.

Step 1: Log in to the Open Payments system and select the "Manage Physicians" tab.

Step 2: Select the physician for which you wish to make updates on the "Manage Physicians" page.

Step 4: Select the "Physician's Profile Details" tab to view the profile information for the selected physician. You will be able to view the physician's personal information, physician information, and the physician's authorized representative information. Select "Update Profile" to begin making updates.

Step 4: Update the necessary information. When your updates are complete, select "Save Updates."

Note that any updates made to the physicians profile will cause the physician to be re-vetted. Once the updated information has been re-vetted, both the physician and authorized official will be able to perform the necessary actions in the Open Payments system. See section 8.3c for information on physician vetting.

8.4c: Updating Personal Profile

As a user of the Open Payments system, you have the ability to update your personal profile information. You will be able to update your name, business email address, business telephone number, job title, and business address. Steps for updating your profile are explained below.

Step 1: Log in to the Open Payments system and select the "My Profile" tab.

Step 2: Select the "My Profile Details" tab. You will be able to view your existing profile information. Select "Update Profile" to begin making edits and/or updates.

Step 3: Update fields as necessary. When changes are complete, select "Save Updates."

Step 3: The updated information will now appear on the "My Profile Details" page.

Section 8.5: Nominations

The nomination process allows the users to assign specific roles to individuals to act on behalf of a physician or teaching hospital. For teaching hospitals, the authorized official must approve **all** self-nominations before users can begin performing actions in the system. Individuals may not self-nominate to serve on behalf of physicians. The physician must directly nominate the individual to serve as the authorized representative.

Nominations can be done during registration or at a later time. The system will generate an email notification to the nominee informing them that they are nominated for a role in the Open Payments system. The email notifying teaching hospital authorized officials and authorized representatives will contain a registration ID and a nomination ID. The email notifying physician authorized representatives will contain only a nomination ID. Users notified of their nomination for a role must use the registration

ID and/or nomination ID received in the nomination email to complete their profile in the Open Payments system to receive access to the functions for that specific role.

The nominee must confirm or reject the role within 10 business days. They can do so by registering in EIDM to obtain credentials and request access to the Open Payments system. Nominees can then log in to the Open Payments system to confirm or reject the role. Instructions on registering in the EIDM system and requesting access to the Open Payments system are in the instructional presentation on steps to complete EIDM registration. The Open Payments system will render the nomination inactive if the nomination has not been accepted or rejected within 10 business days. This information is included in the email notification.

If the nomination is accepted, the individual will be able to complete a user profile, gain access to the system, and perform the duties of their role. If they reject the nomination, the individual will not be able to perform the actions on that entity's behalf and the officer will receive an email notification of the nomination rejection. **Note: Nominees will need to have EIDM credentials in order to access the Open Payments system and accept or reject their nominations.** If there is no action taken by the nominee, a final reminder notification will be sent on the 9th business day, reminding the nominee that they have yet to accept or reject the nomination. If the nomination is still not accepted or rejected by the end of the 10th business day, a deactivated nomination notification will be sent to the nominee. Figure 8.10 shows the five steps in the nomination acceptance process.

Note: The system times out after 15 minutes of inactivity, and it does not have an auto-save feature. If the system times out, your updates will not be saved.

Figure 8.10: Accepting Nominations Process

Log in to Open Payments	Enter Registration and Nomination ID	Confirm or Reject Nomination	[If Confirmed] Enter Personal Information	[If Confirmed] Review and Submit Registration

Specific step-by-step instructions for various scenarios follow.

8.5a (1): Nominating Authorized Representative for a Physician (Returning Users)

If you are a physician that did not delegate an authorized representative during initial registration, follow the steps below to nominate an individual for that role.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "My Profile" tab.

Step 2: Select the "My Profile Details" tab on the "My Profile" page. Here you will be able to view your profile information. Select "Update Profile."

Step 3: You can modify your existing profile information, add or edit state license information, add or edit physician specialty codes, add an authorized representative if you did not do so during initial registration, or update the level of access for an existing authorized representative. If at this time you still do not wish to delegate an authorized representative, select "Not now" and select "Save Updates."

Step 3a: If you wish to delegate an authorized representative, select "Yes, designate an authorized representative." The fields required to nominate an authorized representative will appear on the screen. Please enter information for all required fields. Required fields will appear with an asterisk.

The default level of access is "Read." If you would like the authorized representative to have more access while representing you in the Open Payments system, select "Modify Profile" or "Dispute Records." Access levels are discussed in Section 9.4. When complete, select "Save Updates."

Step 4: The individual that has been nominated will receive an email notification that they have been nominated for a role in the Open Payments system. The email notifying the nominee of the nomination will contain a nomination ID. Users notified of their nomination for a role must use the nomination ID received in the nomination email to complete their profile in the Open Payments system and will receive access to the functions for that specific role. The nominee will have 10 business days to accept or reject the nomination.

8.5a (2): Nominating Additional Roles for a Teaching Hospital (Returning Users)

If you are an authorized official for a teaching hospital that did not delegate additional user roles during initial registration, follow the steps below. The authorized representative can be a physician, an office manager, a practice manager, or any person the teaching hospital would like to designate.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Manage Teaching Hospitals" tab.
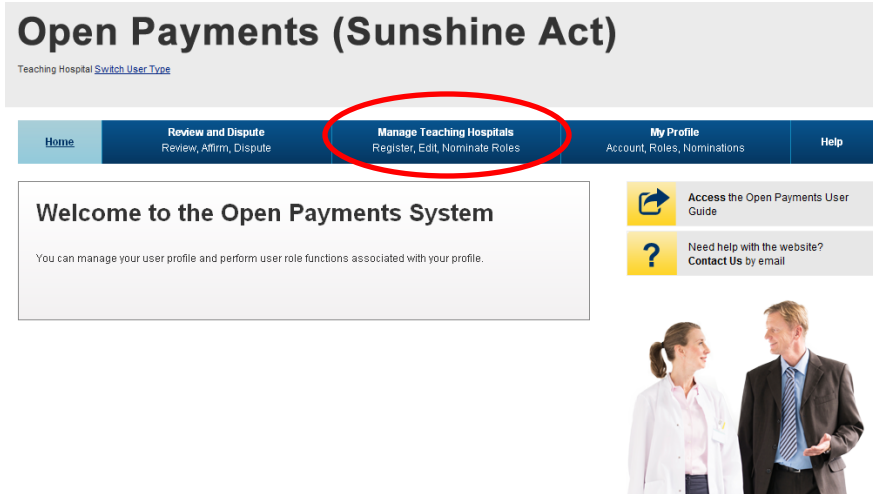
Step 2: Select the teaching hospital for which you wish to nominate a new role.
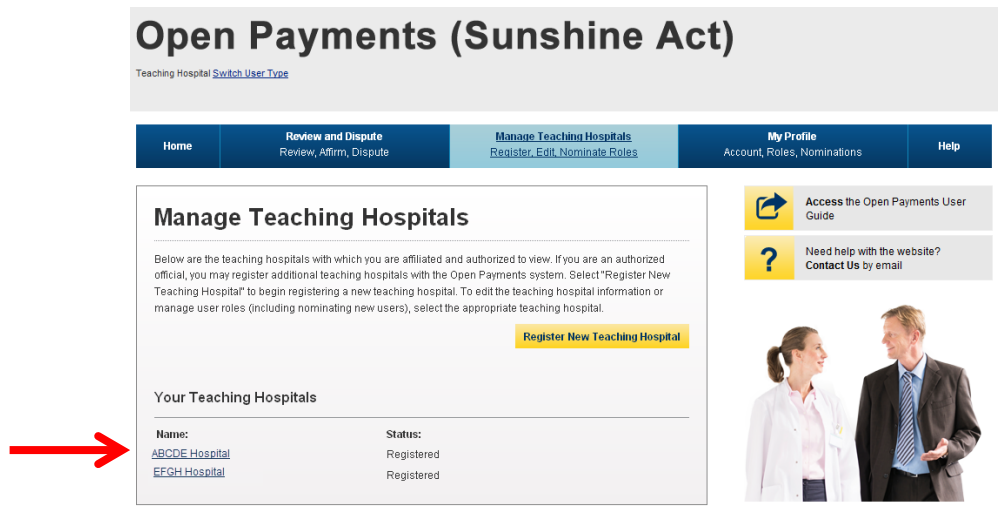
Step 3: Select the "Manage Roles" tab and then select "Nominate New Role."

Step 4: Enter the required fields and select the desired role for the nomination, such as authorized official. All required fields are marked with an asterisk. When finished, select "Send Nomination."

After you send the nomination, you will be brought back to the "Manage Roles" tab and you will see that the new nomination and the status of the nomination are now listed on the page.

The individual that has been nominated will receive an email notification that they have been nominated for a role in the Open Payments system. The email notifying the nominee of the nomination will contain a registration ID and a nomination ID. Users notified of their nomination for a role must use the registration ID and nomination ID received in the nomination email to complete their profile in the Open Payments system and to receive access to the functions for that specific role. The nominee will have 10 business days to accept or reject the nomination.

Instructions for confirming nominations can be found in the next section.

8.5a (3): Accepting a Nomination (Physician Authorized Representative, First Time User)

If you have been nominated for a physician authorized representative role, you will receive an email like the one shown below.

Take note of the information in the email, including registration ID and nomination ID, then follow the steps below to accept the nomination.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.

Step 2: The on-screen text contains important information regarding creating the physician and individual profile. Read the on-screen text and select "Start Profile" at the bottom of the screen when you are ready to continue.

Step 3: Although you are affiliating with a physician, do not select "Physician" on the "Select Profile Type" screen. Instead, select the "I Have a Nomination ID and Registration ID" link on the bottom of the screen.

Step 4: Select the user type "Physician" from the drop-down list and enter the nomination ID that you received in the nomination notification email and then select "Show Nomination."

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Step 5: Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select "Cancel" and contact the nominator directly.

Step 6: Review and confirm the physician information displayed. Select "Continue" to proceed.

Step 7: Review the nomination information on screen. Select "Yes, I accept" if you wish to accept the role and "I do not accept" if you do not wish to accept the role. If you accept the role and select "Continue," you will continue the nomination confirmation process.

If you reject the role for which you have been nominated, press "Continue" after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will receive an email that you rejected the nomination. The nominator will then be allowed to nominate another individual for the role.

Step 8: Enter your personal information and select "Continue."

Step 9: Now you will be asked to review the information you have entered. To correct any errors, select "Back" on the bottom of the page to return to previous pages and make your corrections. If the information is correct, select "Submit."

The following message will appear on-screen to confirm your nomination has been successfully accepted.

8.5a (4): Accepting a Nomination (Existing Role as Physician or Physician Authorized Representative)

If you have been nominated for a physician authorized representative role, and you already have a role in the Open Payments system, you will receive an email like the one shown below.

Take note of the information in the email, including registration ID and nomination ID, then follow the steps below to accept the nomination.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "My Profile" tab from the menu bar on the Open Payments home page.

Step 2: On the "My Roles and Nominations" tab, select "Accept/Reject Nominations."

Step 3: Select the user type "Physician" from the drop-down list and enter the nomination ID that you received in the nomination notification email and then select "Show Nomination."

Step 4: Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select "Cancel" and contact the nominator directly.

Step 5: Confirm the physician information displayed on the screen. You will not be able to edit the information. Ensure that this is the physician that you wish to accept the nomination for. If it is not the correct physician, either select "Back" to return to the previous screen to correct the information you have entered, or select "Cancel" to end the acceptance process.

Step 6: Review and confirm the physician information displayed. Select "Yes, I accept" if you wish to accept the role and "No, I do not accept" if you do not wish to accept the role. If you accept the role and select "Continue," you will continue the nomination confirmation process.

If you reject the role for which you have been nominated, select "Continue" after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will receive an email that you rejected the nomination. The nominator will then be allowed to nominate another individual for the role.

Step 7: Enter your personal information and select "Continue."

Step 8: Now you will be asked to review the information you have entered. To correct any errors, select "Back" on the bottom of the page to return to previous pages and make your corrections. If the information is correct, select "Submit."

The following message will appear on-screen to confirm your nomination has been successfully accepted.

8.5a (5): Accepting a Nomination (Teaching Hospital – First Time User)

If you have been nominated for a teaching hospital user role, you will receive an email like the one shown below.

Take note of the information in the email, including registration ID and nomination ID, then follow the steps below to accept the nomination.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.

Step 2: The on-screen text contains important information regarding creating the physician and individual profile. Read the on-screen text and select "Start Profile" at the bottom of the screen when you are ready to continue.

Step 3: On the "Select Profile Type" screen, though you are affiliating with a teaching hospital, do not select "Teaching Hospital." Instead, select the link on the bottom of the screen, "I Have a Nomination ID and Registration ID."

Step 4: Select the user type "Teaching Hospital" from the drop-down menu. Enter the registration ID and nomination ID that you received in the nomination notification email and then select "Show Nomination."

Step 5: Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select "Cancel" and contact the Open Payments Help Desk (openpayments@cms.hhs.gov).

Step 6: Select "Yes, I accept" for roles you accept and "No, I do not accept" for roles you do not accept. If you reject all roles for which you have been nominated, press "Continue" after selecting "No, I do not accept" for all roles. The system will ask you if you are sure you want to reject these roles. If you confirm your choice to reject the roles, you will exit the system and the nominator will receive an email that you rejected the nominations. The nominator will then be allowed to nominate other people for the roles.

If you accept one or all roles and select "Continue," you will continue the nomination confirmation process.

Step 7: Review your personal information. If the information displayed is correct, select "Continue." If the information displayed is incorrect, update the necessary fields. When finished, select "Continue."

Step 8: Now you will be asked to review the information you have entered. To correct any errors, select "Back" on the bottom of the page to return to previous pages and make your corrections. If the information is correct, select "Continue."

The following message will appear on-screen to confirm your nomination has been successfully accepted.

8.5a (6): Accepting a Nomination (Teaching Hospital – Already Registered User)

If you have been nominated for a teaching hospital user role, and you already have a role in the Open Payments system, you will receive an email like the one shown below.

Take note of the information in the email, including registration ID and nomination ID, then follow the steps below to accept the nomination.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). Select the "My Profile" tab.

Step 2: Select "My Roles and Nominations."

Step 3: Select "Accept/Reject Nominations."

Step 4: Select your user type from the drop-down and enter the registration ID and nomination ID in the appropriate fields. When complete, select "Show Nomination."

Step 5: Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select "Cancel" and contact the teaching hospital directly.

Step 6: Select "Yes, I accept" for roles you accept and "No, I do not accept" for roles you do not accept. If you reject all roles for which you have been nominated, press "Continue" after selecting "No, I do not accept" for all roles. The system will ask you if you are sure you want to reject these roles. If you confirm your choice to reject the roles, you will exit the system and the nominator will receive an email that you rejected the nominations. The nominator will then be allowed to nominate other people for the roles.

If you accept one or all roles and select continue, you will continue the nomination confirmation process.

Step 7: Now you will be asked to review the information you have entered. To correct any errors, select "Back" on the bottom of the page to return to previous pages and make your corrections. If the information is correct, select "Continue."

The following message will appear on-screen to confirm your nomination has been successfully accepted.

8.5a (7): Self-Nomination: Requesting a Role (Teaching Hospital, First Time User)

If you are a first time user and would like to self-nominate for a teaching hospital role as an authorized official or authorized representative, follow the steps below.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.

Step 2: The on-screen text contains important information regarding creating the physician and individual profile. Read the on-screen text and select "Start Profile" at the bottom of the screen when you are ready to continue.

Step 3: Select the profile type "Teaching Hospital." When finished, select "Continue."

Step 4: Search the database for the correct teaching hospital. Select the appropriate state, teaching hospital legal name, teaching hospital business address, and Taxpayer Identification Number (TIN) from the drop-downs.

Step 5: The system will search for the identified teaching hospital. Review the information displayed on the screen, select "Continue" if the information displayed is correct. If the information is not correct, select "Back" to return to the previous page and edit the search information you entered.

Step 6: Review the information displayed on the screen. If the information is correct, select "Continue."
If the information is not correct, select "Back" to select a different teaching hospital.

Step 7: Select the role you wish to nominate yourself for in the teaching hospital: either authorized official or authorized representative. Then enter in the role-related information below. Required fields are marked with an asterisk. Once you've entered in all of the information, select "Continue."

Step 8: Review your information displayed on the screen. Enter your job title and business address. When finished, select "Continue."

Step 9: Review your profile information on the "Review and Submit Profile" page. Select "Back" to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Continue."

The following message will appear on-screen to confirm your profile has been successfully created. You will receive an email when your nomination is approved or modified. Also, the authorized officials for the teaching hospital will receive emails notifying them of your request for a user role.

8.5a (8): Self-Nomination: Requesting a Role (Teaching Hospital, Existing User)

If you would like to self-nominate for a teaching hospital role as an authorized official or authorized representative, and already have a role in the Open Payments system, follow the steps below.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). Select the "My Profile" tab.

Step 2: Select "My Roles and Nominations."

Step 3: Select "Request a Role."

Step 4: Select the teaching hospital state, legal name, business address, and Taxpayer Identification Number (TIN) from the drop-downs. When finished, select "Search."

Step 5: Review the teaching hospital information displayed on the screen. Select "Continue."

Step 6: Review the teaching hospital information. When finished, select "Continue."

Step 7: Choose the role you wish to request. Enter information into all required fields. When complete, select "Continue."

Step 8: Review your profile information for the requested role. When finished, submit your profile by selecting "Continue."

The following message will appear on-screen to confirm your profile has been successfully created. You will receive an email when your nomination is approved or modified. Also, the authorized officials for the teaching hospital will receive emails notifying them of your request for a user role.

8.5a (9): How to Reject a Nomination

To reject a nomination, access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) using the registration ID and nomination ID provided in the notification email and follow the steps below to reject the nomination.

1. Follow steps 1 through 6 outlined in Section 8.5a(3) for accepting a nomination.

2. During step 7, select "No, I do not accept" and select "Continue."

Once you reject a nomination, you will be exited from the system and will be unable to perform any functions in Open Payments. The physician or authorized official(s) of the teaching hospital will receive an email notifying him or her of the rejection. The physician or authorized official(s) of the teaching hospital may nominate another individual for that role.

8.5a (10): Approving a Nomination (Authorized Official Only)

If you are an authorized official for a teaching hospital, and would like to approve a nomination, follow the steps below.

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/). Select "Manage Teaching Hospitals."
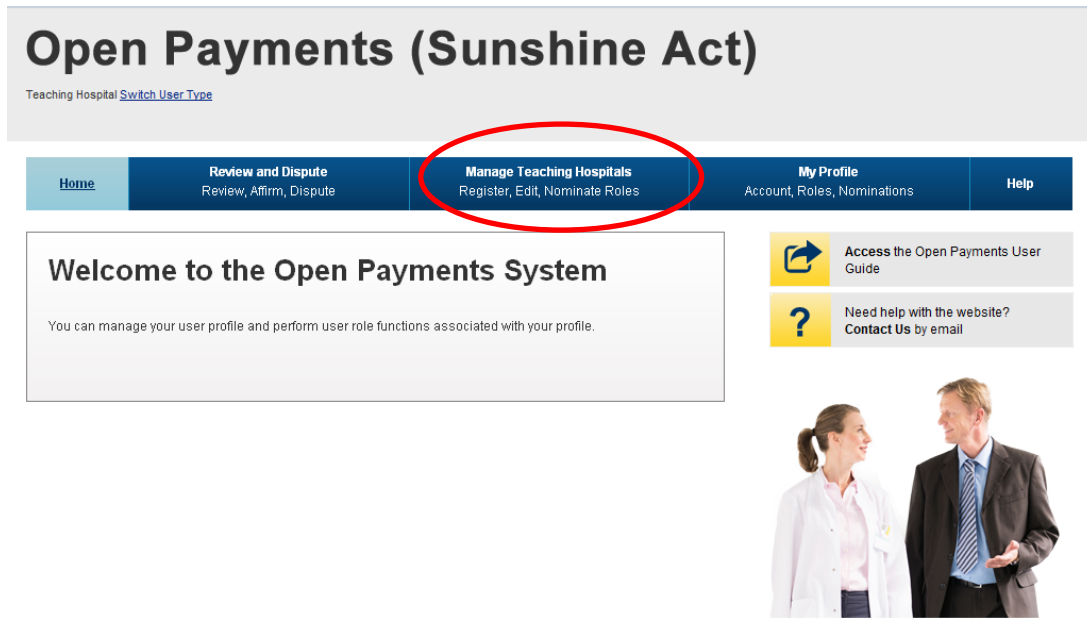
Step 2: On the "Manage Teaching Hospitals" page, select the teaching hospital for which you want to confirm a nomination.

Step 3: Select the "Manage Roles" tab.

Step 4: Select "Approve" for the nomination you wish to approve. Once you have selected the "Approve" button next to a nominee's name, the nomination has been approved. The nominee will receive an email notification informing them of the acceptance of their nomination.

Step 4a: When you select the "Modify" button next to a nominee's name, you can change that individual's role. You can also remove a nomination, rejecting a user's self-nomination. An email will be sent to the nominee informing them of the change made to their role.

Step 5: You will now see an updated list of nominations on the "Manage Roles" tab.

Review and Dispute

For Physicians and Teaching Hospitals

Chapter 9: Review and Dispute for Physicians and Teaching Hospitals

This chapter provides information on the process for physicians and teaching hospitals in the Open Payments system to view records submitted regarding payments and other transfers of value, as well as ownership and investment interests, submitted about them from applicable manufacturers and applicable GPOs.

This chapter is divided into the following sections:

- **Overview of Review and Dispute**, which provides information on the review and dispute process within the Open Payments system.

- **Reviewing and Affirming Payments and Other Transfers of Value**, which provides information on how physicians and teaching hospitals can review and affirm data submitted about them by applicable manufacturers and applicable GPOs.

- **Initiating and Withdrawing Disputes**, which provides information on how physicians and teaching hospitals can initiate or withdraw a dispute of submitted data.

All physicians and teaching hospitals who choose to view data reported about them must register in both EIDM and Open Payments prior to accessing the system. See Chapter 8 for registration information.

Once an applicable manufacturer or applicable GPO has reported a payment or other transfer of value about a physician or teaching hospital, or physician ownership or investment interest, the physician or teaching hospital will be able to review the payment or transfer of value information and affirm or dispute the submitted data prior to it being made public. This process is referred to as "Review and Dispute." Any user who has permission to dispute records may initiate a dispute on any record they have access to.

The review and dispute period will start at least 60 days before the information is to be published for that program year. Physicians and teaching hospitals will work directly with reporting entities to resolve disputes outside of the Open Payments system.

If a dispute is not resolved before the end of the 60-day period, the latest, attested-to data submitted by the applicable manufacturer or applicable GPO will be published in the next data publication and identified as being under dispute.

Reviews and disputes can occur outside of this 60-day period; the review and dispute process is open year-round. If the applicable manufacturer or applicable GPO cannot resolve the dispute with the physician or teaching hospital within those 60 days, all parties should continue to seek a resolution. The process is outlined in Figure 9.1 below.

Figure 9.1: Review, Dispute, and Correction Process

During	What Happens During Review?	What Happens During Dispute?	What Happens During Corrections?
Day 1-45	• Applicable manufacturers, applicable GPOs, physicians and teaching hospitals review their data before it is made public.	• Physicians and teaching hospitals can dispute information reported about them or their institutions. • Disputes initiated during this 45-day period that are not resolved by the end of the period will be reflected in the public data as the record will be shown as under dispute. • CMS will not mediate any dispute.	• Applicable manufacturers and applicable GPOs should work with the disputing physician or teaching hospital to correct disputed data. • Applicable manufacturers or applicable GPOs must submit a revised report to make the corrections and re-attest to the updated data.
> 45 Days	• Applicable manufacturers and applicable GPOs seek to resolve disputes received from physicians and teaching hospitals. • Physicians and teaching hospitals may continue to review the data.	• Physicians and teaching hospitals may continue to initiate disputes during this period but resolutions may not be reflected in publicly displayed data.	• Applicable manufacturers and applicable GPOs should work with physicians and teaching hospitals to make corrections. • Corrections made to disputes may not be included in the next publication of data. • Applicable manufacturers and applicable GPOs must send CMS a revised report to make the appropriate corrections and re-attest to the updated data.

There is an initial 45-day period for physicians and teaching hospitals to review and dispute data submitted about them by reporting entities, and work with reporting entities to resolve the disputes. Immediately following that initial 45 days is an additional 15-day correction period for reporting entities to continue to work with physicians and teaching hospitals on dispute resolution.

Disputes initiated or resolved after the 60-day period will not be published in the initial publication of data. Those disputes and any related data changes will be published in the next publication of data, either in a refresh publication of the program year data or the publication of the next program year's data. In the publication, the data will be associated with the program year of the data, not the date of its publication. Disputes initiated within the initial 45-day review and dispute period, and resolved by the end of the additional 15-day correction period, will be published and identified as non-disputed in the initial public posting of data. Disputes initiated during the 15-day dispute correction period will not be in the initial public posting of data.

Figure 9.2 below explains how the dispute initiation and resolution timing affects the public display status of the data:

Figure 9.2: Dispute Initiation, Resolution, and Public Display of Program Year 2013 Data

Timing of Dispute Initiation	Dispute Resolution Status Within 45-Day Initial Period or 15-Day Correction Period	Public Display Status
Within 45-day review, dispute & correction period	Resolved	Data, with any revisions from resolution, will be published as non-disputed in September 2014.
	Not resolved	Data published as disputed in September 2014.
After 45-day review, dispute & correction period and prior to the review, dispute & correction period before the next data refresh or publication	Resolved	Data published as non-disputed in both September 2014 and the subsequent data publication related to the 2013 program year data. Any revisions to data due to resolution will appear in subsequent data publications
	Not resolved	Data published as non-disputed in September 2014 and as disputed in the subsequent data publication related to 2013 program year.

** The exact date may vary. Note that the rule does not require CMS to display the data as disputed if not resolved during this period.

Records that have been disputed will have one of the following dispute statuses:

- **Initiated:** indicates that a physician or teaching hospital has initiated a dispute against a record submitted by an applicable manufacturer or applicable GPO.

- **Acknowledged:** indicates that an applicable manufacturer or applicable GPO has received and acknowledged a dispute initiated against them by a physician or teaching hospital. Acknowledging a dispute will trigger a notification to the initiating physician or teaching hospital letting them know their dispute has been received.

- **Resolved, No Change**: indicates that either the applicable manufacturer or applicable GPO does not agree with a dispute initiated by a physician or teaching hospital or the applicable manufacturer or applicable GPO has discussed the dispute with the initiating physician or teaching hospital and it was determined that no change in the data was necessary. The physician or teaching hospital who initiated the dispute can initiate a new dispute if they disagree with "resolved, no change" status.

- **Withdrawn**: indicates that a physician or teaching hospital has withdrawn a dispute they initiated against a record submitted by an applicable manufacturer or applicable GPO.

- **Resolved:** indicates that disputed data was updated and then resubmitted and re-attested to by the applicable manufacturer or applicable GPO.

Emails transmitted to applicable manufacturers, applicable GPOs, physicians, and teaching hospitals from the Open Payments system for review and dispute will not contain contact information. For example, an email notifying a reporting entity of a dispute from a physician will contain only the information needed to locate the record in the Open Payments system. You can view a sample notification email for each review and dispute action in Appendix D. Contact information can be obtained only by opening the record within the Open Payments system itself.

Section 9.1: Reviewing and Affirming Submitted Data

Physicians and teaching hospitals that have registered with the Open Payments system may review all payment, other transfer of value, and physician ownership or investment interest data submitted by an applicable manufacturer or applicable GPO about them. When the data has been reviewed and the physician or teaching hospital does not find discrepancies in the data submitted, they may choose to affirm that the record(s) are in good standing.

Records that have not been affirmed will still be included in the next data publication. Note that if you determine that a record you previously affirmed is in error, you can initiate a dispute on that record. The process for reviewing and affirming disputes is illustrated in Figure 9.3 below. Step-by-step walkthroughs of various scenarios follow.

Figure 9.3: Review and Affirmation Process

Log in to Open Payments, Select "Review and Dispute" → Select Covered Recipient and Program Year → View Listed Records for the Covered Recipient → Select Record(s) to Affirm → Review Selected Records and Affirm Records

Section 9.1a: Teaching Hospital - Reviewing and Affirming Submitted Data

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Review and Dispute" tab.

Step 2: Select the teaching hospital and the appropriate program year you wish to review for data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."

Step 3: On the Records page, you will see a list of all submitted records for the selected teaching hospital. If you wish, you may filter the records by selecting the "Entity Making Payment" from the specified drop-down. You may also filter further by including the record ID, date of publication, and/or dispute ID. You do not need to filter the results in order to proceed. Scroll to the right and select "View" under the column title "View Record" to view the record details. Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Step 4: Review the information of the submitted record. When finished, select "Back."

Step 5: Select the record(s) you wish to affirm. You may only affirm records with a review and dispute status of "Resolved, No Change," "Withdrawn," or "Resolved." When the record(s) has been selected, select "Affirm Record."

Step 6: Review the information on the "Affirm Records" page. When finished, select "Affirm Records."

The following message will be displayed on the screen, confirming the successful affirmation of the submitted record(s). Also, the record's "Affirmed Yes/No" indicator, visible in the View Records table, will be set to Y.

Section 9.1b: Physician – Reviewing and Affirming Submitted Data

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Review and Dispute" tab.

Step 2: Select the physician and the appropriate program year for the physician you wish to review for data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."

Step 3: On the records page, you will see a list of all submitted records for the selected physician. You may filter the records by selecting "Entity Making Payment" from the appropriate drop-down menu. You may further filter information by including the Record ID, Date of Publication and/or Dispute ID. You do not need to filter the results in order to proceed. Scroll to the right and select "View" under the column title "View Record" to view the record details. Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Step 4: Review the information of the submitted record. When finished, select "Back" to return to the Records page.

Step 5: Select the record(s) you wish to affirm. You may only affirm records with a review and dispute status of "Resolved, No Change," "Withdrawn," or "Resolved," or record with no review and dispute status given. When the record(s) has been selected, select "Affirm Record."

Step 6: Review the information on the "Affirm Records" page. If the information is correct, select "Affirm Records." We will discuss disputing records later in the User Guide.

The following message will be displayed on the screen, confirming the success affirmation of the submitted record. Also, the record's "Affirmed Yes/No" indicator, visible in the view records table, will be set to Y.

Section 9.2: Initiating and Withdrawing Disputes

Data submitted regarding payments or other transfers of value to physicians or teaching hospitals by applicable manufacturers and applicable GPOs can be disputed by that physician or teaching hospital.

When a physician or teaching hospital initiates or withdraws a dispute, the reporting entity (applicable manufacturer or applicable GPO) will receive an email notification regarding the dispute status with information about their next required actions. The process for initiating and withdrawing disputes is illustrated in Figure 9.4 below. Step-by-step walkthroughs of various dispute scenarios follow.

Figure 9.4: Initiating and Withdrawing Disputes Process

| Log in to Open Payments and Select Review and Dispute | Select Covered Recipient and Program Year | View Records Listed for Covered Recipient | [To Initiate or Withdaw] Select Record(s) | Review Selected Records and Dispute or Withdraw |

Section 9.2a: Teaching Hospital – Initiating a Dispute

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Review and Dispute" tab.

Step 2: Select the teaching hospital and the appropriate program year you wish to review for data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."

Step 3: On the Records page, you will see a list of all submitted records for the selected teaching hospital. If you wish, you may filter the records by selecting the "Entity Making Payment" from the specified drop-down. You may also filter further by including the Record ID, Date of Publication, and/or Dispute ID. You do not need to filter the results in order to proceed. You can also scroll to the right to view more information about the record. Scroll to the right and select "View" under the column title "View Record" to view the record details. Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Select the record(s) you wish to dispute. When the record(s) has been selected, select "Dispute Record."

Step 3: Review the information on the "Dispute Records" page. You must enter a reason for dispute within the text box before continuing. The text box can contain up to 4,000 characters, including spaces. Special characters allowed in the box are limited to apostrophes or single quotes ('), periods (.), ampersands (&), hyphens (-), and commas (,).

Note: As mentioned, you must provide a reason why the records are being disputed in the "Reason for Dispute" text box. If you have different reasons for each of the records being disputed, you may dispute one or more record(s) at a time with a common dispute factor, and enter the relevant reason for dispute. The contents of the "Reason for Dispute" box will be sent in an email to the reporting entity that reported the payment or other transfer of value. If multiple disputes are initiated at the same time across different reporting entities, the same "Reason for Dispute" text will be sent to all of the reporting entities included in the dispute. When finished, select "Send Dispute."

The following "Dispute Confirmed" message will be displayed on the screen. An email notification will be sent to the reporting entity.

Section 9.2b: Teaching Hospital – Withdrawing a Dispute

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Review and Dispute" tab.

Step 2: Select the teaching hospital and the appropriate program year you wish to review for data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."

Step 3: On the Records page, you will see a list of all submitted records for the chosen teaching hospital. If you wish, you may filter the records by selecting the "Entity Making Payment" from the specified drop-down. You may also filter further by including the Record ID, Date of Publication and/or Dispute ID. You do not need to filter the results in order to proceed. You can also scroll to the right to view more information about the record. Scroll to the right and select "View" under the column title "View Record" to view the record details. Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Select the disputed record(s) you wish to withdraw. You may only withdraw disputes on records with a review and dispute status of "Initiated" or "Acknowledged." When the record(s) has been selected, select "Withdraw Dispute."

Step 4: Review the information on the "Withdraw Disputes" page. When finished, select "Withdraw Disputes."

The following message will be displayed on the screen. An email notification will be sent to the reporting entity.

Section 9.2c: Physician - Initiating a Dispute

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Review and Dispute" tab.

Step 2: Select the physician and the appropriate program year you wish to review for data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."

Step 3: On the Records page, you will see a list of all submitted records for the chosen physician. If you wish, you may filter the records by selecting the "Entity Making Payment" from the specified drop-down. You may also filter further by including the Record ID, Date of Publication and/or Dispute ID. You do not need to filter the results in order to proceed. You can also scroll to the right to view more information about the record. Scroll to the right and select "View" under the column title "View Record" to view the record details. Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Select the record(s) you wish to dispute. When the record(s) has been selected, select "Dispute Record."

Step 4: Review the information on the "Dispute Records" page. You must enter a reason for dispute within the text box before continuing. The text box can contain up to 4,000 characters, including spaces. Special characters allowed in the box are limited to apostrophes or single quotes ('), periods (.), ampersands (&), hyphens (-), and commas (,).

Note: As mentioned, you must provide a reason why the records are being disputed in the "Reason for Dispute" text box. If you have different reasons for each of the records being disputed, you may dispute one or more record(s) at a time with a common dispute factor, and enter the relevant reason for dispute. The contents of the "Reason for Dispute" box will be sent in an email to the reporting entity that reported the payment, other transfer of value, or physician ownership or investment interest. If multiple disputes are initiated at the same time across different reporting entities, the same "Reason for Dispute" text will be sent to all of the reporting entities included in the dispute. When finished, select "Send Dispute."

The following "Dispute Confirmed" message will be displayed on the screen. An email notification will be sent to the reporting entity.

Section 9.2d: Physician - Withdrawing a Dispute

Step 1: Access the Open Payments system via the CMS Enterprise Portal (https://portal.cms.gov/) and select the "Review and Dispute" tab.

Step 2: Select the teaching hospital and the appropriate program year you wish to review for data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."

Step 3: On the Records page, you will see a list of all submitted records for the chosen physician. If you wish, you may filter the records by selecting the "Entity Making Payment" from the specified drop-down. You may also filter further by including the Record ID, Date of Publication and/or Dispute ID. You do not need to filter the results in order to proceed. Scroll to the right and select "View" under the column title "View Record" to view the record details. Please note that this information is only available on the Open Payments system, and cannot be downloaded.

Select the disputed record(s) you wish to withdraw. You may only withdraw disputes on records with a review and dispute status of "Initiated" or "Acknowledged." When the record(s) has been selected, select "Withdraw Dispute."

Step 4: Review the information on the "Withdraw Disputes" page. When finished, select "Withdraw Disputes."

Open Payments (Sunshine Act)

Physician Switch User Type

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

Withdraw Disputes

John Doe - 2013

Back

Select "Withdraw Disputes" to confirm the withdrawal of the selected dispute(s). Once the dispute is withdrawn, the status of the dispute will be displayed as "Withdrawn.".

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

For more information about the review and dispute process, refer to the Open Payments User Guide.

You are withdrawing the following [1] dispute(s):

Dispute ID	Record ID	Date of Payment	Amount ($)	Entity Making Payment	Review and Dispute Status	Record Status	Date Dispute Initiated
181	10056	2013-10-21	$7,500.00	ABCDE Medical	Initiated	Attested	

Cancel   Withdraw Disputes

The following message will be displayed on the screen. An email notification will be sent to the reporting entity.

PART V: PUBLIC DATA PUBLISHING

Coming Fall 2014

Appendix

Appendix A: Glossary of Terms for Open Payments

Applicable Manufacturer:

Applicable manufacturers are entities that operate in the United States and (1) are engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological, or medical supply is solely for use by or within the entity itself or by the entity's own patients (this definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply); or (2) are entities under common ownership with an entity described in part (1) of this definition, which provide assistance or support to such entities with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply. (See 42 CFR 403.902)

Applicable Group Purchasing Organization (GPO):

Applicable group purchasing organizations (GPOs) are entities that operate in the United States and purchase, arrange for or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for a group of individuals or entities, but not solely for use by the entity itself. (See 42 CFR 403.902)

Assistance or Support:

Assistance and support means to provide a service or services needed to produce, prepare, propagate, compound, convert, market, promote, sell, or distribute a covered drug, device, biological, or medical supply. (See 42 CFR 403.902)

Biologicals:

For the purpose of Open Payments, biologicals are defined as in Section 1927(k)(2)(B) of the Social Security Act, which includes a cross-reference to licensure under Section 351 of the Public Health Service Act ("PHS Act").

Common Ownership:

Common ownership is when the same individual, individuals, entity, or entities directly or indirectly own five percent or more of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations. (See 42 CFR 403.902)

Consolidated Report:

A consolidated report is a report filed by an applicable manufacturer, which includes payments or other transfers of value to covered recipients, physician owners or investment interests for the applicable manufacturer filing and applicable manufacturers under common ownership. (See 42 CFR 403.908(d))

Covered Recipients:

Covered recipients are any physicians (see *physicians* for an extensive explanation of how Open Payments defines this group) who are not employees of the applicable manufacturer that is reporting the payment; or teaching hospitals that receive payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. (See 42 CFR 403.902)

General Payments:

Payments or other transfers of value not made in connection with a research agreement or research protocol as required in Open Payments.

Open Payments:

Open Payments is a national transparency program which requires:

Applicable manufacturers of covered drugs, devices, biologicals, or medical supplies to send information about payments or other transfers of value to physicians and teaching hospitals to CMS every year.

Applicable manufacturers and applicable group purchasing organizations (GPOs) to send information about ownership and investment interests held by physicians or their immediate family members to CMS every year.

Applicable GPOs to send information about payments or other transfers of value made to physicians owners and investment interests to CMS every year.

Physicians:

For the purposes of Open Payments, physicians are defined as doctors of medicine or osteopathy practicing medicine or surgery, doctors of dental medicine or dental surgery practicing dentistry, doctors of podiatric medicine, doctors of optometry, or chiropractors, all legally authorized to practice by their state.

Physician Owners or Investors:

Physicians who have an ownership or investment interest in an applicable manufacturer or applicable group purchasing organization. Applicable manufacturers and applicable group purchasing organizations are required to report ownership or investment interests held by a physician or a physician's immediate family member in an applicable manufacturer or applicable group purchasing organization.

Research Payments:

Payments or other transfers of value made in connection with a research agreement or research protocol as required in Open Payments.

Special Characters:

Characters that are neither letters nor numbers. Special characters include punctuation, spaces, and other symbols. Open Payments data elements may contain only the special characters noted as allowed in the Submission Data Mapping Document and explained in the Error Code File Document, both of which are found on the Data Submission and Attestation page of the Open Payments website (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html).

Special characters are restricted in Open Payments system, with exception of the following:

Allowed in Name Fields	Allowed in Comment Fields
• (White space) • ' (apostrophe or single quote) • . (period) • & (ampersand) • - (hyphen) • , (comma)	• ' (apostrophe or single quote) • . (period) • & (ampersand) • - (hyphen) • , (comma)

Teaching Hospital:

Teaching hospitals are hospitals that receive payment for Medicare direct graduate medical education (GME), IPPS indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. (See 42 CFR 403.902). The full list of affected teaching hospitals can be found on the Teaching Hospitals page of the CMS Open Payments website (https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Teaching-Hospitals.html).

Appendix B: Submission Error Codes

Error codes generated by the Open Payments system for records with validation errors can be found in the Error Code File document, which is located at http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Error-Code-File-Document-[June-2014].xlsx.

Appendix C: Medicare Provider/Supplier to Healthcare Provider Taxonomy

Provider taxonomy codes can be found at: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf

Appendix D: Open Payments System Notification Emails

Chapter 5

Dispute Acknowledged Notification Email

Open Payments Dispute Acknowledged
From: openpaymentsnotification@cms.hhs.gov
Date: 2014-07-02 13:27   Encoding: English

ABCDE Medical has acknowledged its receipt of your dispute (Dispute ID 173) regarding the following record:

- Record ID: 10043
- Payment or Other Transfer Value Date: 2013-11-25
- Payment Amount or Dollar Amount Invested: $5,000.00
- Payment Category: General Payments

You may view the updated status of this record by logging into the Open Payments system and navigating to the "Review and Dispute" tab. If you have questions pertaining to this dispute, please contact ABCDE Medical directly.

Dispute Resolved Notification Email

Open Payments Dispute Resolved
From: openpaymentsnotification@cms.hhs.gov
Date: 2014-07-02 13:43   Encoding: English

ABCDE Medical has updated the information for the following payment or other transfer of value, or ownership or investment interest record you have disputed:

- Record ID: 10041
- Payment or Other Transfer of Value Date: 2013-11-11
- Payment Amount or Dollar Amount Invested: $10,000.00
- Payment Category: General Payments

The following disputes associated with this record are now considered resolved:

- Dispute ID: 174 initiated on 2014-07-02

You may view the updated record details by logging into the Open Payments system and navigating to the "Review and Dispute" tab. If you are not satisfied with this resolution, you may dispute this transaction again. If you have questions pertaining to this dispute, please contact ABCDE Medical directly.

Chapter 8

Physician Nominee Notification Email

Open Payments System Action Required - Physician AuthorizedRepresentative Nomination
From: openpaymentsnotification@cms.hhs.gov
Date: 2014-07-03 10:13   Encoding: English

You have been nominated in the Open Payments system as an authorized representative for the physician listed below. As a physician's authorized representative, you are able to perform certain functions in the Open Payments system on behalf of the physician. The functions you may perform are specified under your access level listed below.

- Physician: physician@yopmail.com
- Nomination ID: 184845703651
- Access level: Review Data (Read-Only),Edit Physician profile

You have 10 business days to accept or reject this nomination. If no action is taken, the nomination will be deactivated after 10 days.

To accept your nomination, you must register yourself in the Open Payments system. Prior to registering in the Open Payments system, you must first register for the CMS Enterprise Identity Management system (EIDM). To register in EIDM:

1. Access EIDM on the CMS Enterprise portal at https://portal.cms.gov.

2. Select the "New User Registration" hyperlink to create an account on EIDM and follow the on-screen instructions.

Once you are registered with EIDM, or if you already have registered with EIDM, you can register with Open Payments through the following steps:

1. Access the CMS Enterprise portal at https://portal.cms.gov.

2. Log in by entering your user name and password.

3. Click on "Open Payments."

4. Click on "Search Nominations."

5. Enter your Nomination ID and then click "Submit."

6. Continue through physician information to either accept/reject the nomination.

If you have any questions or concerns you can contact us by email at openpayments@cms.hhs.gov or by telephone at 855-326-8366. If you would like more information about the program, please visit the Open Payments website at http://go.cms.gov/openpayments or our existing Frequently Asked Questions. Do not reply to this automatically generated email.

Teaching Hospital Nominee Notification Email

Open Payments System Action Required - Nomination for Authorized Representative for Teaching Hospital in Op...
From: openpaymentsnotification@cms.hhs.gov
Date: 2014-07-03 11:28   Encoding: English

You have been nominated in the Open Payments system for the following user role for the below teaching hospital:

- Teaching hospital: ABCDE Hospital
- Registration ID: 100000000019
- Nomination ID: 786049438133
- List of role of the user roles: Authorized Official

You have 10 business days to accept or reject the nomination for this role in the Open Payments system. Your nomination will be deactivated if you do not register in Open Payments and accept or reject your nomination within 10 business days of this message.

To accept your nomination, you must register yourself in the Open Payments system. Prior to registering in the Open Payments system, you must first register for the CMS Enterprise Identity Management system (EIDM). To register in EIDM:

1. Access EIDM on the CMS Enterprise portal at https://portal.cms.gov.
2. Select the "New User Registration" hyperlink to create an account on EIDM and follow the on-screen instructions.

Once you are registered with EIDM, or if you already have registered with EIDM, you can register with Open Payments through the following steps:

1. Access the CMS Enterprise portal at https://portal.cms.gov.
2. Log in by entering your user name and password.
3. Access the Open Payments system.
4. Continue to "Select Profile Type" page
5. Click on I have Nomination ID and Registration ID
6. Select Teaching Hospital from the list
7. Enter the teaching hospital's registration and nomination ID you received via email, and click "Show Nomination."
8. Confirm the teaching hospital information and continue through to either accept/reject the nomination.

If you have any questions or concerns you can contact us by email at openpayments@cms.hhs.gov or by telephone at 855-326-8366. If you would like more information about the program, please visit the Open Payments website at http://go.cms.gov/openpayments or our existing Frequently Asked Questions. Do not reply to this automatically generated email.

Nomination Accepted Notification Email

Open Payments System Nomination Accepted
From: openpaymentsnotification@cms.hhs.gov
Date: 2014-07-03 12:12   Encoding: English

This email is to inform you that the individual listed below accepted the specified role(s) in the Open Payments system.

- Teaching hospital: ABCDE Hospital
- User name accepting the role: James Doe
- List of role(s) of the user: Authorized Representative

If you have any questions or concerns you can contact us by email at openpayments@cms.hhs.gov or by telephone at 855-326-8366. If you would like more information about the program, please visit the Open Payments website at http://go.cms.gov/openpayments or our existing Frequently Asked Questions. Do not reply to this automatically generated email.

Chapter 9

Dispute Initiated Notification Email

Open Payments Dispute Initiated
From: openpaymentsnotification@cms.hhs.gov
Date: 2014-07-02 13:18   Encoding: English

A dispute has been initiated in relation to a payment or other transfer of value, or ownership or investment interest reported by ABCDE Medical for the 2013 program year. The dispute was initiated regarding the following record:

- Record ID: 10041
- Payment or Other Transfer of Value Date: 2013-11-11
- Payment Amount or Dollar Amount Invested: $10,000.00
- Payment Category: General Payments
- Physician or Teaching Hospital Name: ABCDE Hospital

Dispute ID: 172

Dispute Details
The payment amount is incorrect. The amount received was 7,500 and needs to be updated.

You may acknowledge receipt of the dispute by logging into the Open Payments system, navigating to the "Review and Dispute" tab, and selecting "Acknowledge Dispute." The physician or teaching hospital who initiated the dispute will receive an email acknowledging your receipt of the dispute.

You may review the details of the dispute by navigating to the "Review and Dispute" tab of the Open Payments system and searching for the disputed record using the Record ID or Dispute ID noted above. You may resolve the dispute by submitting and attesting to the corrected data. After reviewing the disputed information, if you determine that no change is required to the data, you may dismiss the dispute or request the physician or teaching hospital who initiated the dispute to withdraw it. If you have questions or require any further information about this dispute, please contact ABCDE Medical directly.

Dispute Withdrawn Notification Email

Open Payments Dispute Withdrawn
From: openpaymentsnotification@cms.hhs.gov
Date: 2014-07-02 13:21   Encoding: English

ABCDE Hospital has withdrawn its dispute (Dispute ID 172) regarding the following record:

- Record ID: 10041
- Payment or Other Transfer of Value Date: 2013-11-11
- Payment Amount or Dollar Amount Invested: $10,000.00
- Payment Category: General Payments

No further action is required on this record at this time. You may view the updated status of this record by logging into the Open Payments system and navigating to the "Review and Dispute" tab.