

User Guide

OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY INTO INDUSTRY-PHYSICIAN FINANCIAL RELATIONSHIPS

September 2017

Disclaimer: The Centers for Medicare & Medicaid Services (CMS) is providing this guidance document as informational material on Open Payments. Although every reasonable effort has been made to assure the accuracy of the information, it is the responsibility of the user to ensure adherence to the requirements of the Open Payments implementing regulations, the Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests Final Rule codified at 42 C.F.R. Parts 402 and 403 [CMS-5060-F]. This User Guide is not intended as a supplement or replacement of the Final Rule.

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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
- 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
3.1	August 2014	Update	Minor corrections and updates
4.0	December 2014	Update	Updates made to Chapter 5
5.0	January 2015	Update	Chapter 10 and updates for registration and data submission
6.0	March 2015	Update	Updates for registration and data submission
7.0	April 2015	Update	Updates for review and dispute
8.0	June 2015	Update	Updated Chapter 10 for PY2014 data publication
9.0	January 2016	Update	Updated throughout to reflect system updates in Jan 2016
10.0	June 2016	Update	Updated publication chapter, added to glossary
11.0	January 2017	Update	Updated to reflect changes to registration and data submission
12.0	June 2017	Update	Updated publication chapter, removed outdated information
13.0	September 2017	Update	Updated to reflect system updates

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 entity 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 <u>covered recipients</u> and <u>physician owners or investors</u>, by manufacturers of drugs, devices, <u>biologicals</u>, 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 <u>applicable manufacturers</u> and <u>applicable group purchasing organizations (GPOs)</u>, as well as reporting payments or other 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 & 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 interest, 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 <u>common ownership</u> with applicable manufacturers who also provide <u>assistance and support</u>, 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 physicians or their immediate family members.
- Applicable GPOs are required to annually report to CMS:
 - o Payments or other transfers of value made to physician owners or investors.
 - Certain ownership or investment interests held by physicians or their immediate family members.

While not required to participate, 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 Dates for Open Payments Program Years

For each program year, the following dates are of key importance:

Applicable manufacturers and applicable GPOs are required to **collect data** documenting their financial relationships with certain physicians and teaching hospitals for the period of January 1 to December 31 of each year.

Data submission for a program year begins in February of the following year and runs through the end of March. For example, data submission for program year 2016 took place in February and March of 2017.

The review and dispute period occurs after the submission period ends and extends for at least 45 days. During this period, physicians and teaching hospitals review and, if necessary, dispute data submitted by reporting entities. Applicable manufacturers and applicable GPOs can then correct the data to resolve any disputes for an additional fifteen-day correction period. Review, dispute, and correction activities can occur until the end of the calendar year that the record was submitted, though the initial publication of the program year data will reflect the state of the record as of the end of the correction period.

Disputes initiated after the review and dispute period or corrections made after the end of the correction period will be reflected in later publications. See Chapter 8, "Data Publication," for details.

Data publication occurs twice per year, with a June 30 publication and an early year publication.

June 30 Publication - Initial Publication

- o The first publication of the eligible records submitted and attested on or before the submission closing date of the latest program year.
- The republication of eligible records from prior program years, including updates to previously published records made since the previous publication.
- The data published is the latest attested version of the payment records at the end of the correction period of the latest program year.

• Early Year Publication - Refresh Publication

- o Publishes updates to the data made since the Initial Publication.
- The second publication of eligible records submitted and attested on or before the submission closing date of the latest program year.
- Contains updates made to records after the correction period of the latest program year and before the end of the calendar year (or before the modified-without-dispute cutoff date in November for records not under dispute).
- o The data published is the latest attested version of the data at the end of the calendar year.

For example, the June 30, 2017 data publication included the initial publication of the program year 2016 data and republication of prior program years. The early 2018 data publication will include the refresh publication of program year 2016 data and republication of prior program years.

Registration for the Open Payments system, and the ability to dispute data, is available year-round. Information on these activities and time periods is provided throughout this document.

The table below lists key program dates for a program year, which is the year the reported payments or other transfers of value were made.

Figure 1.1: Key Dates for an Open Payments Program Year

Program Activities	Program Timeline
Industry collects data	January 1-December 31 of program year
Industry submits and attests to data in the Open Payments system	February-March of the calendar year after the program year
Physicians and teaching hospitals review the	Review and dispute period: April-May
reported data and dispute any data they believe is inaccurate; industry makes corrections to the data	AM/GPO Correction period: May-June
(reflected in the initial publication)	
Initial program year initial data publication	June 30
Prior program year data refresh publication	
Physicians and teaching hospitals continue to	June – December 31
review and dispute data; industry continues to make corrections to the data (reflected in the data	
refresh publication)	
Open Payments data refresh	Early in the following year

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 transfers of value to CMS.

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

- <u>Step 1:</u> 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 1.2.**
- 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 1.2.**
- <u>Step 3:</u> 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 4: If the entity possesses the characteristics illustrated in Figure 1.2, 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 that 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 operates in the United States (includes any territory, possession, or commonwealth of the United States). See the reference guide in Figure 1.3.

Step 6:

Determine if the entity engages in activities of an applicable GPO. See the reference guide in Figure 1.3.

Step 7:

Determine if the entity's products are covered drugs, devices, biologicals, or medical supplies, or covered products. See the reference guide in Figure 1.3.

Step 8:

If the entity possesses the characteristics illustrated in Figure 1.3, the entity is determined to be an applicable GPO in Open Payments.

If the entity does not possess the characteristics as illustrated in Figure 1.3, the entity is not determined to be an applicable GPO in Open Payments.

Figure 1.2 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 1.2** also outlines the characteristics for two types of applicable manufacturers.

Figure 1.2: 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 1.3 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 1.3** also outlines the characteristics of applicable GPOs.

Figure 1.3: 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 other 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.

Applicable manufacturers, applicable GPOs, physicians, and teaching hospitals who participate in the Open Payments program must register in the Open Payments system. **Figure 1.4** provides a high-level process flow.

Figure 1.4: High-Level Process Flow for Open Payments

Data Applicable manufacturers and applicable GPOs collect data about Collection their financial relationships with physicians and teaching hospitals. Applicable manufacturers, applicable GPOs, physicians, and teaching EIDM hospitals register in CMS's Enterprise Portal and request access to Registration the Open Payments system. Applicable manufacturers, applicable GPOs, physicians and teaching Open Payments hospitals register in the Open Payments system. System Registration Applicable manufacturers and applicable GPOs submit detailed data Data and legally attest to the accuracy of the data. Submission Physicians and teaching hospitals review and dispute (if necessary) Review and data in the Open Payments system. Applicable manufacturers and Dispute applicable GPOs correct data and resolve disputes as appropriate. CMS posts the data on the public website. Publication

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) or Mozilla Firefox.

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 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 or affirm the data.

This User 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 (i.e., "Back", "Cancel" or "Continue" 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 openpaymentsnotifications@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 1.5** 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 1.5: 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 are made of forms. The F key allows JAWS users to determine what fields are on the Open Payments form pages quickly.
н	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 supports Open Payments system users through a number of different methods. These include webinars, Frequently Asked Questions (FAQs), step-by-step quick reference guides (QRGs), and technical support provided by the Open Payments Help Desk.

1.5a: Open Payments Website

The Open Payments website at https://www.cms.gov/openpayments is your primary resource for information about Open Payments. This website contains numerous resources aimed at preparing and informing users about Open Payments regulations as well as the system. Check this website often for updated tools, resources, and important announcements pertaining to Open Payments.

1.5b: Open Payments Resources

CMS has developed many resources to help applicable manufacturers, applicable GPOs, physicians, and teaching hospitals understand and participate in the Open Payments program. These resources cover topics such as registration, data collection and submission, the review and dispute process, and data publication. They can be found on the Resources page of the Open Payments website, at https://www.cms.gov/openpayments/About/Resources.html.

1.5c: Open Payments Help Desk

The Open Payments Help Desk serves as the single point of contact for all Open Payments-related inquiries. The Help Desk offers guidance on Open Payments, actions users can take in the system, and technical support. You can submit inquiries to openpayments@cms.hhs.gov or call 1-855-326-8366. The Help Desk's hours of operation are posted on the Open Payments website.

1.5d: Open Payments Mailing List

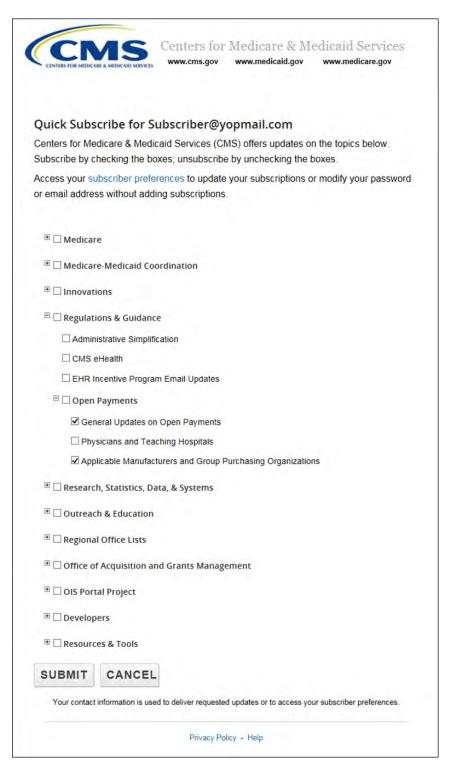
By registering for the Open Payments mailing list, you will be signed up to receive periodic email notifications regarding program, system, and resource updates. This is a good way to keep informed on any updates, changes, or important messages from CMS. To sign up for the Open Payments mailing list, visit the Open Payments website at https://www.cms.gov/openpayments and enter your email address at the bottom of the home page.



Entering your email address will take you to a page where you can select which mailing list you want to subscribe to.



Under the Section "Regulations and Guidance," select "General Updates on Open Payments" and then the "Submit" button at the bottom of the page to join the mailing list. You may also select either the boxes entitled "Physicians and Teaching Hospitals" or "Applicable Manufacturers and Group Purchasing Organizations." Make sure you also select the general updates box to ensure you receive all appropriate email updates.



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.

Data is reported to the Open Payments system through bulk file uploads using character-separated values (CSV) files and through manual data entry through a graphic user interface (GUI). See Chapter 4 for details on how to prepare and submit the data.

A complete listing of metadata elements used for payments data input into the Open Payments system can be found in the "Submission Data Mapping Document." Due to changes in record formats, there are two versions of the Submission Data Mapping document, one for program years 2013-2015 and one for program year 2016 and upcoming years. Both are available on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html. These documents provide specific, detailed descriptions of the information that must be collected by reporting entities to document general, research, and physician ownership/investment interest 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.

- 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 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 transfers of value.
- Payment or Other Transfers of Value Information specifies information regarding the general payment or other transfers of value.

• **General Record Information** captures other general information about the payment or other transfers of value.

On the Resources page of the Open Payments website

(https://www.cms.gov/OpenPayments/About/Resources.html), you can find and download the CSV sample files (also referred to as templates) that show how the data elements listed below will be reported to the Open Payments system.

Users who hold a submitter role can also access the sample files within the Open Payments system on the "Resources" tab.

Due to changes in record formats, there is a general payments sample file for PY 2013-2015 and another for PY 2016 and upcoming years.

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 <u>research payments</u> made by applicable manufacturers and applicable GPOs to covered recipient physicians and teaching hospitals should be captured during data collection; these categories are shown in the bulleted list below.

- 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 transfers of value.
- Payment or Other Transfers of Value Information specifies information regarding the research payment or other transfers of value.
- **Research-related Information** captures specific information about payments or other transfers of value for research activities.

On the Resources page of the Open Payments website

(https://www.cms.gov/OpenPayments/About/Resources.html), you can find the CSV sample files (also referred to as templates) that show how the data elements listed below will be reported to the Open Payments system.

Users who hold a submitter role can also access the sample files within the Open Payments system on the "Resources" tab.

Due to changes in record formats, there is a research payments sample file for PY 2013-2015 and another for PY 2016 and upcoming years.

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

This section on physician ownership/investment interests reporting and data collection provides information about data collection for reporting entities required to report physician ownership or investment interests 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.

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

On the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html), you can find the CSV sample files (also referred to as templates) that show how the data elements listed below will be reported to the Open Payments system.

Users who hold a submitter role can also access the sample files within the Open Payments system on the "Resources" tab.

There is only one physician ownership/investment sample file for all program years.

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 at 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 make payments or other transfers of value to covered recipients and physician owners or investors for the Open Payments program 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 reporting entities submitting data in a single report as well as reporting entities submitting data as part of a consolidated report.

This chapter is divided into the following sections:

- **Two-Step Registration Process Overview,** which provides information about the registration process. Registration includes user registration in EIDM via the CMS Enterprise Portal, as well as registration in the Open Payments system.
- **EIDM Registration**, which provides details on registering for EIDM and requesting access to the Open Payments system.
- Registering Applicable Manufacturers and Applicable GPOs for the Open Payments System, which contains instructions for registering, logging in to the system, and managing the applicable manufacturer or applicable GPO registration and user roles.
- **Entity Recertification**, which contains instructions for recertifying reporting entity information in the Open Payments system for entities that registered for the prior program year.
- 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.
- Vetting, which contains information on the reporting entity vetting process and timeframes.

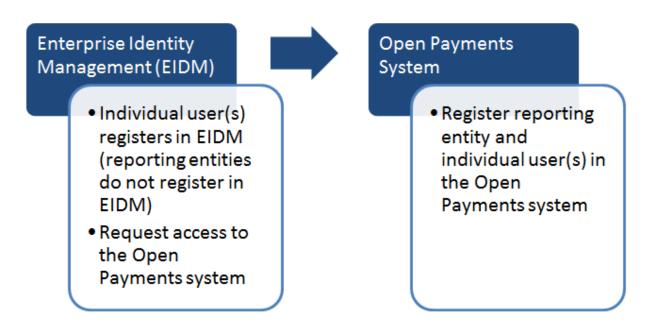
Section 3.1: Two-Step Registration Process Overview

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 log in credentials. Once the user has registered in EIDM, they will be able to register in the Open Payments system.

Open Payments registration is completed in two steps, illustrated in Figure 3.1. First, users must obtain EIDM credentials and request access to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov. Second, users must register their reporting entity in the Open Payments system. If their reporting entity already has been registered, they can register themselves as an individual and affiliate themselves with that reporting entity.

Figure 3.1: Applicable Manufacturer and Applicable GPO Registration



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

Enterprise Identity Management (EIDM) is an identity management and services system that (1) serves as an identity proofing tool to verify a person's identity; and (2) provides users with access to various CMS applications. Registering in EIDM provides users with log in 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 users to log in to the CMS Enterprise Portal and 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 at https://portal.cms.gov. A list of EIDM FAQs is available on the CMS portal at https://portal.cms.gov/wps/portal/unauthportal/faq, and information about EIDM registration can be found on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html. 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 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, 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 a user's account has been deactivated, that user will not be able to access CMS applications, including the Open Payments system. You must 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.

3.2a: EIDM New User Registration

<u>Step 1:</u> Go to the CMS Enterprise Portal at https://portal.cms.gov and select "New User Registration." "New User Registration" is on the right side of the page, inside the "Login to CMS Secure Portal" box.



<u>Step 2:</u> On the "Terms and Conditions" page, check the box at the bottom of the page to agree to the Terms and Conditions of the CMS Enterprise Portal page, then select the "Next" button to continue.



<u>Step 3:</u> 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: Selecting the "Cancel" button will cause you to lose all data entered.** Select the "Next" button when all information has been entered.

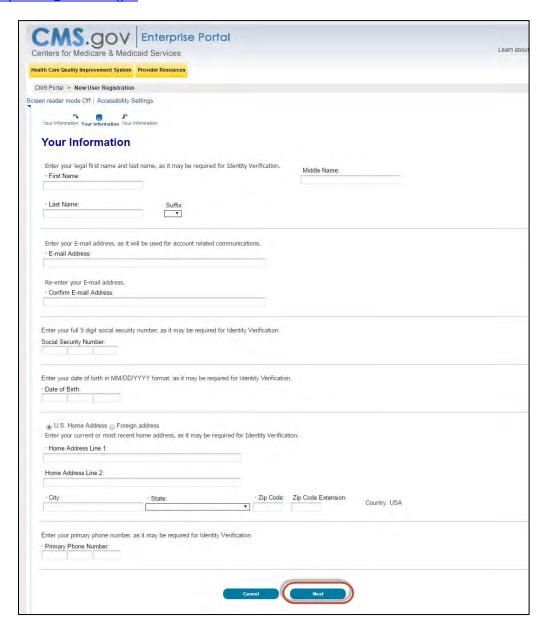
Data fields to be completed are the following:

- Name (First, Middle, Last, Suffix)
- Home Address, City, State, Zip Code
- 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.

In the event of failed identity proofing, EIDM will give you a "control number." Contact Experian Proofing Support Services at 1-866-578-5409 and provide them with the control number for assistance.

If you lost the number and need another, you must fail identity proofing again to generate a new one. If after working with Experian you still need assistance, contact the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366.



NOTE FOR INDIVIDUALS WITH FOREIGN ADDRESSES: Individuals with addresses outside of the United States can register in EIDM via the online portal, but the identity proofing must be conducted manually. Once you have entered your information into the CMS Enterprise Portal, contact the Open Payments Help Desk at openpayments@cms.hhs.gov for assistance with the manual identity proofing process.

<u>Step 4:</u> 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: Selecting the "Cancel" button will cause you to lose all data entered.



- The CMS Portal User ID must:
 - Must be a minimum of 6 and a maximum of 74 characters; and
 - Can contain alphanumeric characters, dashes (-), underscores (_), apostrophes ('), at signs (@), and periods (.).
- Your EIDM password must:
 - Be changed every 180 days;
 - Be changed no more than once per day;
 - Be a minimum of 8 and a maximum of 20 characters;
 - Contain at least one uppercase letter, one lowercase letter, one number, and one special character;
 - Not contain any of the following special characters: Question mark (?), less than (<), greater than (>), left bracket ((), right bracket ()), apostrophe ('), quotation marks ("), forward slash (/), backslash (\), and ampersand (&);
 - Not contain any commonly used words and have no more than two letters in a row;

- Not contain the User ID; and
- Not be one of your last six passwords.

Once EIDM registration is completed, select the "OK" button to take you to the CMS Portal home page. After selecting "OK" you will receive an email confirmation that contains your confirmed EIDM User ID along with a link to the CMS Enterprise Portal.



<u>Step 5:</u> Request access to the Open Payments system. Proceed to Section 3.2b for instructions on how to do so.

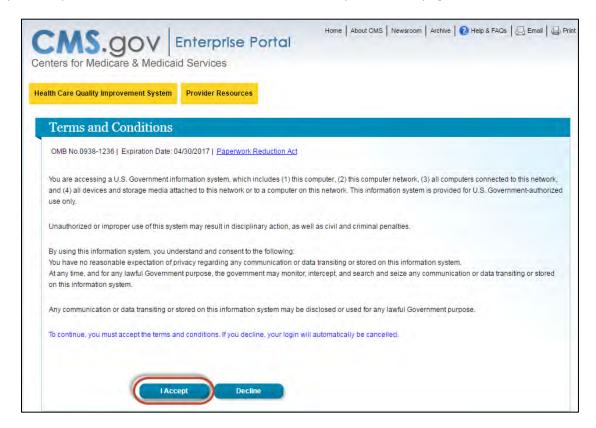
3.2b: Requesting Access to Open Payments with EIDM Credentials

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

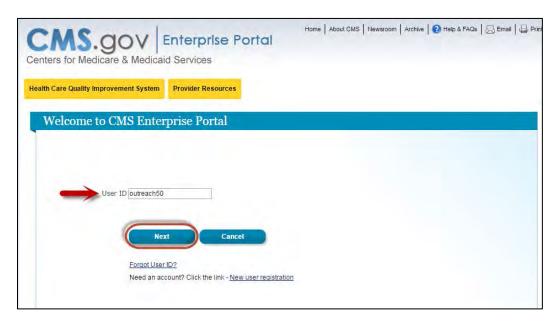
Step 1: On the Enterprise Portal home page, select "Login to CMS Secure Portal."



Step 2: Accept the Terms and Conditions on the "CMS Enterprise Portal" page.



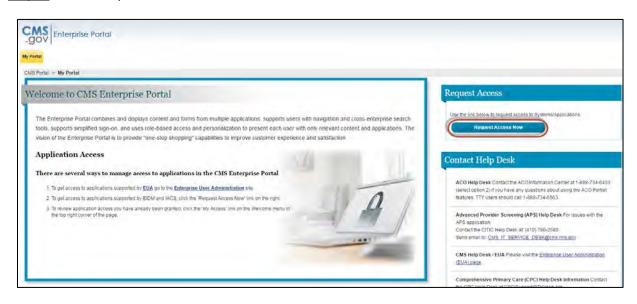
Step 3: Once you have accepted the terms, enter your existing user ID and select "Next."



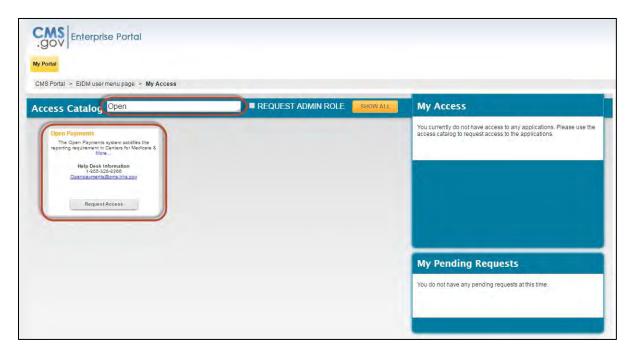
<u>Step 4:</u> Enter the password associated with the User ID entered on the previous page and select "Log In."



Step 5: Select "Request Access Now."

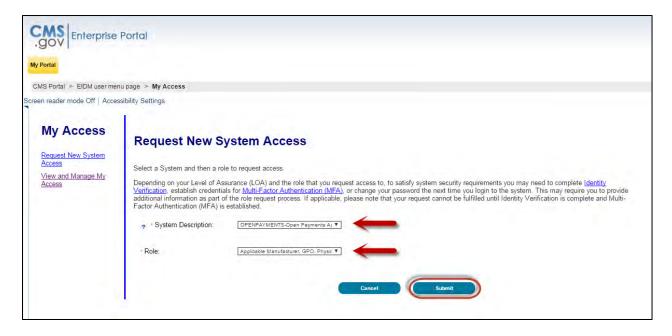


<u>Step 6:</u> Search for the Open Payments application by typing "Open" into the search box at the top of the page or by scrolling down the page until you reach "Open Payments." Select "Request Access" under the Open Payments application box.

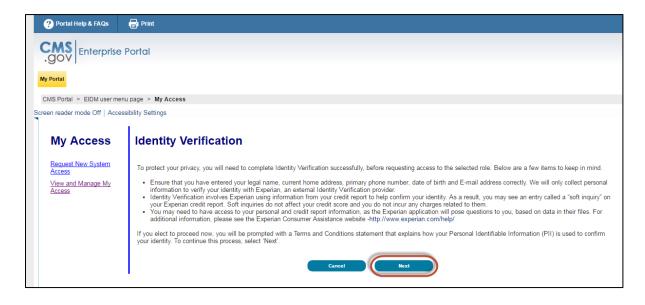


<u>Step 7:</u> From the drop-down menu, select "Open Payments – Open Payments Application" from the "Application Description" drop-down menu. Select "Applicable Manufacturer, GPO, Physician, or Teaching Hospital" from the "Role" drop-down menu. Select the "Submit" button when complete.

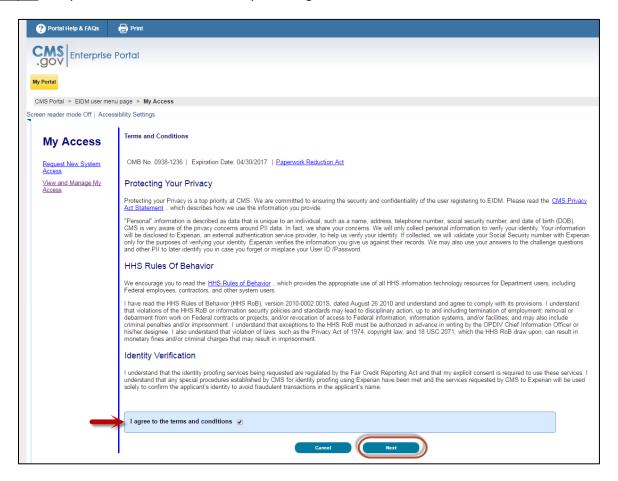
Note: Selecting the "Cancel" button will cause you to lose your selected choices.



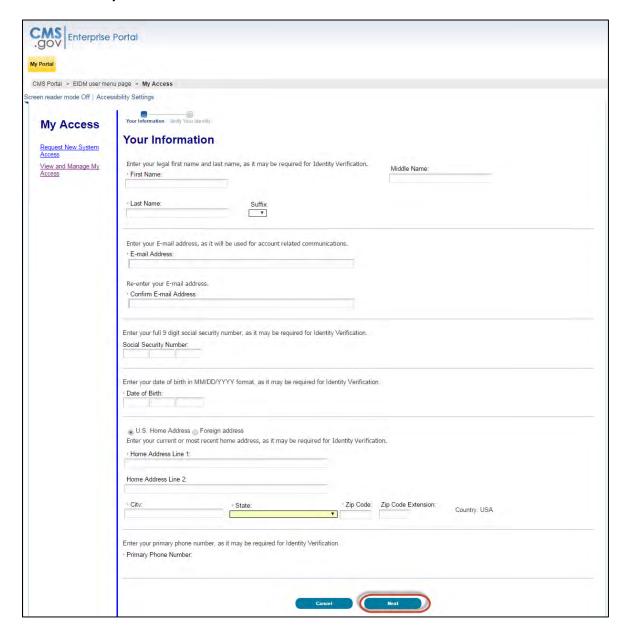
<u>Step 8:</u> Once you have requested access to the Open Payments application, you will then be asked to review the identity verification information. Select the "Next" button once you have reviewed the information.



Step 9: Accept the Terms and Conditions by selecting the checkbox. Select the "Next" button.

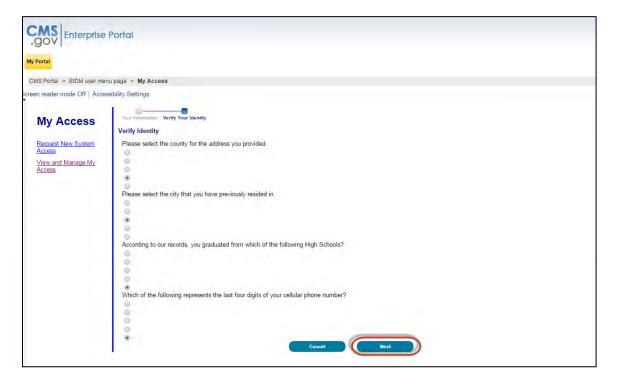


<u>Step 10:</u> Verify your information and make any updates as necessary. **Note: Selecting the "Cancel" button will cause you to lose all data entered.** Select "Next" when finished.



Step 11: Verify your identity by answering the identity proofing questions. The identity proofing questions are created by Experian based upon the information you entered during EIDM registration as well as information in 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. Credit inquiries 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 & 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 Customer Assistance at http://www.experian.com/help/.

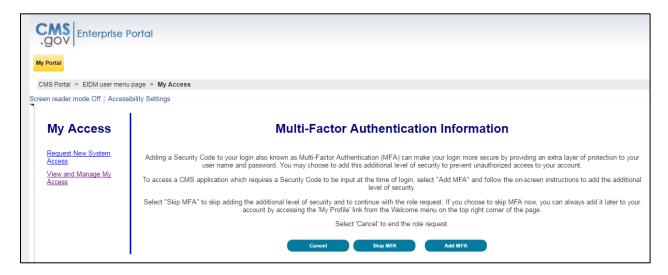
Select the "Next" button when you have completed this page. **Note: Pressing the "Cancel" button will** cause you to lose all data entered.



<u>Step 12:</u> You will receive an on-screen confirmation message that you have successfully completed the identity proofing process. Select "Next" to proceed.



<u>Step 13:</u> You will now be taken to the Multi-Factor Authentication (MFA) Registration page. During the MFA registration process, you will have the option of registering a phone, computer, or email to add an additional level of security to your account. It is **not required** to complete this step to obtain access to the Open Payments system. You may also register the device(s) at a later time. Refer to the "CMS Enterprise Identity Management System (EIDM) User Operations Guide," available at https://portal.cms.gov for more information on the MFA process.

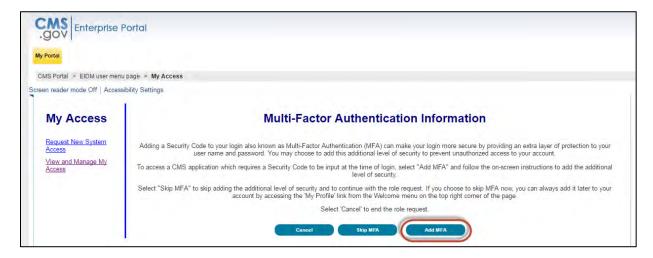


<u>Step 13a:</u> **To proceed without MFA**, select "Skip MFA." A confirmation screen will be displayed that you have successfully requested access to the Open Payments system. Access to the Open Payments system will be instantaneous. Nevertheless, after you register, you will need to log out of the Enterprise Portal and then log back in before the link to the Open Payments system will appear in the menu bar at the top.

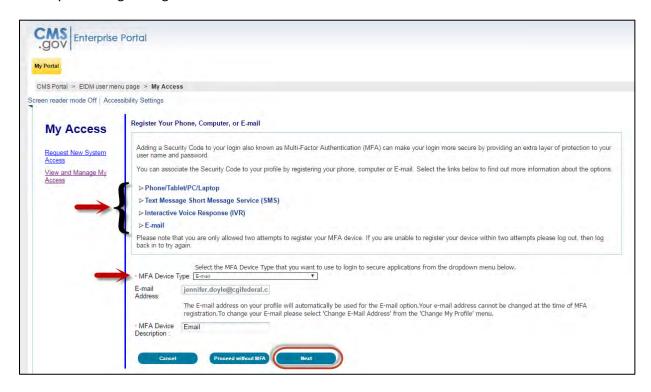




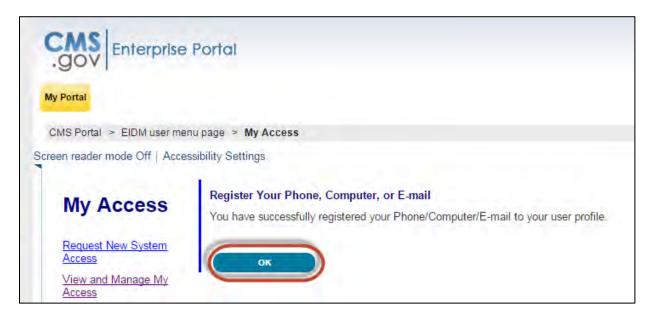
Step 13b: To proceed with MFA, select, "Add MFA."



Select the device you wish to register. Depending on the device you choose to register, you will be asked to provide information about that device. You may only register one device at this time. You can add additional devices later through your EIDM profile settings. Enter the required information for the device you are registering and select "Next" to continue.



You will receive a confirmation that the MFA device you entered has been successfully registered. Select "OK" to continue.



A confirmation screen will be displayed that you have successfully requested access to the Open Payments system. Access to the Open Payments application will be instantaneous. Nevertheless, 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 menu bar at the top.



Section 3.3 Registering Applicable Manufacturers and Applicable GPOs

Once your reporting entity has decided who should fill the required user roles, you can begin Open Payments registration. During 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



The authorized official enters all required information to create the entity's profile. The authorized official should be highly placed within the entity (e.g., a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable GPO. Specific titles may vary depending on the management structure of the reporting 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 partially completed entries for completion 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 30 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 or Optional?
Reporting Entity Type	Required
Reporting Entity Legal Name	Required
Business Type	Required
Doing Business As (DBA) Name	Required
Reporting Entity Business Address	Required
Reporting Entity Business Phone Number	Required
Reporting Entity Type of Ownership	Required
Taxpayer Identifier Number (TIN)/ Employer Identification Number (EIN)	Required
Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS)	Optional
Food and Drug Administrator (FDA) Establishment Identifier (FEI)	Optional
Uniform Resource Locator (URL) of Parent Company*	Required
Consolidated Report Indicator (Y/N) (default N)	Required
Primary Point of Contact Name	Required
Primary Point of Contact Business Phone Number	Required
Primary Point of Contact Title at the Entity	Required
Primary Point of Contact Email Address	Required
Backup Point of Contact Name	Required
Backup Point of Contact Business Phone Number	Required
Backup Point of Contact Title at the Entity	Required
Backup Point of Contact Email Address	Required
Contact Information for Review and Dispute	Required

^{*} If the reporting entity does not have a URL, enter the value https://www.cms.gov in the "Uniform Resource Locator (URL) of Parent Company" field.

Figure 3.4: User Profile Fields

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

The list of required information is also available in the quick reference guide "Required Fields for Registration," which can be downloaded from the Resources page of the Open Payments website (https://www.cms.gov/openpayments/About/Resources.html).

After submitting both the entity and user profiles, Open Payments will vet the entity to ensure it is a valid entity. See Section 3.7 for information on vetting. Users cannot perform any functions in the Open Payments system until the reporting entity has been successfully vetted and registered.

Important Notes:

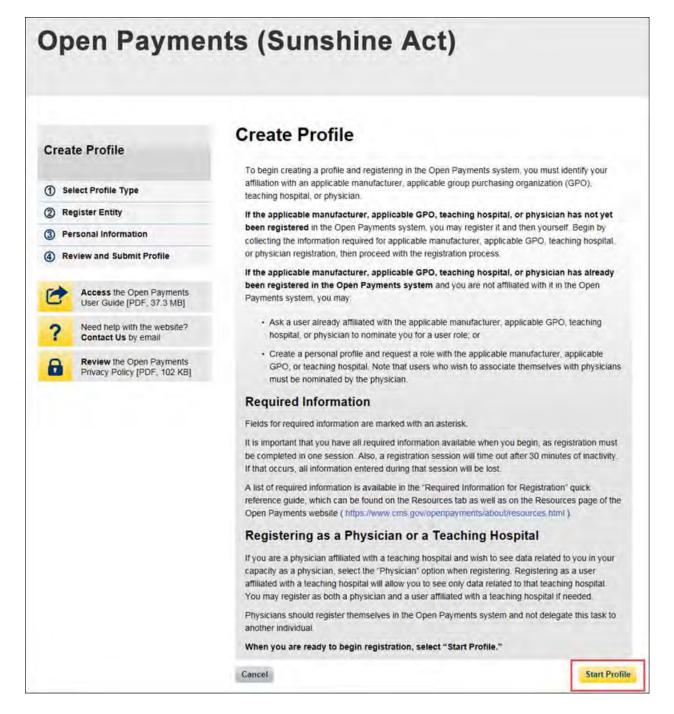
- Registration for both the reporting entity and authorized official must be completed in one session.
- The Open Payments system will log out all users after 30 minutes of inactivity.
- Never use the navigation buttons on your browser toolbar. Only use the navigation buttons (i.e., "Back" button) within the Open Payments system itself.

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

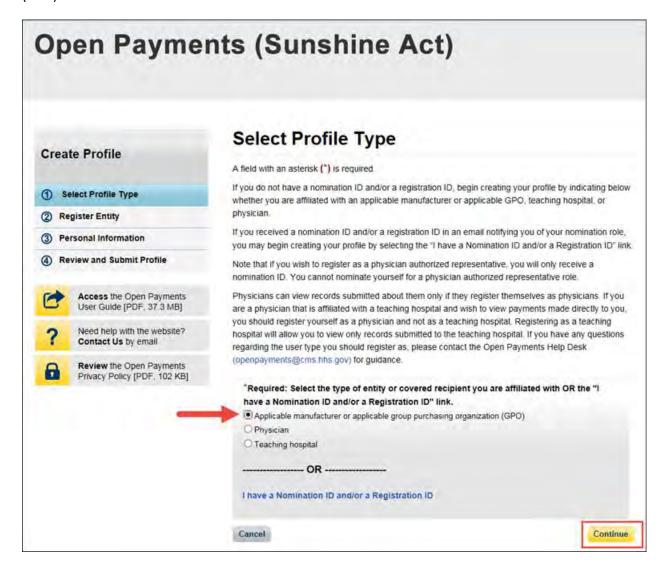
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.



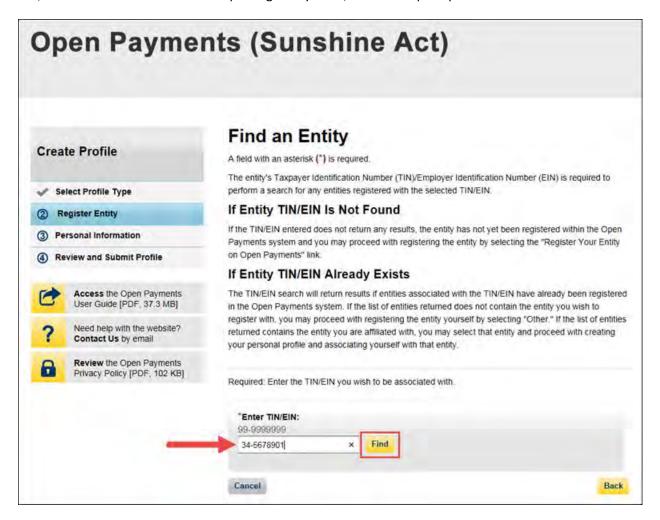
<u>Step 2:</u> The on-screen text contains important information regarding creating the reporting entity and individual profile. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile" at the bottom of the page when you are ready to continue.



<u>Step 3:</u> Select the profile type "Applicable manufacturer or applicable group purchasing organization (GPO)" and select "Continue."



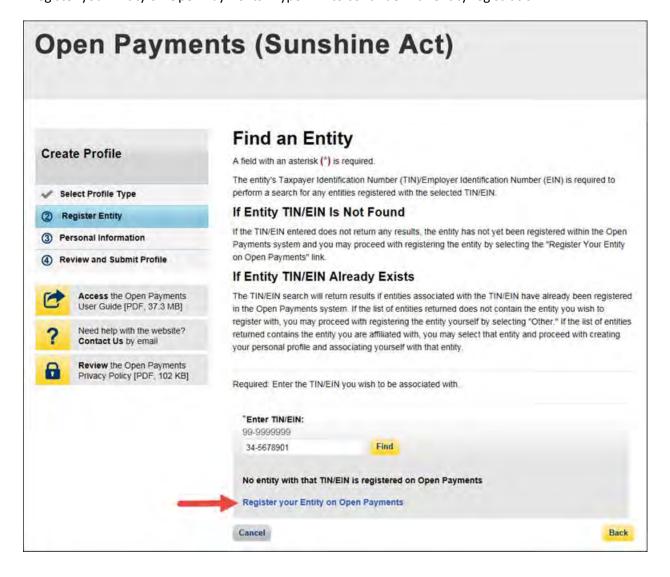
<u>Step 4:</u> Once your entity type is selected, provide the reporting entity's Taxpayer Identification Number/Employer Identification Number (TIN/EIN). This will be the reporting entity's Employer Identification Number (EIN), a nine-digit number used by the entity for tax reporting. The format for the TIN/EIN is 99-999999. Enter the reporting entity's TIN/EIN in the space provided and select "Find."



Step 5: The system will perform a search for that TIN/EIN to determine if it has already been registered.

If the TIN/EIN returns a match, your reporting entity has already been registered. You may choose to proceed by nominating yourself for a role with that entity by selecting the reporting entity name, or you may select "Cancel" to exit entity registration. See Section 3.6d 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 reporting entity. Select the "Register your Entity on Open Payments" hyperlink to continue with entity registration.



<u>Step 6:</u> Enter the reporting entity's 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. Take care to use proper field formatting required by the system. For example, when entering the entity phone number and Taxpayer Identification Number/Employer 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 reporting entity you are registering does not have a website, enter the generic URL of https://www.cms.gov into this field. When you are done, select "Continue." Selecting 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 4.12 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:

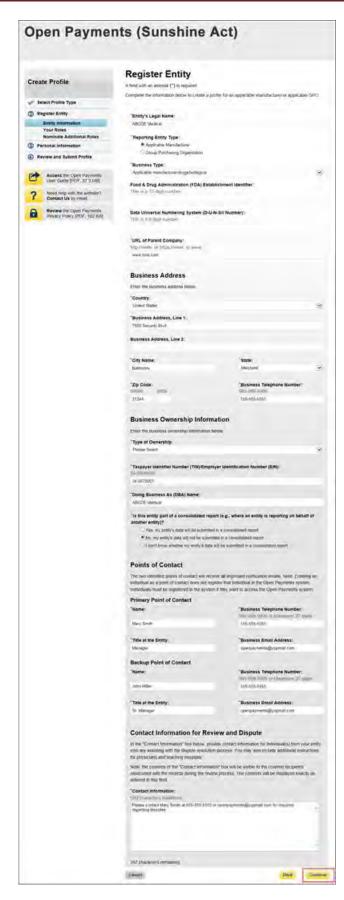
- applicable manufacturer-drugs/biologicals
- applicable manufacturer-devices/medical supplies
- applicable manufacturer-drugs/biologicals and devices/medical supplies
- applicable manufacturer-physician-owned distributor
- applicable manufacturer-hospital-owned distributor
- applicable manufacturer-distributor/supplier (non-hospital, non-physician-owned)

Applicable GPO

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

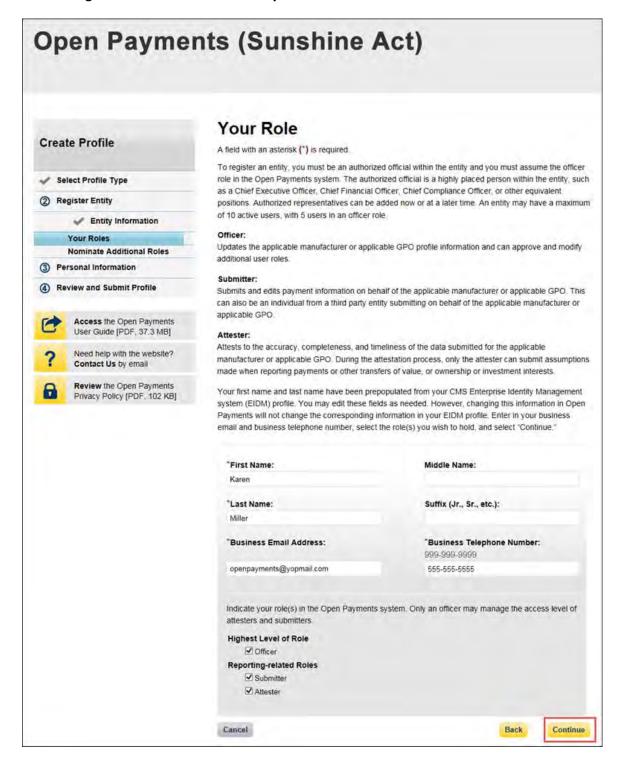
- GPO-drugs/biologicals
- GPO-devices/medical supplies
- GPO- drugs/biologicals and devices/medical supplies
- GPO-physician-owned

- GPO-hospital-owned
- GPO-hospital and physician-owned
- GPO-non-hospital, non-physician-owned
- GPO-government-owned
- The **Primary** and **Backup Points of Contact** are individuals who will serve as the points of contact for the reporting entity and CMS. These must be separate individuals. They do not have to be registered in the Open Payments system.
- The Contact Information for Review and Dispute field is to provide contact information for individual(s) from your entity who will assist with the dispute resolution process. Individuals listed as contacts for review and dispute do not have to be registered in the Open Payments system. You may also include additional instructions for physicians and teaching hospitals in this field. The contents of the "Contact Information" box will be visible on your entity's profile page as well as the "Record ID" pages of all records the entity has submitted.



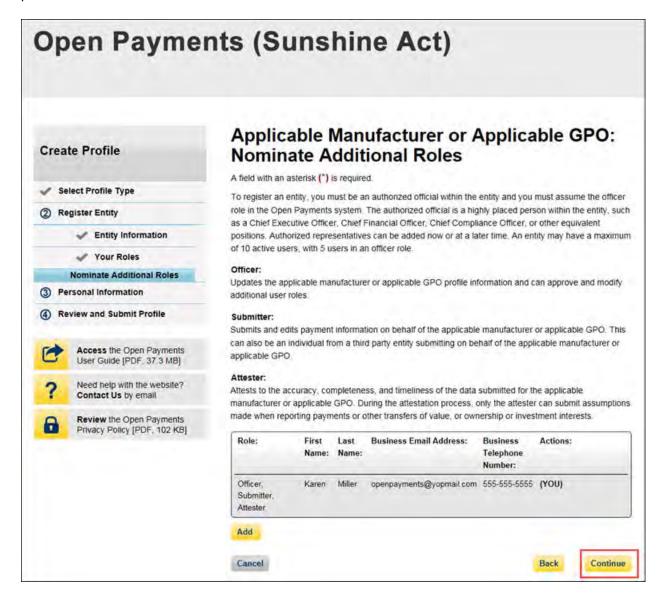
<u>Step 7:</u> Enter the required information and select your user roles. For a description of user roles, see Section 3.5. When registering a new reporting entity, you must select the role of officer for yourself. The system will not allow you to proceed if this role is not selected. You may also select the role of submitter and/or attester for yourself. When you are done, select "Continue."

Note: Selecting the "Back" button will cause you to lose all data entered.



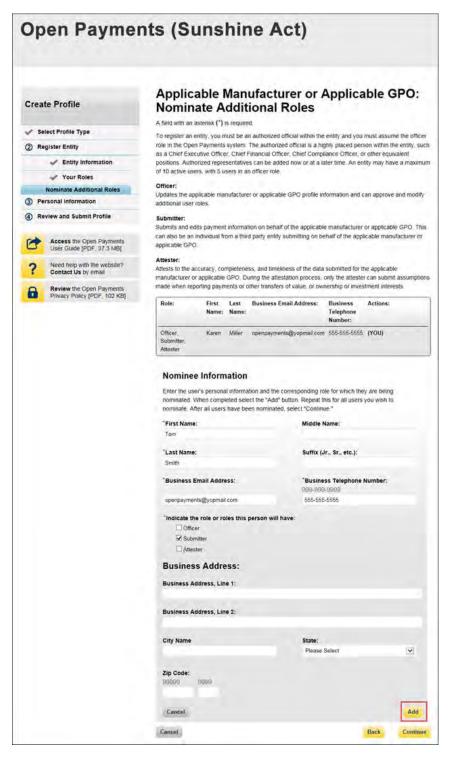
<u>Step 8:</u> You may nominate additional individuals for the officer, submitter, and attester roles at this step. To add a nomination, select the "Add" button and proceed to Step 9. If you do not wish to nominate additional individuals, select "Continue" and proceed to Step 10.

If you will not be fulfilling all three user roles yourself, you must nominate at least one other individual to fill each of the remaining roles. At least one individual must be identified for each of the three roles in the Open Payments system during initial entity registration. The system will not allow you to proceed without at least one individual associated with each user role.



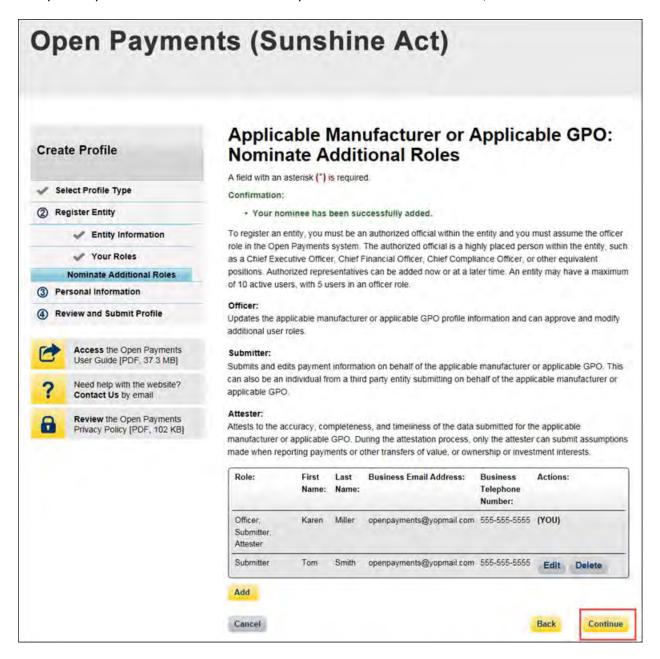
<u>Step 9:</u> If you selected "Add," the page will expand to show nominee information fields that will need to be completed. Fill in the information for the individual being nominated. Once you are done, select the "Add" button at the bottom of the page again. This will add the nominee information to the reporting entity's profile, as well as open another set of information fields to enter an additional nominee.

Note: Selecting the "Back" button will cause you to lose all data entered.



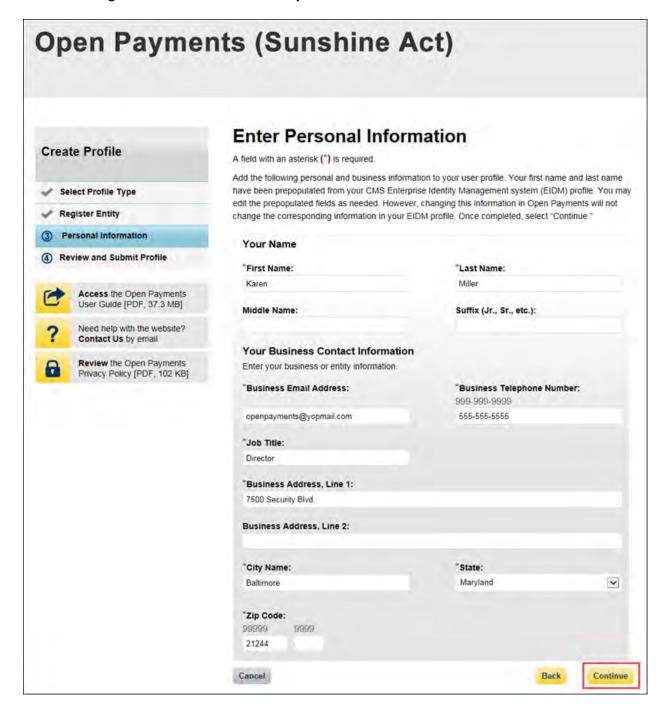
Repeat the process until you have entered all individuals you wish to nominate at this time. An entity can have up to 10 unique users with a maximum of five holding the role of officer. Note that individuals can be nominated for user roles after entity registration is complete.

The page will display a summary of all of the individuals being nominated for user roles for this reporting entity. Once you have entered all nominations you wish to include at this time, select "Continue."

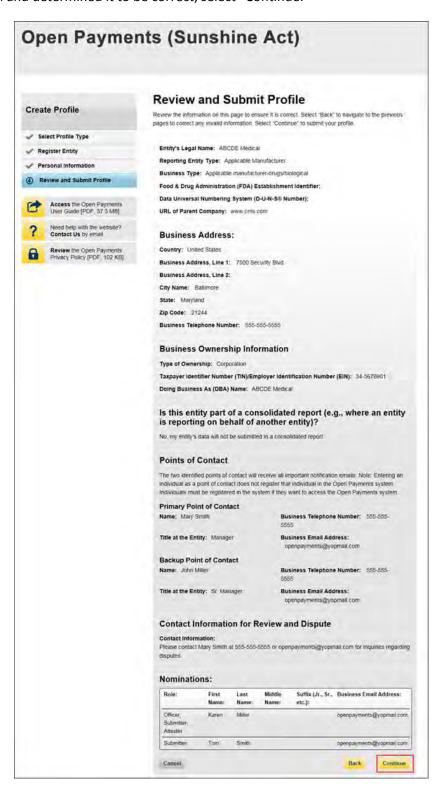


<u>Step 10:</u> Review any pre-populated information for accuracy and enter other personal information. Required fields are marked with an asterisk (*). Users will not be able to proceed with registration until all of the required fields have been completed. Once your personal information has been entered, select "Continue."

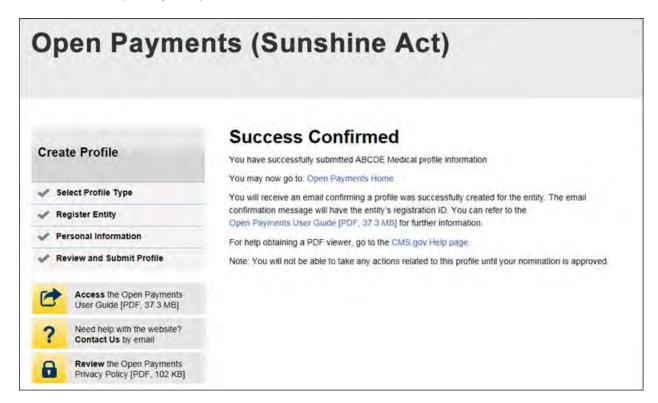
Note: Selecting the "Back" button will cause you to lose all data entered.



<u>Step 11:</u> Review the information entered for your reporting entity and personal profile. Select the "Back" button at the bottom of the page 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 reporting entity and personal profile have been successfully created. An email notification with the entity's registration ID will be sent to you, the individuals you nominated for user roles during registration, and the individuals listed as points of contact for the reporting entity.



After both the reporting entity profile and officer profile are created, the Open Payments system vets the reporting entity based on the information provided in the entity profile. An overview of the vetting process can be found in Section 3.7.

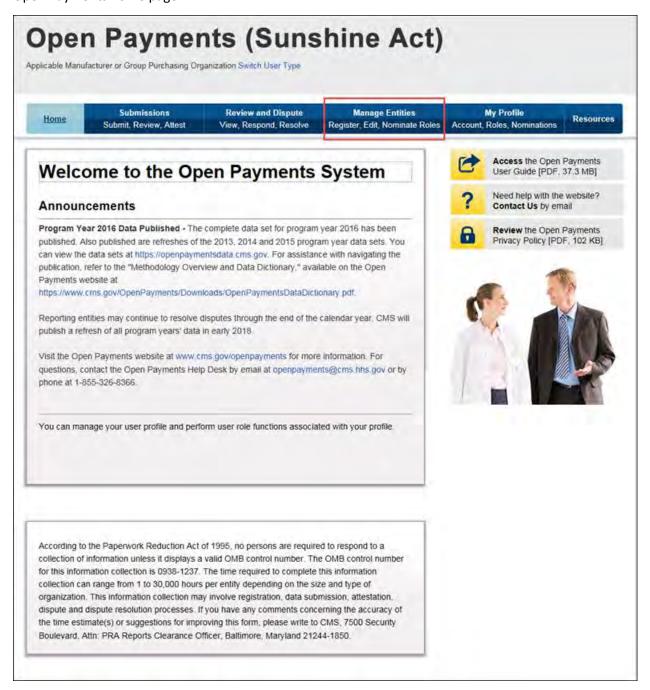
If the reporting entity's registration is successful, Open Payments will send an email notification to the officer(s) as well as the primary and backup points of contact. This email will state that the entity has been successfully registered. Users will be able to access the entity's profile in the Open Payments system and begin performing their tasks.

If the reporting entity's registration is unsuccessful, Open Payments will send an email notification to the officer(s) and points 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 reporting entity with the system, follow these steps:

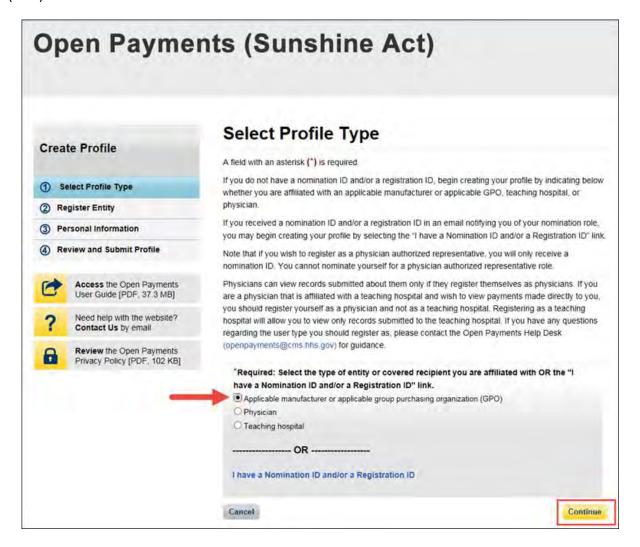
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "Manage Entities" tab from the menu bar on the Open Payments home page.



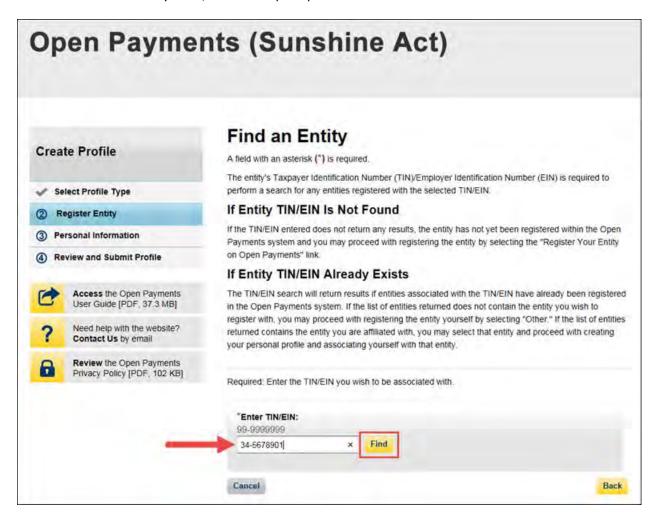
Step 2: Select "Register New Entity."



<u>Step 3:</u> Select the profile type "Applicable manufacturer or applicable group purchasing organization (GPO)" and select "Continue."



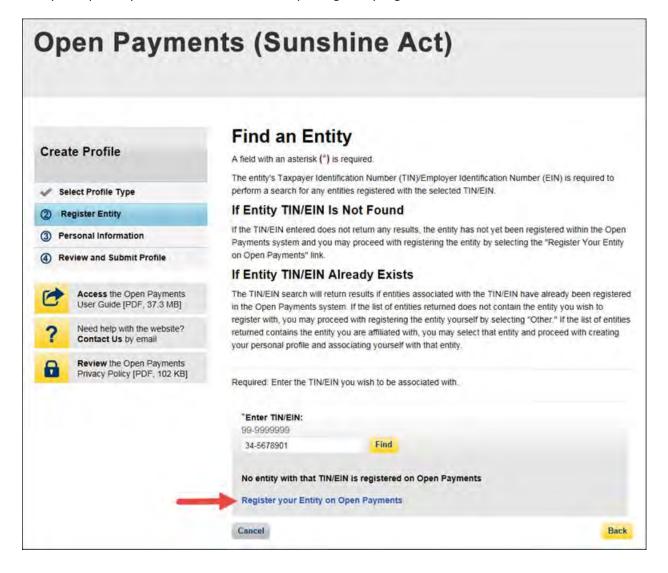
<u>Step 4:</u> Once your entity type is selected, provide the reporting entity's Taxpayer Identification Number/Employer Identification Number (TIN/EIN). This will be the entity's Employer Identification Number (EIN), a nine-digit number used by the entity for tax reporting. The format for the TIN/EIN is 99-999999. Enter the entity's TIN/EIN in the space provided and select "Find."



Step 5: The system will perform a search for that TIN/EIN to determine if it has already been registered.

If the TIN/EIN returns a match, your reporting 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 3.6d 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 reporting entity registration.



<u>Step 6:</u> Enter the reporting 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.

Also, take care to use proper field formatting required by the system. For example, when entering the reporting entity phone number and Taxpayer Identification Number/Employer Identification Number (TIN/EIN), you must include the hyphen ("-") in the proper place within the field to pass field validation.

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

When you are done, select "Continue." Selecting 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 4.12 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:

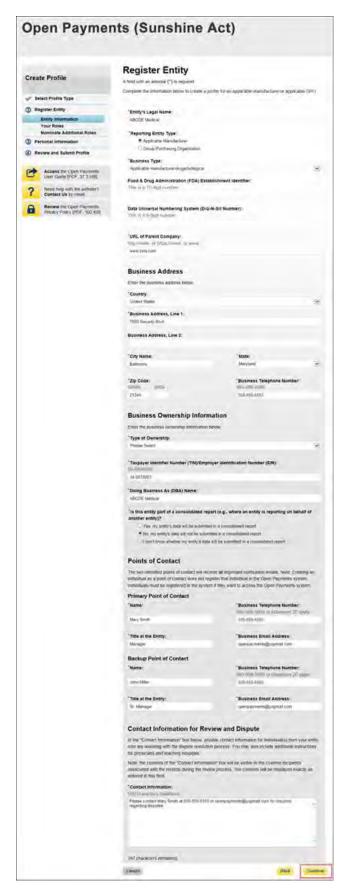
- applicable manufacturer-drugs/biologicals
- applicable manufacturer-devices/medical supplies
- applicable manufacturer-drugs/biologicals and devices/medical supplies
- applicable manufacturer-physician-owned distributor
- applicable manufacturer-hospital-owned distributor
- applicable manufacturer-distributor/supplier (non-hospital, non-physician-owned)

Applicable GPO

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

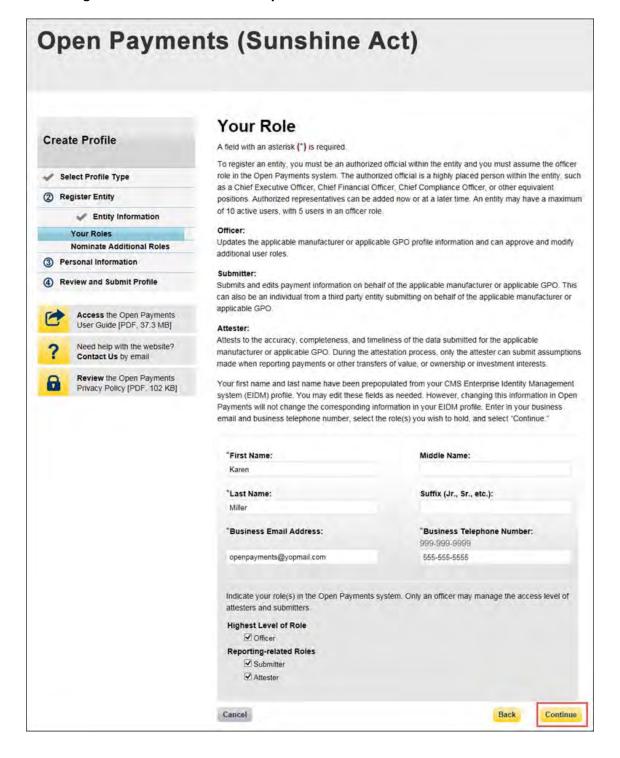
- GPO-drugs/biologicals
- GPO-devices/medical supplies
- GPO- drugs/biologicals and devices/medical supplies
- GPO-physician-owned

- GPO-hospital-owned
- GPO-hospital and physician-owned
- GPO-non-hospital, non-physician-owned
- GPO-government-owned
- The **Primary** and **Backup Points of Contact** are individuals who will serve as the points of contact for the reporting entity and CMS. These must be separate individuals. They do not have to be registered in the Open Payments system.
- The **Contact Information for Review and Dispute** is to provide contact information for individual(s) from your entity who are assisting with the dispute resolution process. You may also include additional instructions for physicians and teaching hospitals. The contents of the "Contact Information" box will be visible on your entity's profile page as well as the "Record ID" pages of all records the entity has submitted.



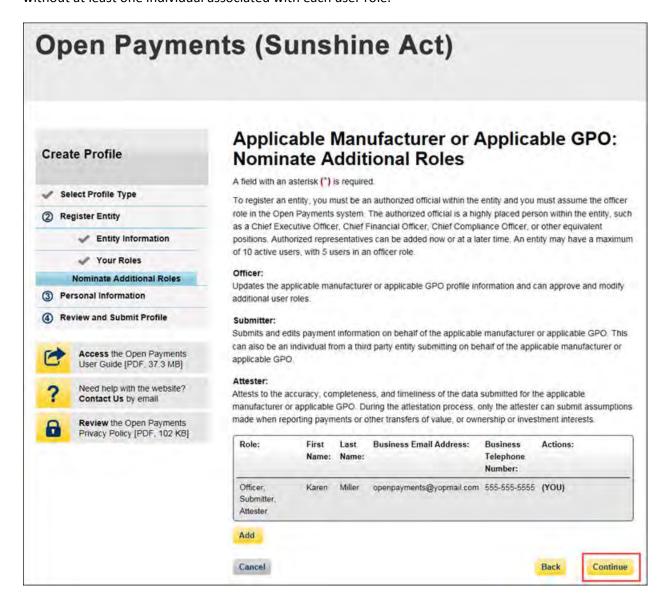
<u>Step 7:</u> Enter the required information and select your user roles. For a description of user roles, see Section 3.5. When registering a new reporting entity, you must select the role of officer for yourself. The system will not allow you to proceed if this role is not selected. You may also select the role of submitter and/or attester for yourself. When you are done, select "Continue."

Note: Selecting the "Back" button will cause you to lose all data entered.



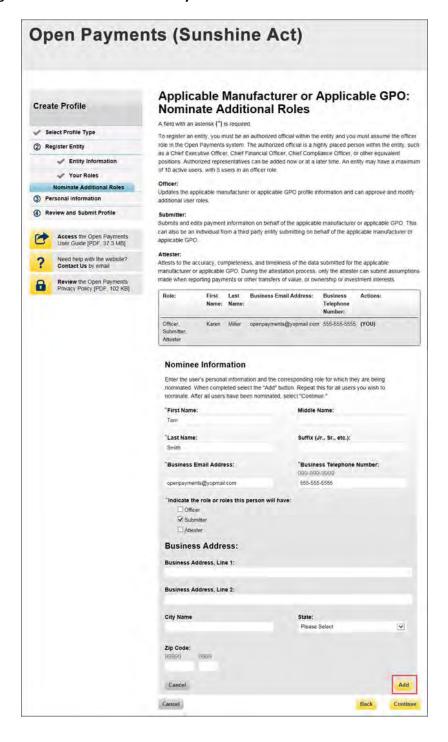
<u>Step 8:</u> You may nominate additional individuals for the officer, submitter, and attester roles at this step. If you do not wish to nominate additional individuals, select "Continue."

If you will not be fulfilling all three user roles, you must nominate at least one other individual to fill each of the remaining roles. At least one individual must be identified for each of the three roles in the Open Payments system during initial entity registration. The system will not allow you to proceed without at least one individual associated with each user role.



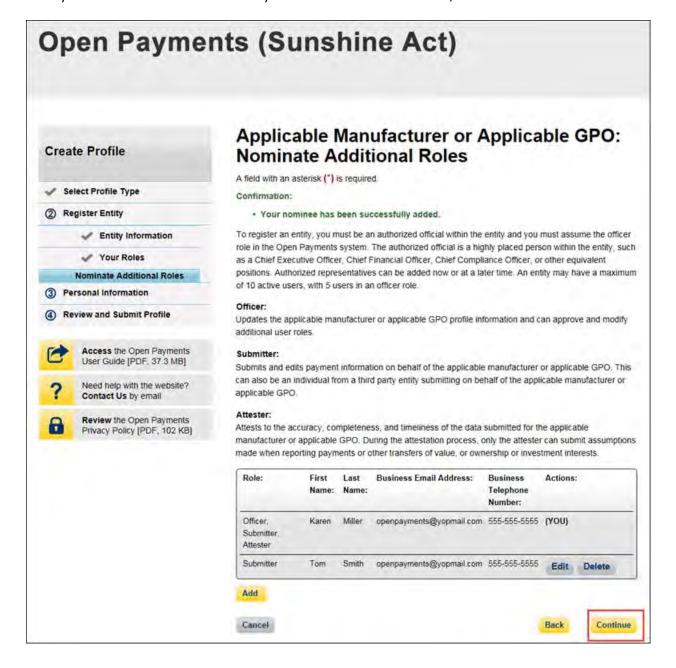
<u>Step 9:</u> To add a nominee, select "Add." The page will expand to show nominee information fields that will need to be completed. Fill in the information for the individual being nominated. Once you are done, select the "Add" button at the bottom of the page again. This will add the nominee information to the reporting entity's profile, as well as open another set of nominee information fields to enter an additional nominee.

Note: Selecting the "Back" button will cause you to lose all data entered.



Repeat the process until you have entered in all individuals you wish to nominate at this time. An entity can have up to 10 unique users with a maximum of five holding the role of officer. Note that individuals can be nominated for user roles after registration is complete.

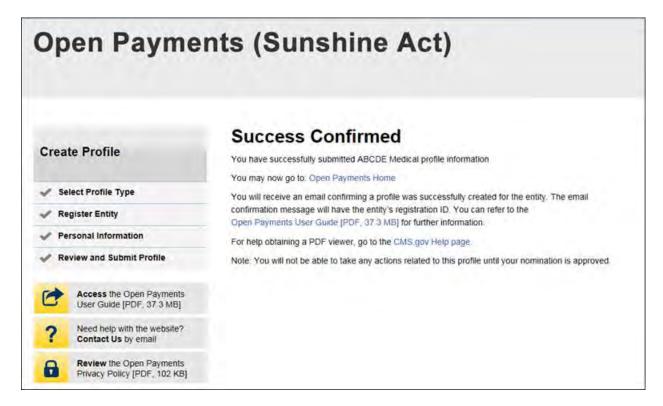
The page will display a summary of all of the individuals being nominated for user roles for this entity. Once you have entered all nominations you wish to include at this time, select "Continue."



<u>Step 10:</u> Review the information entered for your reporting entity and personal profile. Select the "Back" button at the bottom of the page 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 reporting entity and personal profile have been successfully created. An email notification with the entity registration ID will be sent to the identified officer(s) and points of contact.



After both the reporting entity and officer profiles are created, the Open Payments system vets the entity based on the information provided in the entity profile. An overview of the vetting process can be found in Section 3.7.

If the reporting entity's registration is successful, Open Payments will send an email notification to the officer(s) as well as the primary and backup points of contact. This email will state that the entity has been successfully registered. Users will be able to access the entity's profile in the Open Payments system and begin performing their tasks.

If the reporting entity's registration is unsuccessful, Open Payments will send an email notification to the officer(s) and points 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.

Section 3.4: Entity Recertification

Applicable manufacturers and applicable GPOs who registered for Open Payments in a previous calendar year are required to recertify themselves each year prior to submitting data or performing review and dispute activities. You will not be able to perform any submission or review and dispute activities for a registered entity until that entity is recertified. If you attempt to perform any such actions before recertification an error message will notify you that your entity requires recertification.

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You can recertify an entity starting on January 1 of each calendar year. After recertification, you can perform user role management activities for the entity as well as view and download previously submitted data. However, you will not be able submit new data, edit data, or delete existing data until the start of the submission period.

During recertification, you either confirm that the details of the entity's profile in the Open Payments system are accurate or update the entity's profile information if its profile in Open Payments is inaccurate or outdated. Note that only users who hold the role of officer in the reporting entity can recertify. If you do not have an active officer for your entity, you will need to contact the CMS Open Payments Help Desk.

If your entity has a status of "Failed Vetting" due to unsuccessful attempts to register in a previous calendar year, you must recertify after updating your entity's profile.

To recertify a reporting entity, follow these steps.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "Manage Entities" tab from the menu bar on the Open Payments home page.



Step 2: From the "Manage Entities" page, select the hyperlink for the entity you wish to recertify.



Step 3: On the entity page, select the "Update Entity" button.



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Step 4: Review the entity information and edit the fields as needed. Note that the reporting entities must supply a point of contact for review and dispute activities which will be used to aid in review and dispute activities. This review and dispute contact information will be visible on your entity's profile page, as well as the "Record ID" pages of all records the entity has submitted. Once you have entered all required information and made other changes, if necessary, check the box at the bottom of the page that says "I certify that the entity information entered above is accurate." Then select the "Submit" button.





Once you have made changes, you will receive an onscreen confirmation message.

Changes made to the Entity Name, TIN, or DUNS Number fields will trigger your entity to be re-vetted. Updating any of the remaining fields will not trigger the vetting process. You will be able to perform the submission and review and dispute functions once your entity is successfully re-vetted.

Section 3.5: 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.

Reporting 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 unique 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:

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- 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 reporting entity.
- **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 disputes against the reporting entity's submitted data initiated by physicians and teaching hospitals.
- 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 Roles

User Roles	Functions	Requirements
Officer	 Manage the reporting entity's profile in the Open Payments system Nominate (approve) other individuals for 	Must be an officer as designated by the applicable manufacturer or applicable GPO
	 submitter, attester, and officer roles Modify nominations and user roles for other users associated with reporting entity Deactivate other users from the reporting 	If nominated, must either accept or reject the nomination
Submitter	 Submit data in the Open Payments system on behalf of the applicable manufacturer or 	Not required to be an officer of the applicable manufacturer or
	 applicable GPO May nominate individuals for user roles May edit payments or other transfers of 	applicable GPOIf nominated, must either accept or reject the nomination
	value and ownership/investment interests submitted to the Open Payments system	
	Receives emails regarding data disputed by physicians and teaching hospitals	
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
	May nominate individuals for user roles	the Open Payments Final Rule at 42 C.F.R. § 403.908(e)
		If nominated, must either accept or reject the nomination

Section 3.6: Nominations

The nomination process allows a user to nominate an individual(s) to fill specific roles within the reporting entity. Users nominated for a particular role are able to perform certain tasks in the Open Payments system once they accept the nomination. Once a reporting entity is successfully registered in the Open Payments system, users can begin nominating additional users to fill user roles. There are two ways that individuals can be nominated for a user role:

- 1. Nominated by an existing Open Payments user for a role with a reporting entity; or
- 2. An individual may nominate him- or herself for a role ("self-nomination").

Any user may nominate other individuals for specific 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.

During initial reporting entity registration, the authorized official must nominate at least one user for each of the three roles (officer, submitter, and/or attester). This process is shown in the entity registration process shown in Section 3.3. Reporting entities can also nominate individuals after registration is complete. The process for this is shown in Section 3.6a.

One individual can hold multiple roles. Entities may nominate up to 10 unique users with a maximum of five holding the role of officer. 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

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. Nominees have 10 calendar days to accept or reject the nomination. If an individual does not take action on their nomination within 10 days, the nomination will expire. The process for individuals accepting or rejecting nominations is shown in Sections 3.6b and 3.6c.

If the nomination is accepted, the individual will be able to complete a user profile, gain access to their entity's profile, and perform the duties of their role. An email notification, generated by the Open Payments system, will be sent informing all users holding the role of officer with the entity that the nomination has been accepted. If the individual rejects the nomination, that individual will not be able

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to perform the actions on that reporting entity's behalf and the reporting entity's officers will receive an email notification of the rejection. Nominees will need to have EIDM credentials in order to access the Open Payments system and accept or reject their nominations.

If an individual has been nominated for multiple user roles with a reporting entity, an officer with that entity must confirm all of the individual's user role nominations before the nominee can begin performing actions in the system.

Reporting 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 4.13 for more information on third-party data submission.

Self-nominations occur when a user nominates him- or herself for a user role within the Open Payments system. A user holding the officer role with the reporting entity 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.

Access Open
Payments via
Using
Select User
Complete

User Profile

Figure 3.6 Self-Nomination Process

TIN/EIN

Obtain

Credentials

Enterprise

Portal

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 reporting 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. Section 3.6d provides instructions for self-nomination and Section 3.6f provides instructions for officers with the reporting entity on how to approve or reject self-nominations.

Note: If the entity no longer has a user in the system who holds the officer user role to approve a self-nomination, the self-nominator can contact the Open Payments Help Desk at openpayments@cms.hhs.gov to nominate themselves as an officer. If the entity does not have an officer and the user wants to nominate themselves for a non-officer role, the nomination will not be approved until the reporting entity has an active officer.

Users can also be deactivated from a reporting entity. Deactivation removes an individual's association with a reporting entity in the Open Payments system, including removing the individual's access to that reporting entity's information and records. It does not remove the individual from the Open Payments

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system. Section 3.6g provides information and instructions on user deactivation. In the "My Profile" page of the Open Payments system, user roles are listed with a status. An explanation of those statuses is in the table below.

Figure 3.7: User Role Statuses for Reporting Entities

User Role Status	Meaning
Nominated	The individual has been nominated for the user role with the reporting entity.
Nomination Approved	The individual's nomination has been approved by an officer. The individual has not yet accepted or declined the nomination.
Declined	The individual declined the user role.
Accepted	The individual accepted the user role.
Requested	An individual self-nominated for the user role.
Approved	The individual's self-nomination for the user role has been approved by an officer with the entity.
Vetted	The entity has successfully been vetted by the Open Payments system. The individual holds the officer user role. (Applicable only to the individual who registered the reporting entity and only for that individual's officer user role)
Conditionally Active	The entity has been conditionally approved by the Open Payments Help Desk. The individual holds the officer user role. See Section 3.7a. (Applicable only to the individual who registered the reporting entity and only for that individual's officer user role)

3.6a: Nominating Individuals for a Role with an Existing Reporting Entity

Nominations can be done when registering a new reporting entity or after the entity has been successfully registered. To nominate individuals after an entity has been successfully registered, follow the process detailed below:

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Manage Entities" tab from the menu bar on the Open Payments home page.



<u>Step 2:</u> On the "Manage Entities" page, indicate the reporting entity for which you will nominate an individual for a user role by selecting the reporting entity's hyperlinked name.



Step 3: Select the "Manage Roles" tab.

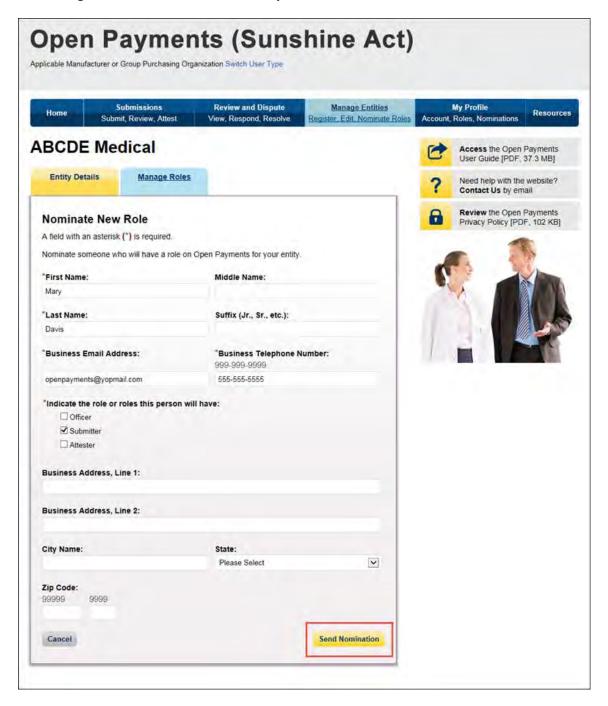


Step 4: Select "Nominate New Role."

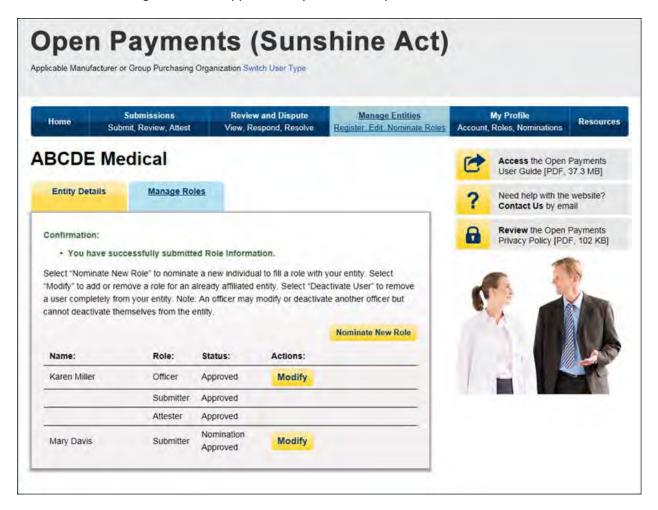


Step 5: Enter the required nominee information. Once you are done, select "Send Nomination."

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



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



If the nomination was made by a user with an officer role, the nominee will receive an email notification that he or she has been nominated for a role in the Open Payments system. The email will contain instructions for accepting or rejecting the nomination as well as a registration ID and a nomination ID.

If the nomination was made by a user who does not hold the role of officer, an email notification is sent to all officers of the reporting entity to approve or modify the nomination. If one of the officers approves the nomination, the Open Payments system sends a notification email to the nominee informing him or her of the approval of their nomination and provide instructions on how to accept or reject the nomination and a registration ID and nomination ID.

3.6b: 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 receive access to the functions for that specific role.

Individuals will have 10 calendar days to accept or reject a nomination. If the nominee has not taken action on their nomination within 10 days, the nomination will expire. If the individual wants a user role after the nomination expires, that individual will have to nominate themselves for a user role (see Section 3.6d for instructions on self-nomination).

The process for accepting nominations is outlined in **Figure 3.8**, below.

Figure 3.8: Accepting Nominations

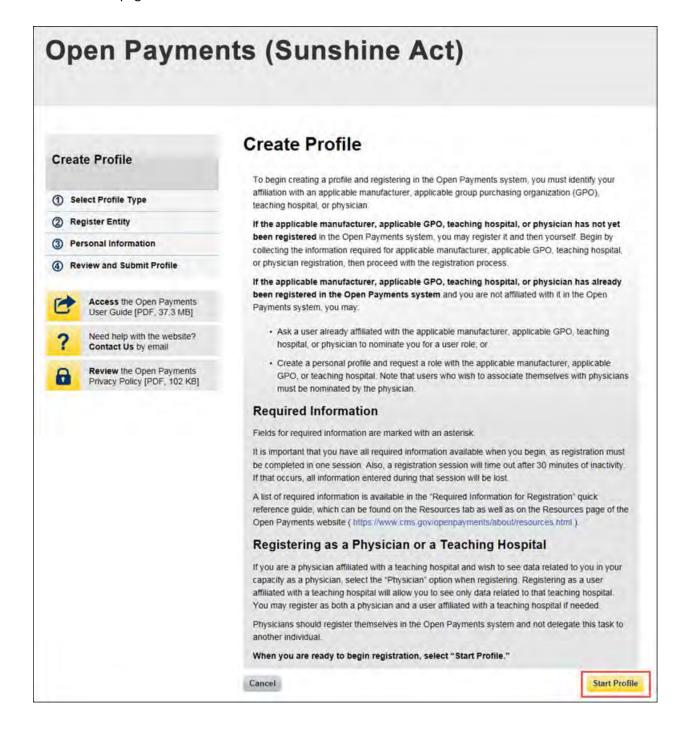


To accept a nomination in the Open Payments system, follow the steps below:

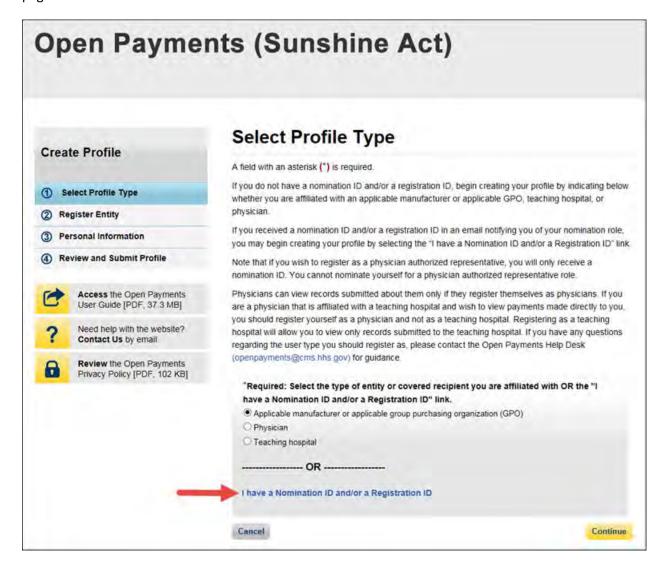
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select "Create My Profile."



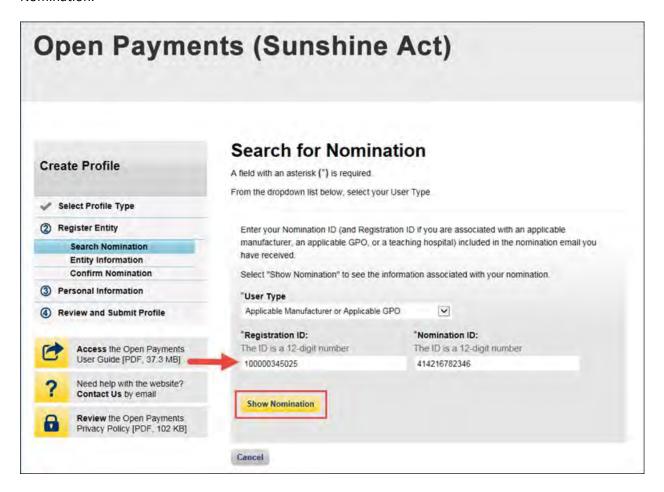
<u>Step 2:</u> Read the instructions on the "Create Profile" page. Once done, select "Start Profile" at the bottom of the page.



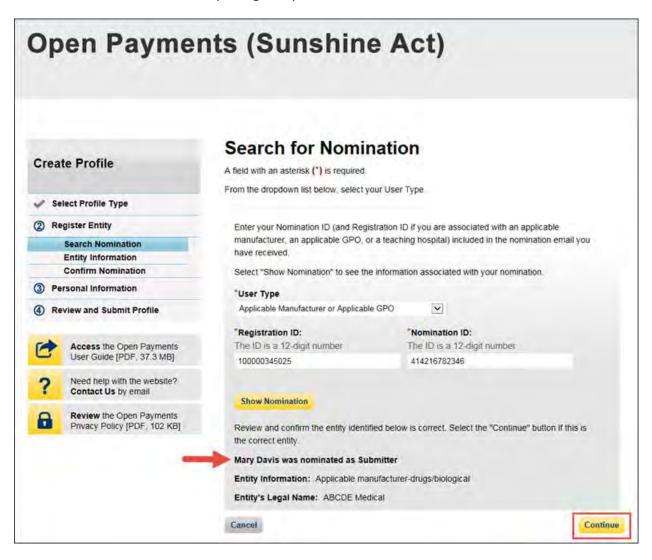
<u>Step 3:</u> Select the "I have a Nomination ID and/or a Registration ID" link on the "Select Profile Type" page.



<u>Step 4:</u> Select the User Type "Applicable Manufacturer or Applicable GPO." Enter the registration ID and nomination ID that you received in the nomination notification email and then select "Show Nomination."



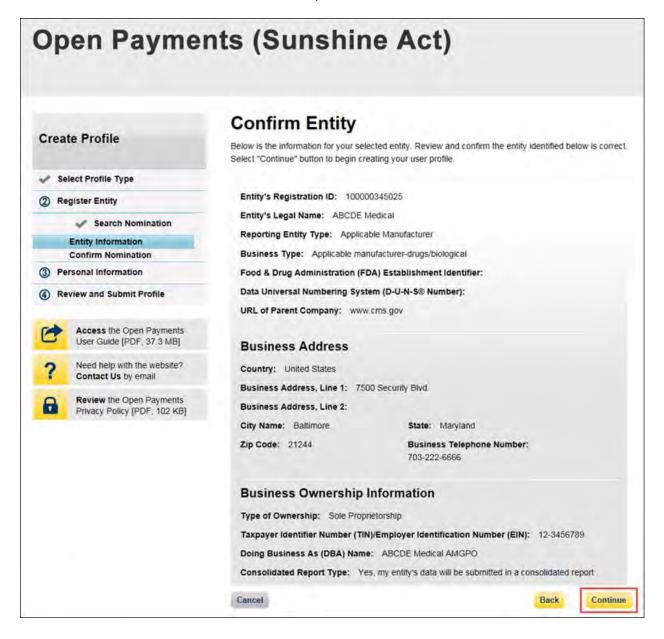
<u>Step 5:</u> Review the nomination information displayed. If the information is correct, select "Continue." If it is not correct, select "Cancel" to cancel the nomination process and contact an individual who holds the user role of officer with the reporting entity for assistance.



Step 6: Review and confirm the reporting entity information displayed on the page.

If this information is not correct, you may still proceed with registration. After you complete registration, contact an individual who holds the user role of officer for the reporting entity in the Open Payments system to notify them of the inaccurate information. Officers may edit the entity's profile.

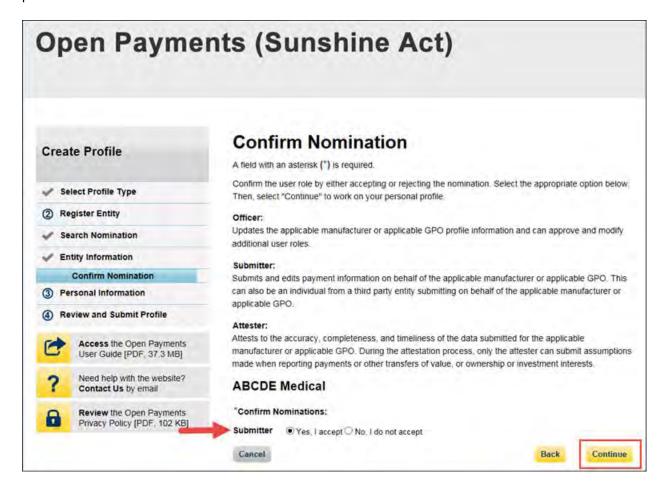
If the information is correct, select "Continue" to proceed.



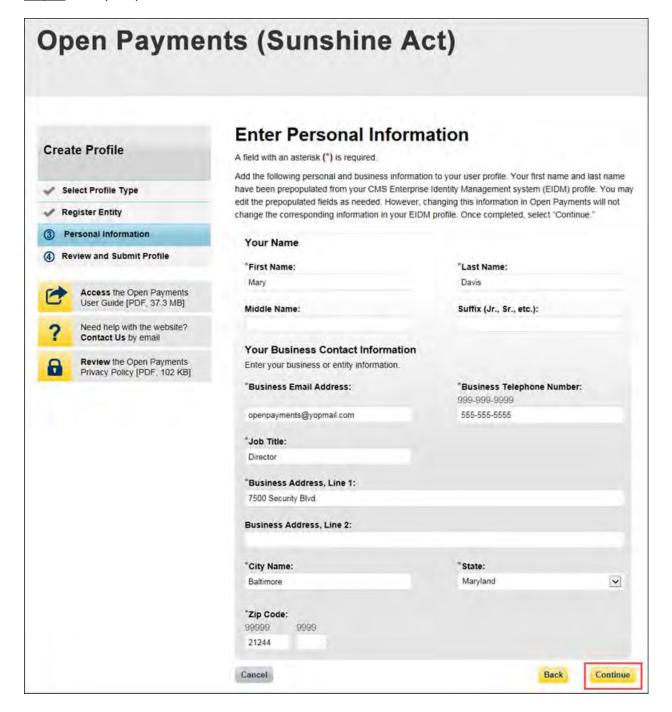
Step 7: Select "Yes, I accept" for roles you accept and "No, I do not accept" for roles you do not accept.

If you reject all roles for which you have been nominated, select "Continue" after selecting "No, 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 not be able to perform any actions on behalf of the reporting entity and the nominator will receive an email notifying him or her that you rejected the nominations. The nominator will then be allowed to nominate other people for the roles.

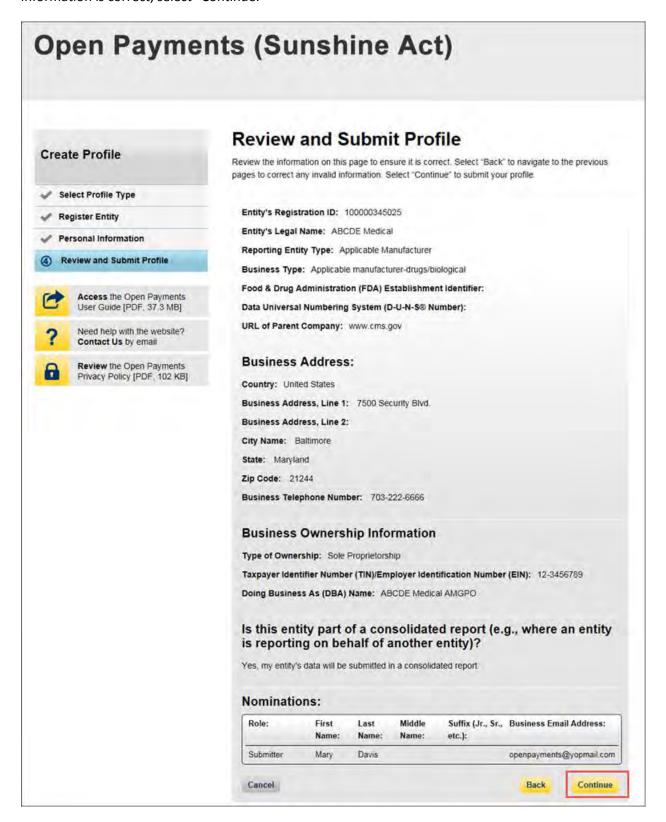
If you accept one or all roles and select "Continue," you will continue the nomination confirmation process.



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



<u>Step 9:</u> You will be asked to review the information you have entered. To correct any errors, select the "Back" button at 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. Notification emails will be sent to all of the users who hold the role of officer with that entity that you have accepted your nomination.



3.6c: Accepting a Nomination (Returning System Users)

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "My Profile" tab from the menu bar on the Open Payments home page.



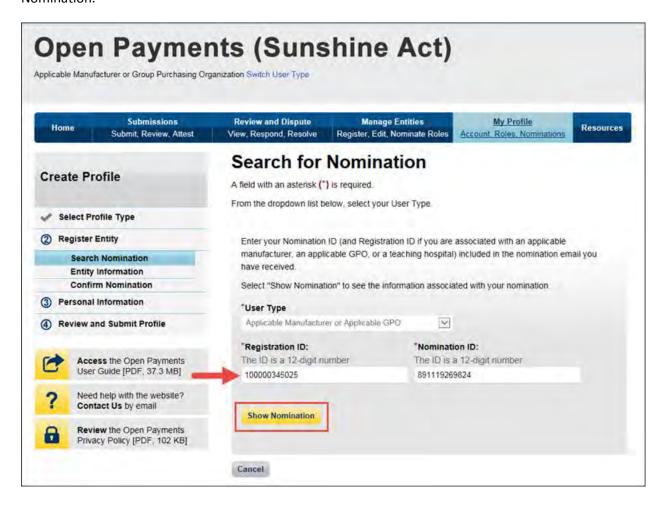
Step 2: Select the "My Roles and Nominations" tab.



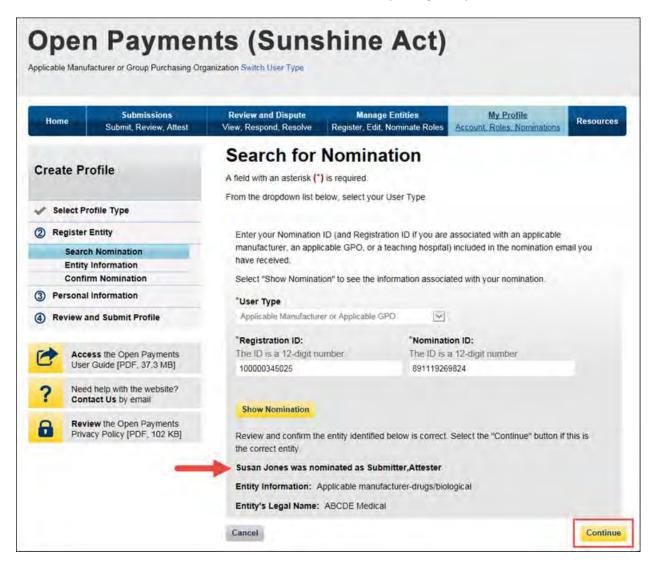
Step 3: On the "My Roles and Nominations" tab, select "Accept a Role."



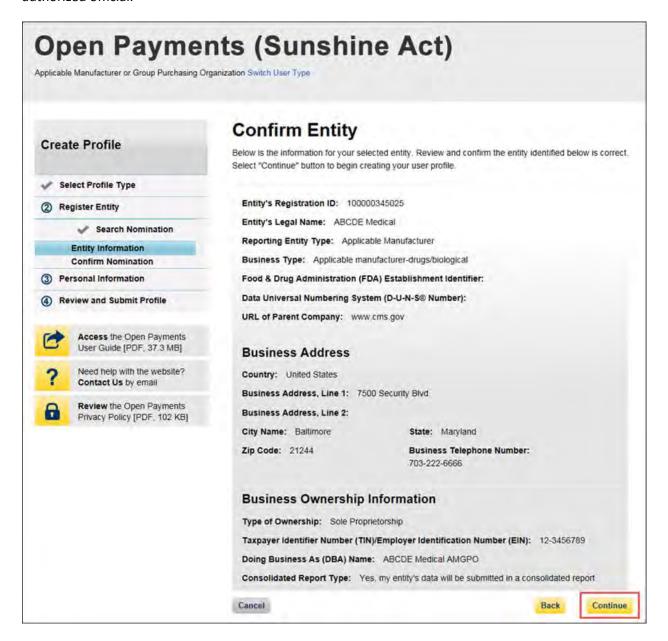
<u>Step 4:</u> Enter the registration ID and nomination ID provided in the email notification and select "Show Nomination."



<u>Step 5:</u> 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.



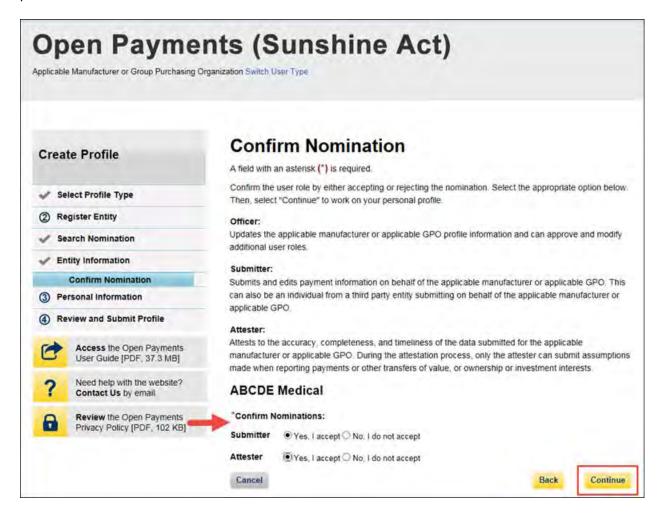
<u>Step 6:</u> Review the reporting entity information on the page and select "Continue" to proceed with the nomination confirmation process. If any of the entity details are incorrect, contact the reporting entity's authorized official.



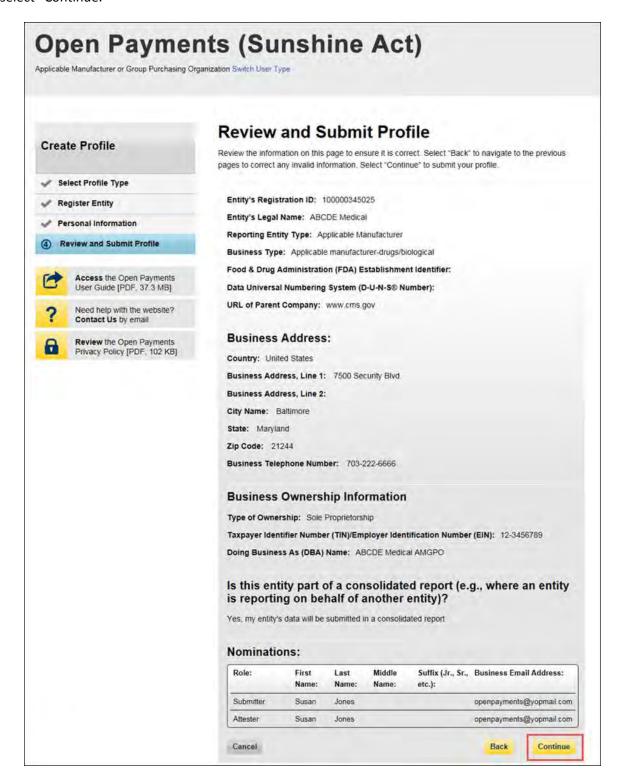
Step 7: Select "Yes, I accept" for roles you accept and "No, I do not accept" for roles you do not accept.

If you reject all roles for which you have been nominated, Select "Continue" after selecting "No, 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 not be able to perform any actions on behalf of the entity and the nominator will receive an email notifying him or her 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.



<u>Step 8:</u> Review the reporting entity information and personal profile. Select the "Back" button at the bottom of the page 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. Notification emails will be sent to all of the users who hold the role of officer with that entity that you have accepted your nomination.

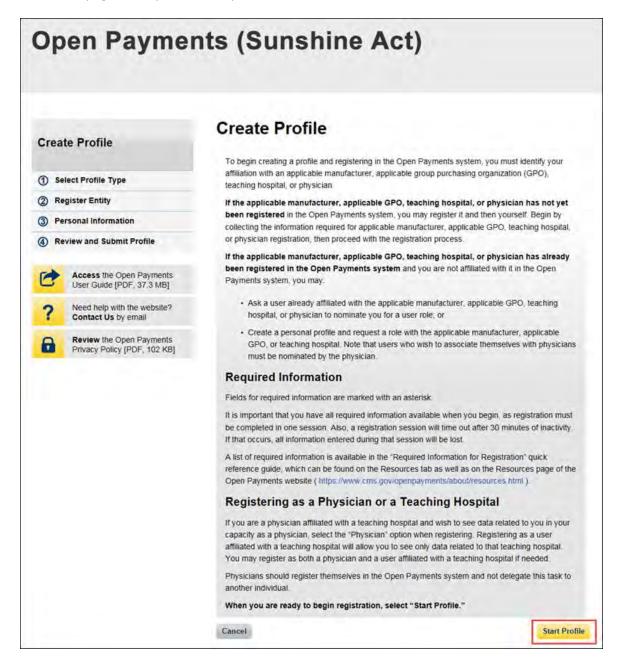


3.6d: Self-Nomination with a Registered Entity (First Time System Users)

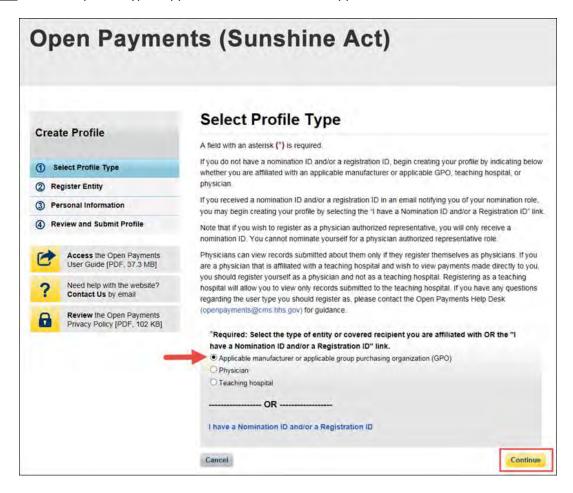
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" to begin the registration process.



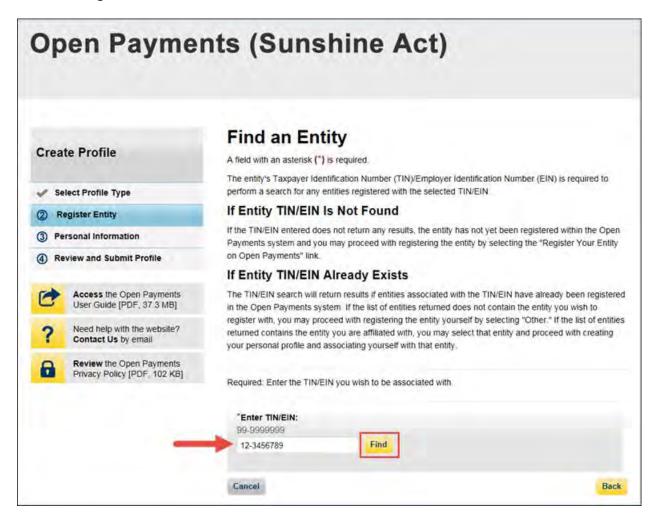
<u>Step 2:</u> The on-screen text contains important information regarding creating the reporting entity and individual profile. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile" at the bottom of the page when you are ready to continue.



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

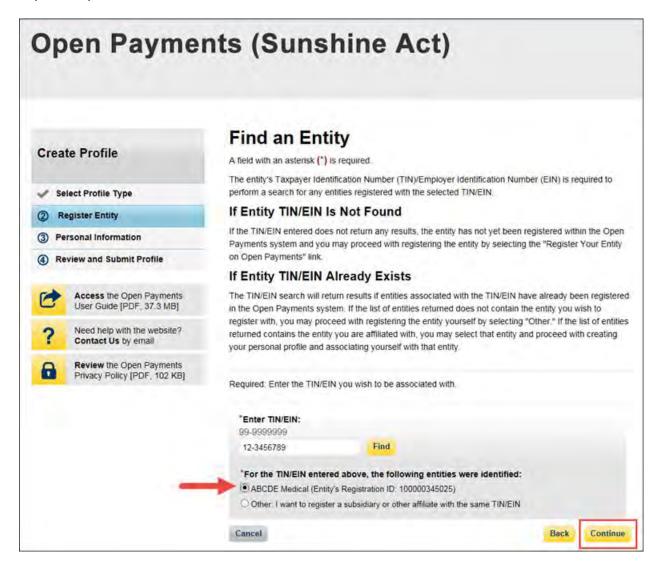


<u>Step 4:</u> Enter the Taxpayer Identification Number/Employer Identification Number (TIN/EIN) of the reporting entity that you want to associate yourself with. The TIN must be nine digits, with a dash after the second digit. Select "Find."



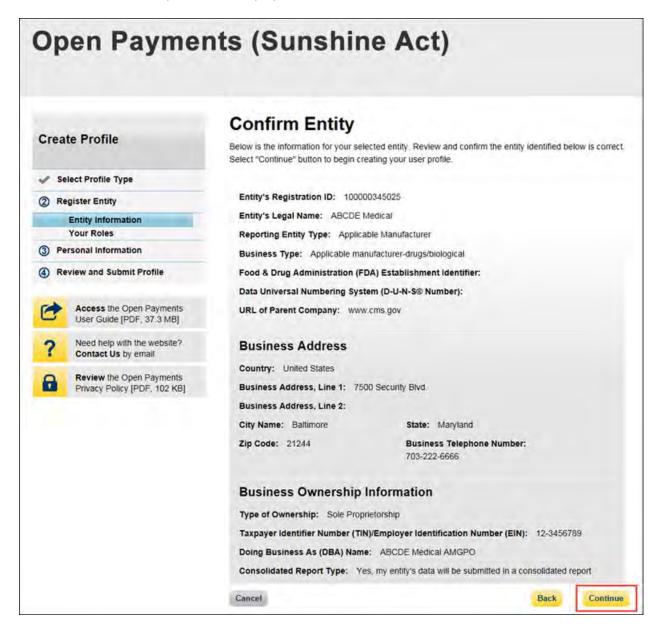
Step 5: Select the correct entity from the list displayed and select "Continue."

Note that if no reporting entity is found for the TIN/EIN you supplied, the entity has not yet been registered in the Open Payments system. You may register the entity in Open Payments yourself if you are an officer for the reporting entity. If you are not, or do not wish to register the entity yourself, you may contact an officer within the entity to request that he or she register the entity in the Open Payments system.

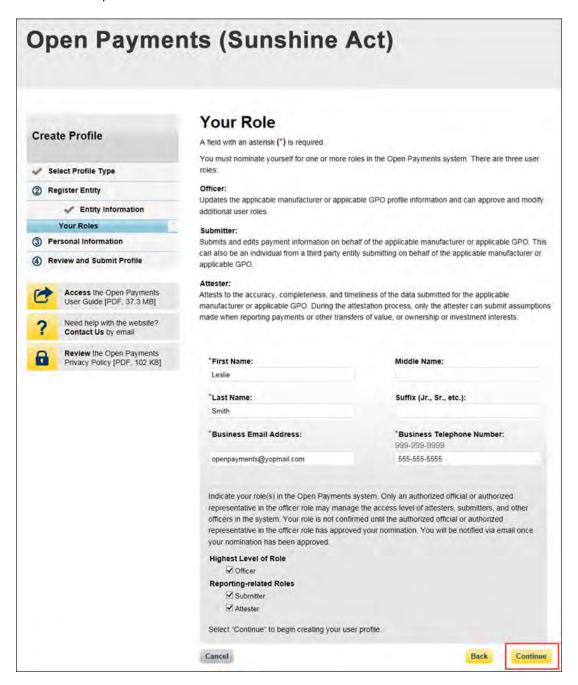


Step 6: Review and confirm the reporting entity information displayed on the page.

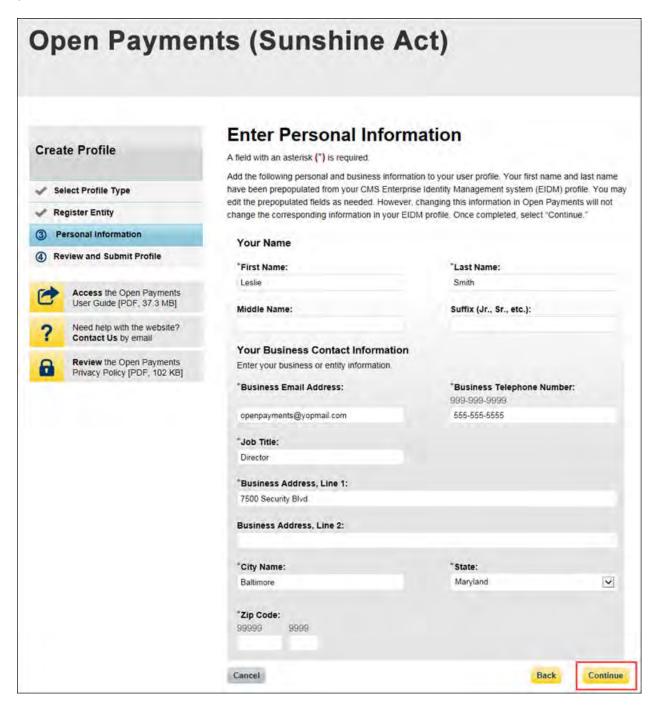
If the information is correct, select "Continue" to proceed. If this information is not correct, you may still proceed with registration. After you complete registration, contact an individual who holds the user role of an officer for the reporting entity in the Open Payments system to notify them of the inaccurate information. Officers may edit the entity's profile.



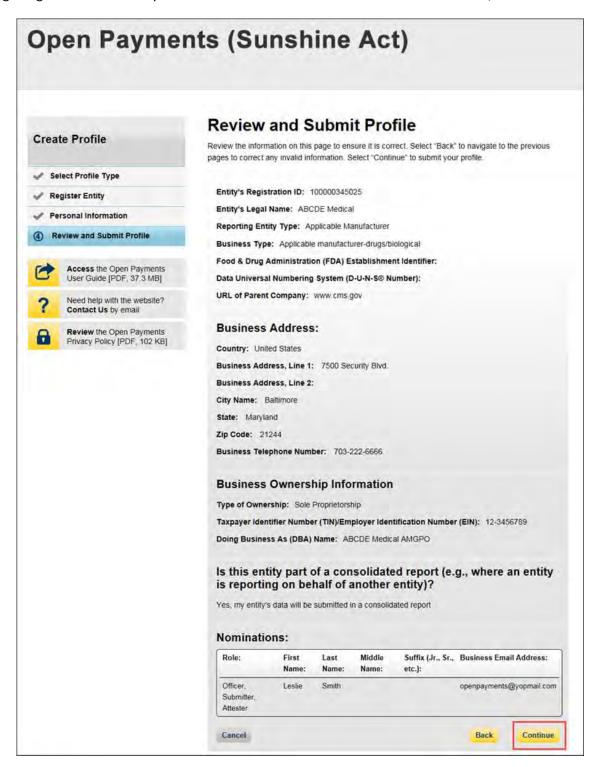
<u>Step 7:</u> Enter your personal information and select the roles for which you want to nominate yourself. Select "Continue" to proceed.



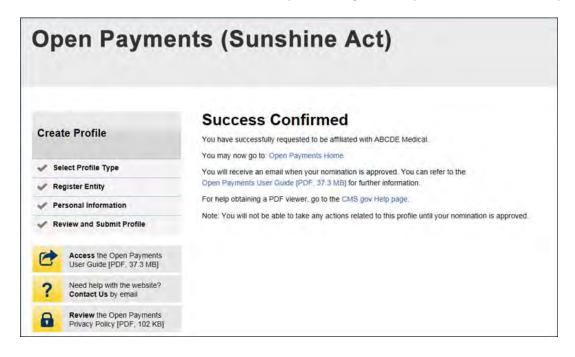
<u>Step 8:</u> On the "Enter Personal Information" page, enter your personal information and business contact information. Required fields are marked with an asterisk (*). When entering a telephone number, be sure to place hyphens (-) between the area code and prefix, and the prefix and the last four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



<u>Step 9:</u> Review the information entered in your profile. Select the "Back" button at the bottom of the page to go back and edit any incorrect information. When the information is correct, select "Continue."



The following on-screen message will appear to confirm your profile creation was successful. A notification email will be sent to officers of the entity, informing them of your self-nomination request.



3.6e: Additional Self-Nomination with a Registered Entity (Returning System Users)

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "My Profile" tab from the menu bar on the Open Payments home page.



Step 2: From the "My Profile Overview" page, select the "My Roles and Nominations" tab.



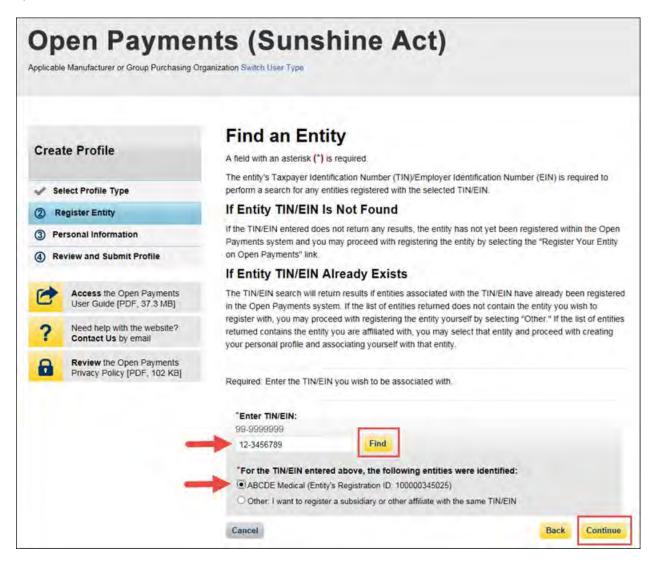
Step 3: From the "My Roles and Nominations" tab, select "Request a Role."



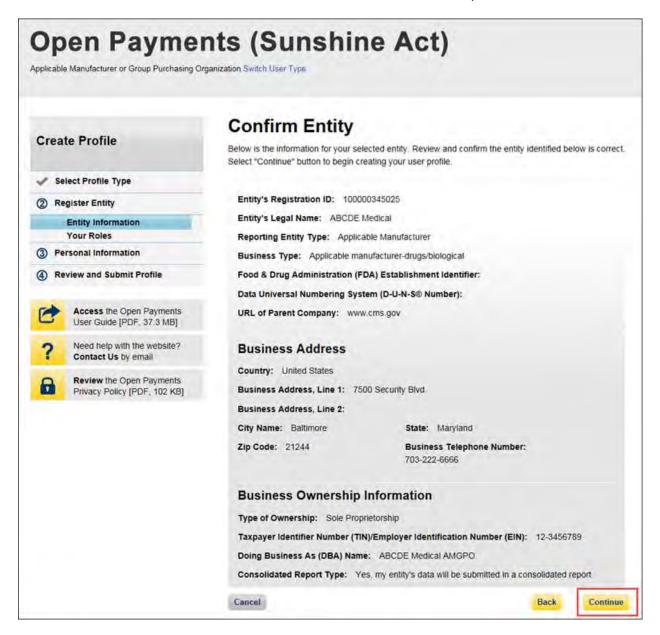
<u>Step 4:</u> Enter the Taxpayer Identification Number/Employer Identification Number (TIN/EIN) of the reporting entity that you want to associate yourself with. The TIN must be nine digits, with a dash after the second digit. Select "Find."

Select the correct entity from the list displayed and select "Continue."

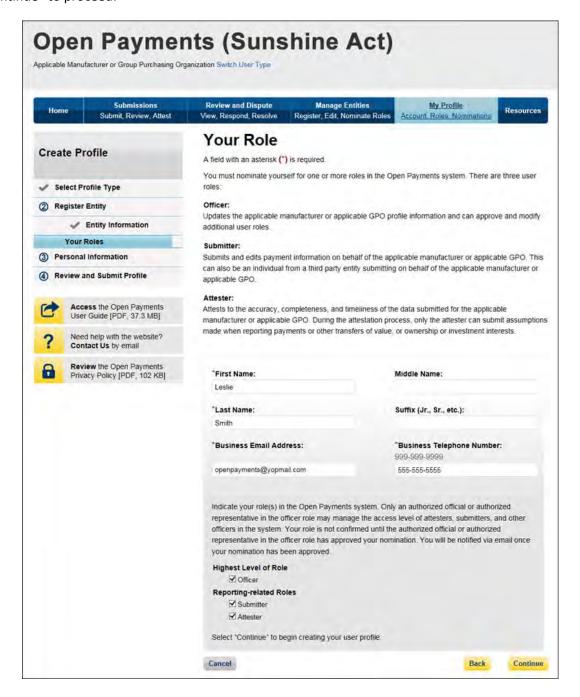
Note: If no reporting entity is found for the TIN/EIN you supplied, the entity has not yet been registered in the Open Payments system. You may register the entity in Open Payments yourself if you are an officer for the reporting entity. If you are not, or do not wish to register the entity yourself, you may contact an officer within the entity to request that he or she register the entity in the Open Payments system.



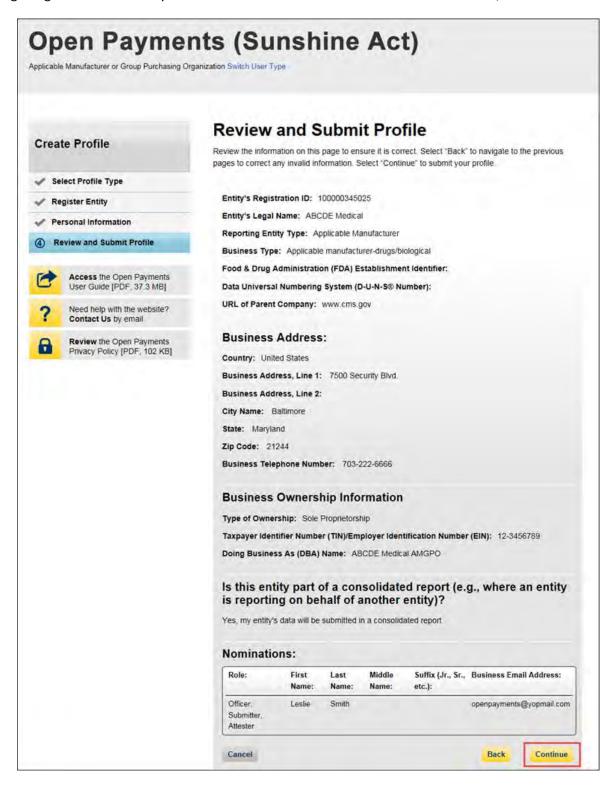
<u>Step 5:</u> Review and confirm the reporting entity information displayed on the page. If any of the entity information is incorrect, stop this process and inform a user holding the role of officer for that entity of the incorrect information. If the information is correct, select "Continue" to proceed.



<u>Step 6:</u> Enter your personal information and select the roles for which you want to self-nominate. Select "Continue" to proceed.



<u>Step 7:</u> Review the information entered in your profile. Select the "Back" button at the bottom of the page to go back and edit any incorrect information. When the information is correct, select "Continue."



You will receive the following on-screen notification. A notification email will be sent to officers of the entity, informing them of your self-nomination request.



3.6f: Approving or Modifying Nominations (Officers Only)

Note: If your reporting entity does not have an active user who holds the officer role with the entity in Open Payments, an individual must self-nominate for the officer role, then contact the Open Payments Help Desk for assistance. That individual will be required to provide documentation to confirm that he or she can assume the role for the entity.

If your reporting entity does have at least one active user who holds the officer role with the entity in Open Payments, that officer can follow the steps below to approve and modify self-nominations.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Manage Entities" tab from the menu bar on the Open Payments home page.



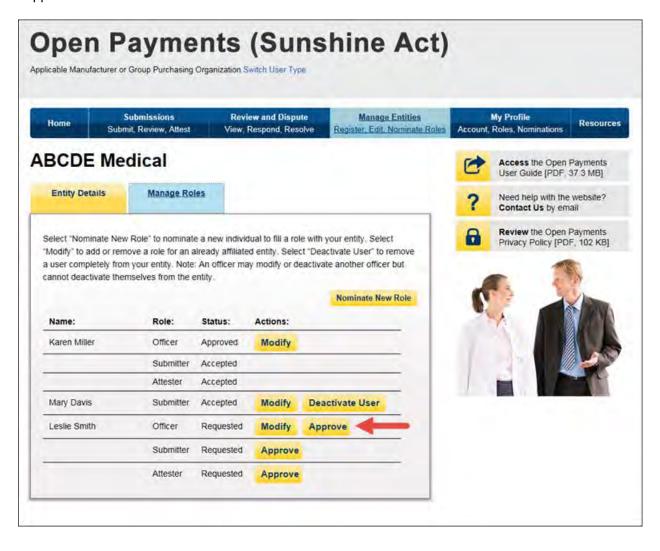
<u>Step 2:</u> You will see a list of all of the reporting entities you are associated with. Select the hyperlink for the entity for which you will be confirming nominations.



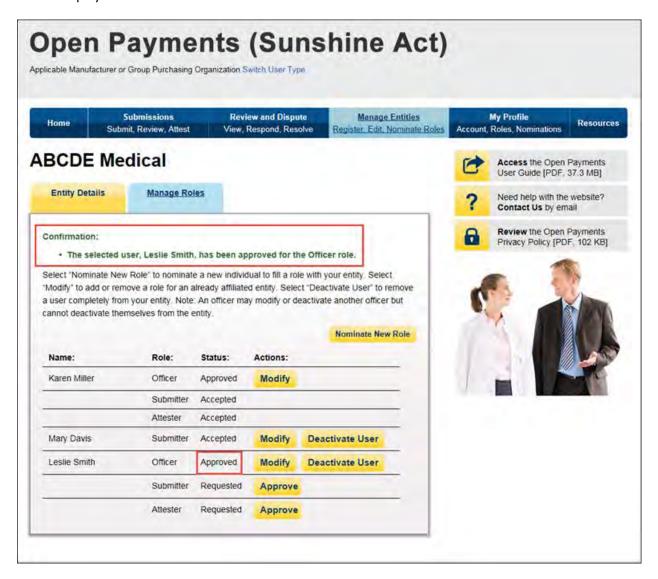
<u>Step 3:</u> You will be taken to the "Entity Details" tab, which displays the profile details for the reporting entity selected. Select the "Manage Roles" tab to continue with the process.



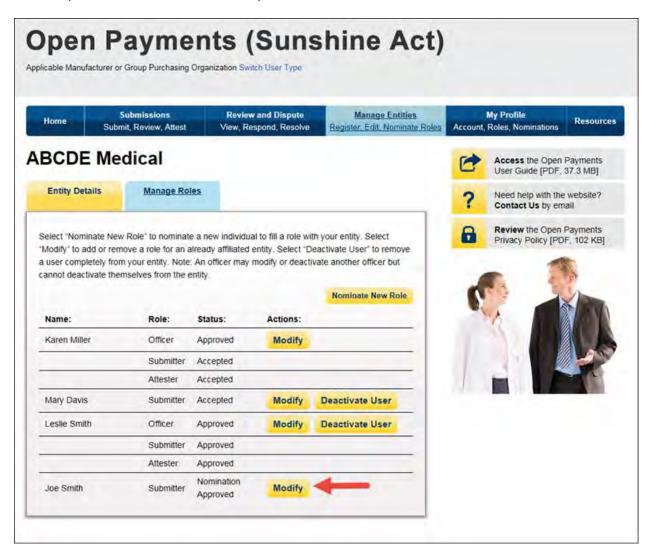
<u>Step 4:</u> View the nominations waiting for approval. To approve the nominations with no changes, select "Approve" next to the name and role.



The status will change directly on the page from "Requested" to "Approved." A confirmation message will be displayed as well.

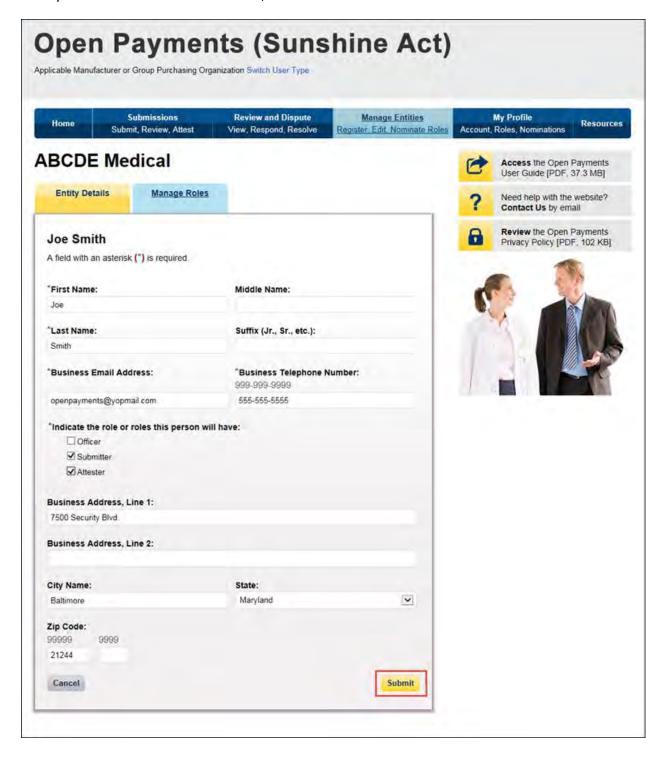


To modify the nomination, select "Modify."

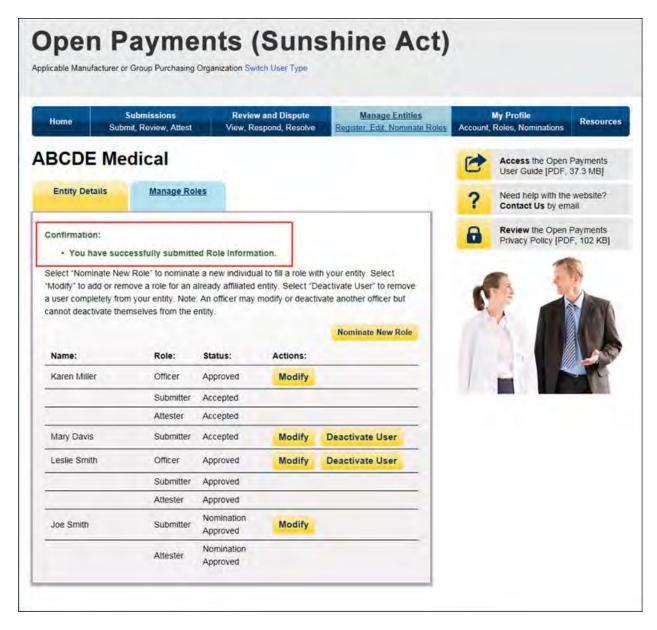


To modify the nomination, change the information on the page. You may also modify the roles for the user by checking or unchecking user role boxes. Note that you cannot remove all of an individual's roles via "Modify."

Once you have modified the nomination, select "Submit."



You will receive an onscreen confirmation of the information submission.



If an officer approves a self-nomination, an email notification will be sent to the self-nominator informing them that their self-nomination has been approved. If an officer approved a nomination made by an individual who was not the nominee, the nominee will receive an email notification that they have been nominated for a user role in the Open Payments system.

3.6g: Deactivating Users (Officers Only)

A user holding the role of officer with a reporting entity can deactivate individuals for that reporting entity, including other officers. Deactivation removes the individual's access to that reporting entity's information and records. It does not remove the individual from the Open Payments system.

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Note that officers cannot deactivate themselves, though an officer can deactivate another officer. If you wish to be deactivated, contact the Open Payments Help Desk or another individual who holds the user role of officer in your reporting entity. Note that a reporting entity must have at least one active user who holds the officer role. If the sole remaining officer of a reporting entity leaves, an individual can nominate him- or herself for the role and must contact the Open Payments Help Desk to complete the nomination.

Only active users can be deactivated; individuals who have not yet accepted or rejected a user role nomination cannot be deactivated, nor can individuals who have self-nominated for a user role but their nomination has not yet been approved or denied.

To deactivate an individual from your reporting entity, follow these steps.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Manage Entities" tab from the menu bar on the Open Payments home page.



<u>Step 2:</u> You will see a list of all of the reporting entities you are associated with. Select the hyperlink for the entity for which you will be deactivating a user.



Step 3: On the "Entity Details" page, select the "Manage Roles" tab.

Step 4: Select the "Deactivate User" button associated with name of the individual's name

<u>Step 5:</u> The system will ask you to confirm the deactivation. Select "Continue" to confirm deactivation or "Cancel" to return to the Manage Roles page with no action taken. If you confirm deactivation, the Open Payments system will send notification emails to you and the deactivated individual announcing the individual's deactivation from the reporting entity.

Section 3.7: 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 reporting entity registration is not considered complete until the vetting process has been successfully completed.

3.7a: Entity Vetting

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

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The system will send you an email notifying you of the success or failure of the entity's vetting. You can also view the vetting status of all reporting entities you are associated with on the Open Payments home page in a section called "Entity Status."

If a reporting entity fails vetting, its name in the home page's "Entity Status" section will contain a hyperlink. This link will take you to the reporting entity's profile for editing and resubmission. You can resubmit an entity for automated vetting three times. If your entity is unable to be successfully vetted automatically, you will need to contact the Open Payments Help Desk to receive a "Conditionally Active" status to gain access to the Open Payments system. "Conditionally Active" 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 you believe all of the information provided in the entity profile is correct and the entity should have been successfully vetted, 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 Active" 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.

3.7b: Vetting Timeframe

The automatic vetting process normally takes a short time, but is dependent on the information provided by the user and the number of reporting 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 interests information, to the Open Payments system. The Open Payments system provides two data entry and submission options: (1) bulk data entry via character-separated values (CSV) files, or a ZIP file that contains CSV files 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 contains information on data submission for the Open Payments system.
- **Preparing Your Data** contains information on how to prepare data files, payment types, and location of data submission resources.
- **Bulk File Upload** contains information and instructions for the preparation and upload of CSV files (or ZIP file containing 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 (GUI).
- **Record Validation and Matching** contains information about how submitted records are verified in the Open Payments system for accuracy.
- **Correcting Validation and Matching Errors** contains information about how to understand error reporting and how to correct errors in submitted records.
- Deleting Records contains information about how to delete individual records and entire CSV files.
- **Final Submission of Data** contains information about the final data submission process after all records are uploaded and ready for submission.
- Delay in Publication contains information about the requirements and rules for requesting delays in publication for certain types of records.
- Consolidated Reporting contains information about reporting entities under common ownership having their data collectively submitted by one entity in the group in consolidated reports.

- **Third Party Data Submitters** contains information about the use of third parties by reporting entities to submit data to the Open Payments system.
- Attestation and Assumptions contains information about the attestation to the accuracy of data submitted to Open Payments.

Section 4.1: Overview of Data Submission and Attestation

The Open Payments program requires applicable manufacturers and applicable GPOs to submit detailed information regarding payments or other transfers of value made to physicians and teaching hospitals, and attest to the accuracy of that data. To complete these tasks, reporting entities must first upload their data to the Open Payments system. Once the data has been successfully uploaded, it must undergo final submission. After final submission, the reporting entity must legally attest to the accuracy of the data. Finally, after attestation, the data will be made available for physicians and teaching hospitals to review and dispute.

Figure 4.1 provides an overview of the data submission and attestation process.

Submit and upload data

Complete final submission

Attest to accuracy of data

Data made available for review and dispute

Figure 4.1: The Four Steps of Data Submission and Attestation

Notes:

- 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 reporting entity's compliance for five years from the date of publication.
- Data reporting is complete <u>only</u> after electronic attestation is received for the program year.
- To assist with the preparation of data for submission, CMS has made resources available to help reporting entities confirm physician and teaching hospital identifying information. Physician identifying information can be found in the Validated Physician List (VPL), which can be downloaded from the "Submissions" page of the Open Payments system. Teaching hospital identifying information can be found in the Teaching Hospital list, which can be downloaded from the Resources page of the Open Payments website at https://www.cms.gov/openpayments/About/Resources.html.

Section 4.2: Data Submission

The data submission process requires reporting entities to submit detailed information regarding payments or other transfers of value made to physicians and teaching hospitals, and then 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.

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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. To perform data submission, users in the role of submitter should:

- Submit data files to validate the file structure;
- Use the error report generated by the Open Payments system to fix any data errors in submitted files; and finally
- Perform final data submission.

Then, the attester can attest to the accuracy of the submitted data. All submission activities must be completed before the close of the data submission period for that program year. Resources related to data submission can be found on the Resources page of the Open Payments website at https://www.cms.gov/openpayments/About/Resources.html.

Section 4.3: Preparing Your Data

Chapter 2 of this User Guide presents detailed descriptions of the information that must be collected for reporting by reporting entities. This section provides guidance on preparing data for submission. Sections 4.4 and 4.5 provide details on how to submit the collected data through bulk upload and manual data entry, respectively.

4.3a: Covered Recipient Demographic Resources

Prior to data submission, check the demographic information for each physician (including all principal investigators) and teaching hospital included in the records to ensure that it is current and accurate. To assist with this validation, CMS provides the Validated Physicians List (VPL) and the CMS Teaching Hospital List.

- The Validated Physicians List (VPL) contains only information on physicians who have been reported on in the Open Payments system and have NPIs; it is not an exhaustive list of all physicians who should be included in Open Payments reporting. The VPL can only be accessed within the Open Payments system, on the "Submissions" tab. Physicians who do not appear on the VPL may still be successfully matched. The VPL is merely a tool to help prepare records. Check with the National Plan and Provider Enumeration System (NPPES) for information on physicians you cannot find on the VPL.
- The Teaching Hospital Lists include all teaching hospitals that should be included in Open Payments reporting. They can be accessed via the Resources page on the Open Payments website (https://www.cms.gov/openpayments/About/Resources.html).
 - For program years 2014 and later, use the hospital's "Doing Business As" name as the hospital name in the submitted record. The "Doing Business As" name is found in the Teaching Hospital List under the heading of "Hospital Name."

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- o For program year 2013 records, use the hospital's legal business name as the hospital name in the submitted record.
- For the address for the hospital in the submitted record, use the "NPPES Business Address" in the Teaching Hospital List.

Another key resource is the "Submission Data Mapping Document," which maps each data element in Open Payments records to the appropriate CSV field names. (Note that there are different versions of this document for PY 2013-2015 data and PY 2016 and upcoming years.) The "Data Element Name", Column B in the "Submission Data Mapping Document," can be mapped to the "CSV Element Name" column of the sample file (template). You may also use this document as a guide when entering payments manually. Submission Data Mapping Documents can be found on the Resources page on the Open Payments website (https://www.cms.gov/openpayments/About/Resources.html).

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 4.12 for information on Consolidated Reporting).

Bulk files may be used to perform four actions:

- Add new records to the Open Payments system (refer to Section 4.4a and 4.4b);
- Change existing records in the Open Payments system (refer to Section 4.8a);
- Delete existing records (refer to Section 4.9); and
- Update the delay in publication status of existing records (refer to Section 4.11).

An individual record's action is indicated by the value given in the field "Resubmission File Indicator." A bulk file must include records of only one action (i.e., the "Resubmission File Indicator" must be the same value for all records in a bulk file). To accomplish multiple actions, multiple bulk files must be prepared. Records with "R" or "D" for the Resubmission File Indicator field have a smaller number of fields that are required for file submission. Refer to the Submission Data Mapping documents for details. Data supplied in fields identified as optional for these file types, will not be validated or saved in the Open Payments system.

Character-separated value (CSV) is the only file format accepted by the Open Payments system for bulk data files. ZIP files are permissible if they contain only CSV files. CSV files must be prepared and formatted properly for successful submission. See Section 4.4a for guidance.

Submitted bulk 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 file or compress the CSV file into a ZIP file. A ZIP file containing compressed CSV files must be under 250MB after compression.

There are no system limitations to the number of data lines or rows that can be included in a file as long as the file size remains below 250MB.

4.4a: Creating CSV Files

CSV sample files, also called CSV templates, are available on the Resources page of the Open Payments website at https://www.cms.gov/openpayments/About/Resources.html. Users who hold a submitter role can also access the templates within the Open Payments system on the "Resources" tab.



The templates define the exact format and layout of the files accepted in the Open Payments system. The sample files correspond to the three reporting categories.

- <u>CSV Sample File: General Payments</u> (called "General Template CSV" in the Open Payments system) For general payments or other transfers of value not made in connection with a research agreement or research protocol.
- <u>CSV Sample File: Research Payments</u> (called "Research Template CSV" in the Open Payments system) For research payments or other transfers of value made in connection with a research agreement or research protocol.
- <u>CSV Sample File: Physician Owner/Investor</u> (called "Owner/Investor Template CSV" in the Open Payments system) For ownership/investment information submissions.

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The correct sample file must be used for the corresponding reporting category (i.e., general payments records must be in general payments sample file format, etc.). Data entered for the records must conform to the restrictions for the data fields given in the "Submission Data Mapping Document." The "Submission Data Mapping Document" is also available on the Resources page of the Open Payments website.

Multiple versions of the "Submission Data Mapping Document" and CSV sample files (templates) are available, reflecting changes in the formatting of payment records starting with program year 2016. The list below explains which guidance documents to use:

- To prepare general payment and research payment records for program year 2016 and upcoming years, refer to the guidance in the "PY 2016 and upcoming years Submission Data Mapping Document." The names of the templates vary depending upon where you locate them:
 - On the "Resources" page of the Open Payments website, the templates are named "PY 2016 and upcoming years CSV Sample File: General Payments" and "PY 2016 and upcoming years CSV Sample File: Research Payments."
 - On the "Resources" tab within the Open Payments system, the templates are named "PY 2016 and upcoming years General Template" and "PY 2016 and upcoming years Research Template."
- To prepare physician owner/investor records for program year 2016 and upcoming years, refer to the guidance in the "PY 2016 and upcoming years Submission Data Mapping Document." The names of the templates vary depending upon where you locate them:
 - On the "Resources" page of the Open Payments website, the template is named "PY 2013-2016 and upcoming years CSV Sample File: Physician Owner/Investor."
 - On the "Resources" tab within the Open Payments system, the template is named "PY 2013
 2016 and upcoming years Ownership Investor Template."
- To prepare payment records of any type from program years before 2016, refer to the guidance in the "PY 2013-2015 Submission Data Mapping Document." Template names vary depending upon where you locate them:
 - On the "Resources" page of the Open Payments website, the templates are named "PY 2013-2015 CSV Sample File: General Payments," "PY 2013-2015 CSV Sample File: Research Payments," and "PY 2013-2016 and upcoming years CSV Sample File: Physician Owner/Investor."
 - On the "Resources" tab within the Open Payments system, the templates are named "2013-2015 General Template," "2013-2015 Research Template," and "2013 - 2016 Ownership Investor Template."

Open Payments User Guide

The delimiter for CSV files for Open Payments submission files is a pipe (|). Therefore, when creating CSV files for Open Payments 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 selecting backslash (i.e., "\"). Note that this "regional setting" change is not necessary when using Open Office.

To create a CSV 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").

To create a CSV 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 select 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:

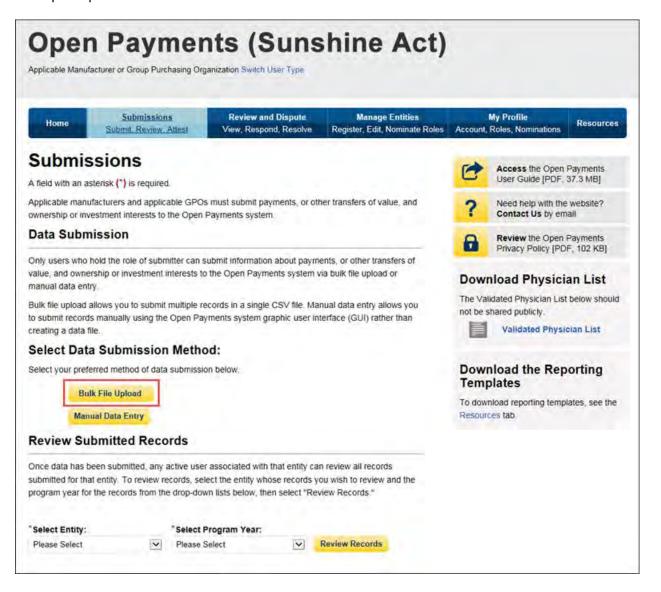
- Open the CSV file in a text editor (Notepad for Windows, Text Editor for Macintosh) and confirm that the rows are delimited with pipes; and
- Ensure that rows of data are not contained within quotation marks to avoid the data being rejected by the system.

4.4b: Bulk File Upload Instructions

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Submissions" tab.



<u>Step 2:</u> You will be brought to the "Submissions" page. Select the "Bulk File Upload" option to begin the bulk upload process.

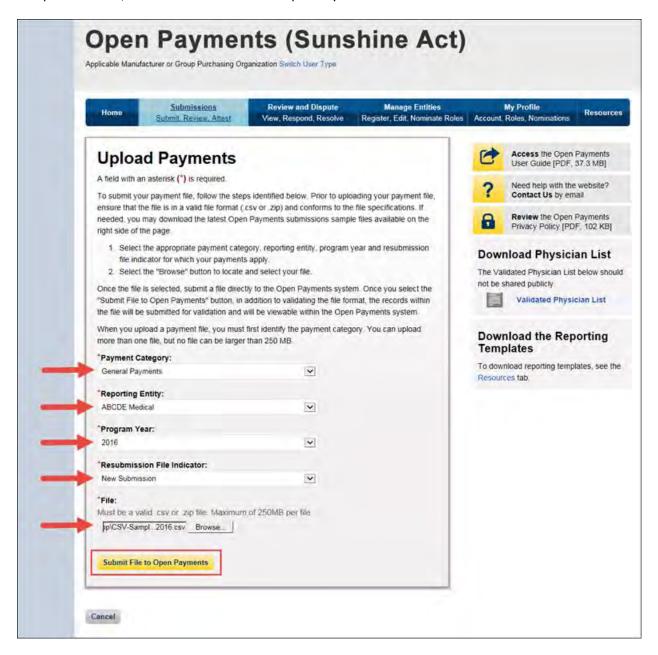


<u>Step 3:</u> Select the payment category for the type of file being submitted: general, research, or ownership/investment interests. Then select the reporting entity for which you will be uploading the files and the program year of the data. For the Resubmission File Indicator drop-down, select the value that matches the value given in the "Resubmission File Indicator" in the file's records (e.g., if the file's records have a "Resubmission File Indicator" value of "N," select "New Submission").

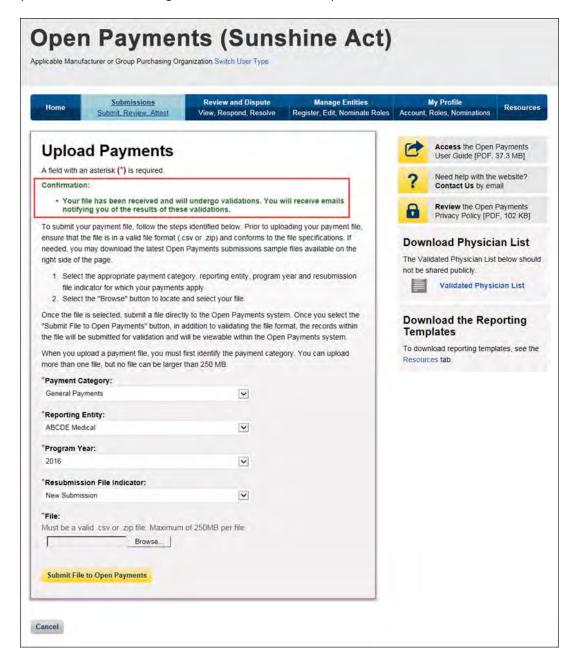
Select the "Browse" button to find and select the file to be uploaded.

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

To upload the file, select the "Submit File to Open Payments" button.



Upon upload, the file will undergo several validations, as explained in Section 4.6.



You will receive an email notification if records did not pass validation or matching. Records that failed validation and/or matching cannot proceed to final submission. See Section 4.8 for details on record correction and resubmission. You may check the status of your upload at any time via the "Review Records" page. Records in the submission process will be in one of the following statuses:

- System Processing Records which the Open Payments system is still processing and validating.
- Ready for Submission Records which are successfully validated and matched, and ready for final submission.

- Failed Validation Records which did not pass field validation checks.
- Failed Matching Records which were not successfully matched to a valid covered recipient.

Take note that once the data has been uploaded to the system and undergone these checks, it still must undergo the final submission process in 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 and matching requirements. **You must complete the final submission and attestation process for the data to be considered reported.** See Section 4.10 for details on final submission and Section 4.14 for details on attestation.

Note: Records with errors that failed validations that prevent them from being loaded into the system are not saved in the Open Payments system and will not appear on the "Review Records" page. See Sections 4.6 and 4.7 for more information.

Section 4.5: Manual Entry Using the Graphic User Interface (GUI)

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 Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html, provides guidance and descriptions on each of the fields that will be entered during the manual data entry process. There are two versions of the Submission Data Mapping document, one for program years 2013-2015 and one for program year 2016 and upcoming years. Both are available on the Resources page. Have the appropriate version of this document available during manual entry for reference.

Note that applicable GPOs cannot submit general or research payment records for a physician without having previously submitted an ownership/investment interest record for that physician.

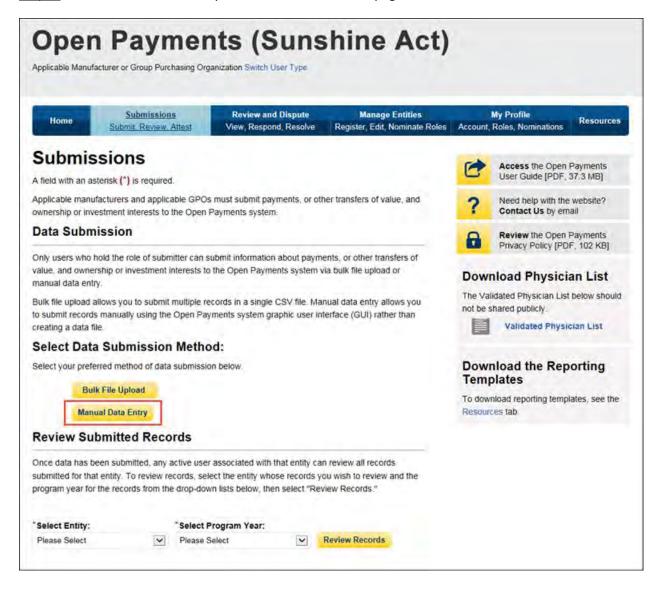
4.5a: Manual Entry of General Payments

To enter general payments data manually, follow these steps:

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Submissions" tab from the home page.



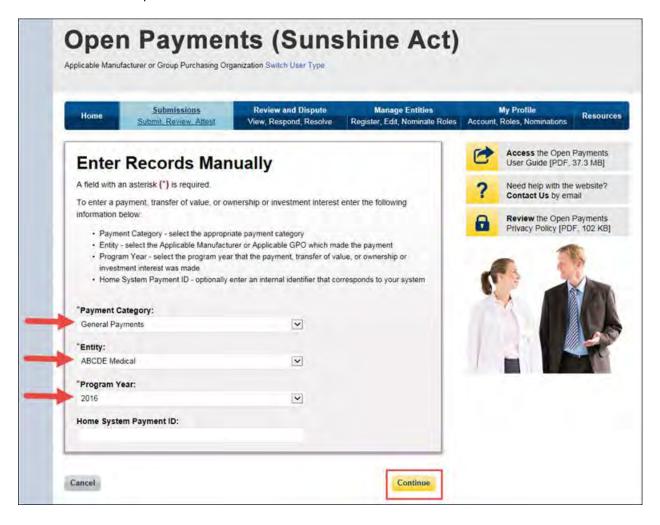
Step 2: Select "Manual Data Entry" from the "Submissions" page.



<u>Step 3:</u> On the "Enter Records Manually" page, use the drop-down menus to select the Payment Category, Entity Name, and Program Year for the record to be entered.

In addition, you may enter the Home System Payment ID (if applicable) of the record you will submit. "Home System Payment ID" is the identifier associated with the payment transaction in your home system.

Select "Continue" to proceed.



<u>Step 4:</u> On the "Covered Recipient Demographic Information" page, select the covered recipient type: Physician or Teaching Hospital.

The next steps will differ depending on the covered recipient type selected.

For teaching hospitals: Enter information as requested on the page. Required fields are marked with asterisks.

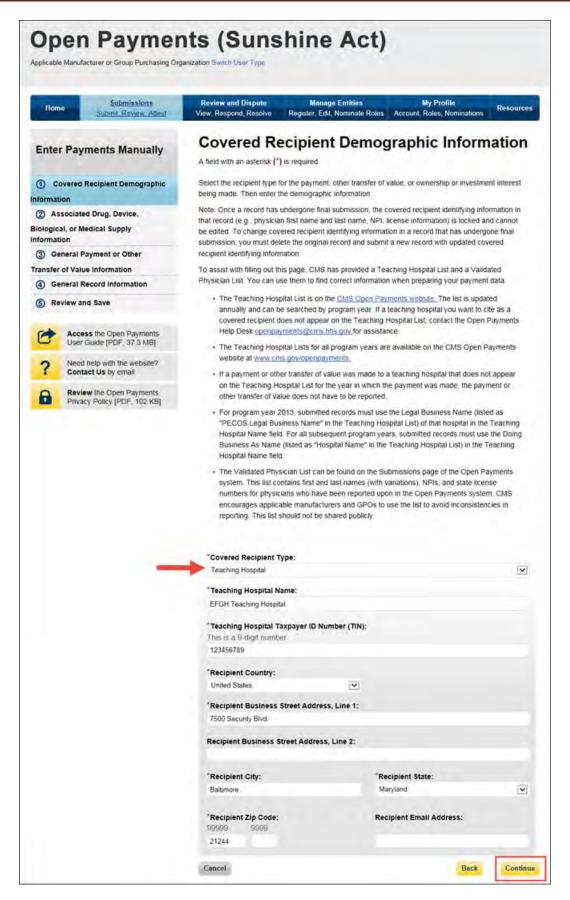
For complete and accurate identifying information for a teaching hospital, refer to the CMS Teaching Hospital List. This list, vetted and compiled by CMS, contains identifying information for teaching hospitals and is updated annually. Refer to the Teaching Hospital List of the same year as the program year of the record.

You can access the Teaching Hospital List by selecting the link on the "Covered Recipient Demographic Information" page to the CMS Open Payments website and from there going to the website's Resources page, or you can go directly to the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html Teaching Hospital List.

When entering record information, the name supplied in the "Teaching Hospital Name" field should match the name listed in the "Hospital Name" field of the Teaching Hospital List (also known as the "Doing Business As" (DBA) name), unless the record is for program year 2013, in which case the hospital's legal name from the 2013 Teaching Hospital List should be used.

The address should match the "NPPES Business Address" in the Teaching Hospital List.

When you have entered all of your information, select "Continue."



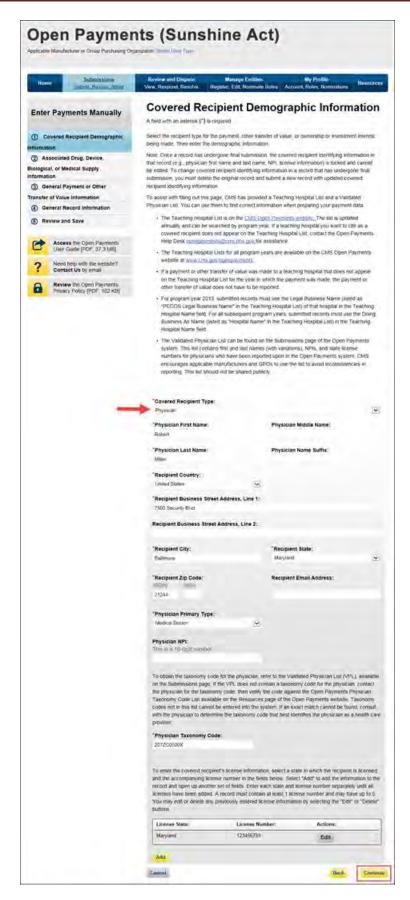
For physicians: Enter information as requested on the page below. Required fields are marked with asterisks. Consult the Validated Physician List (VPL), downloadable from the "Submissions" tab, to confirm the identifying information for the physician.

To fill in the taxonomy code value, refer to the taxonomy code list linked to in <u>Appendix C</u> or on the Resources page of the Open Payments website

(https://www.cms.gov/OpenPayments/About/Resources.html) for a complete listing of the available taxonomy codes. Taxonomy codes not on the taxonomy code list should not be entered. If the physician's taxonomy is not on the list, select the code that most closely represents the physician's specialty.

To add the physician's license information, select "Add License" and enter the state in which the license is held and the license number. The license number field may contain up to 25 characters, including special characters such as hyphens (-). When done, select "Add License." If you input data into the field and select "Continue" before selecting "Add License," the system will throw an error message. To proceed, either select "Add License" or clear the information from the license field. If the physician has licenses in more than one state, enter in one state and license number and then select "Add License." This will add the information to the record and open up another set of license fields. Repeat until all of the physician's state licenses have been added. You can enter up to five licenses.

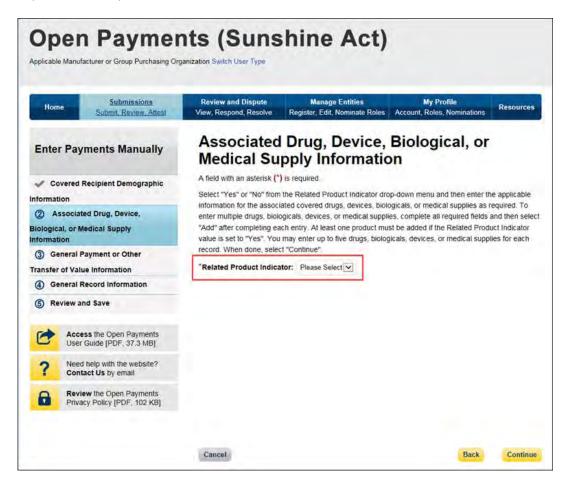
When you have entered all of your information, select "Continue."



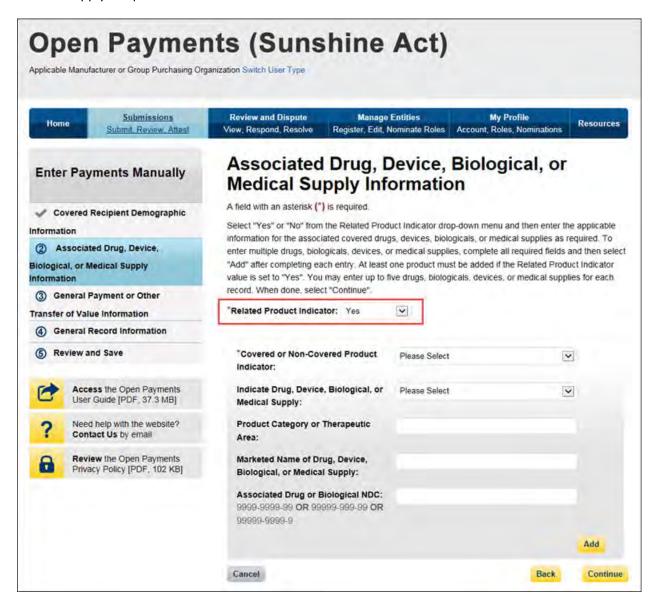
<u>Step 5:</u> On "Associated Drug, Device, Biological, or Medical Supply Information" page, enter the associated drugs, biologicals, devices, or medical supplies, if applicable, to the record.

For program year 2016 and upcoming years:

You can enter up to five drugs, biologicals, devices, or medical supplies per record. Begin by selecting the appropriate value in the "Related Product Indicator" drop-down list. Select "Yes" if the payment record needs to include a drug, biological, device, or medical supply and follow the instructions for the rest of step 5 below. If the payment did not include a drug, biological, device, or medical supply, select "No" and proceed to step 6.



If you selected "Yes," several fields will appear that will allow the entry of one drug, biological, device, or medical supply. Required fields are marked with an asterisk.



First select a value for the "Covered or Non-Covered Product Indicator."

- "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.

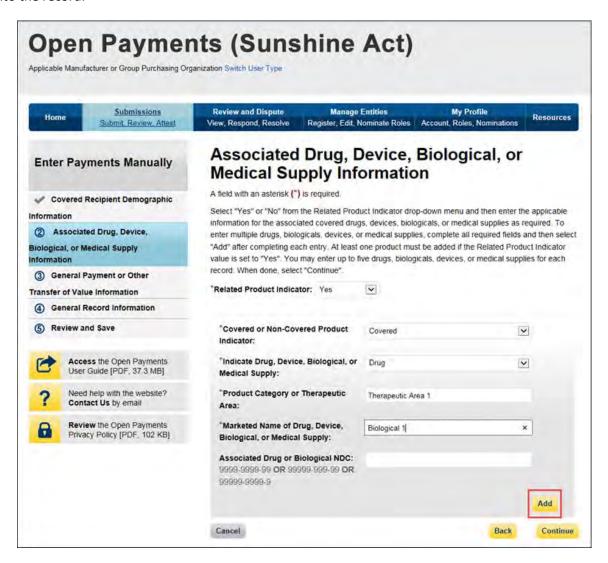
In the "Indicate Drug, Device, Biological, or Medical Supply" drop-down, select the appropriate value. Enter the appropriate information in the "Product Category or Therapeutic Area" text field and the marketed name of the drug, biological, device, or medical supply in the name field. If the product is a

drug or biological, enter the National Drug Codes (NDC) for the drug or biological in the NDC field. NDCs are unique identifiers with 12 characters and must be in one of the following formats:

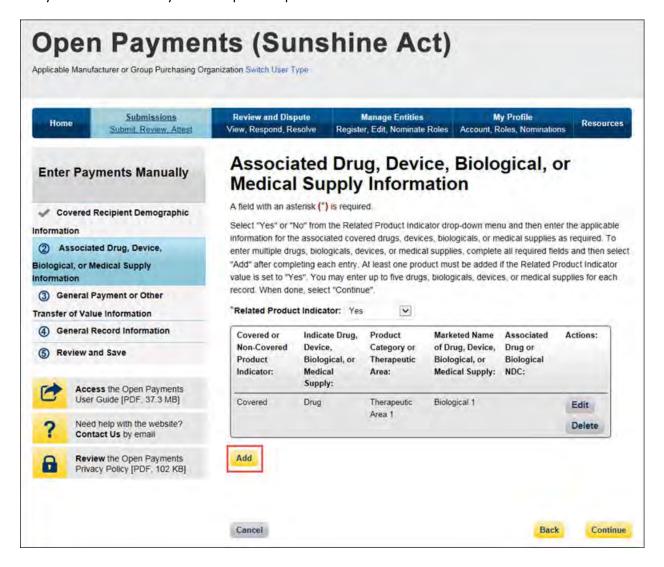
- 9999-9999-99
- 99999-999-99
- 99999-9999-9

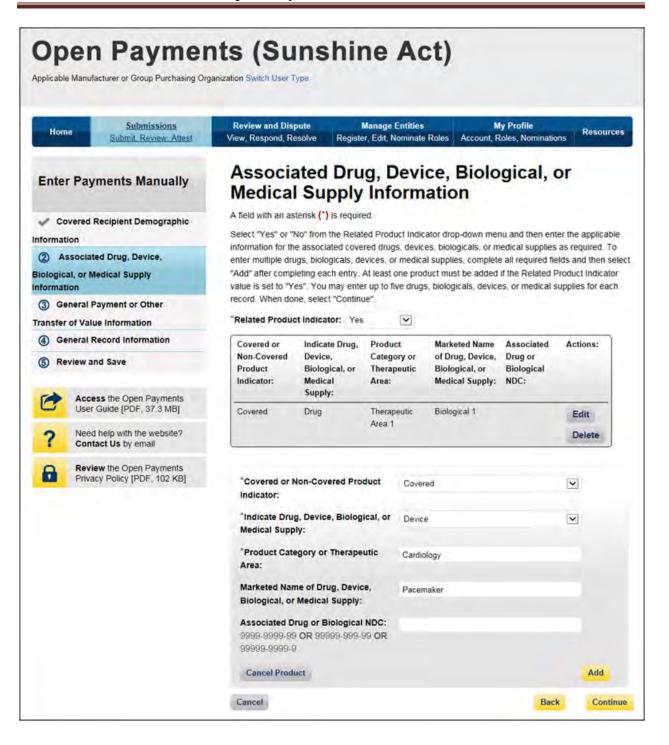
NDCs entered that do not match one of these three formats or contain all zeroes will not be accepted. NDCs can be found on the <u>U.S. Food and Drug Administration's website at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm</u>.

Once you have entered in the information for the product, select "Add." This will save the information into the record.

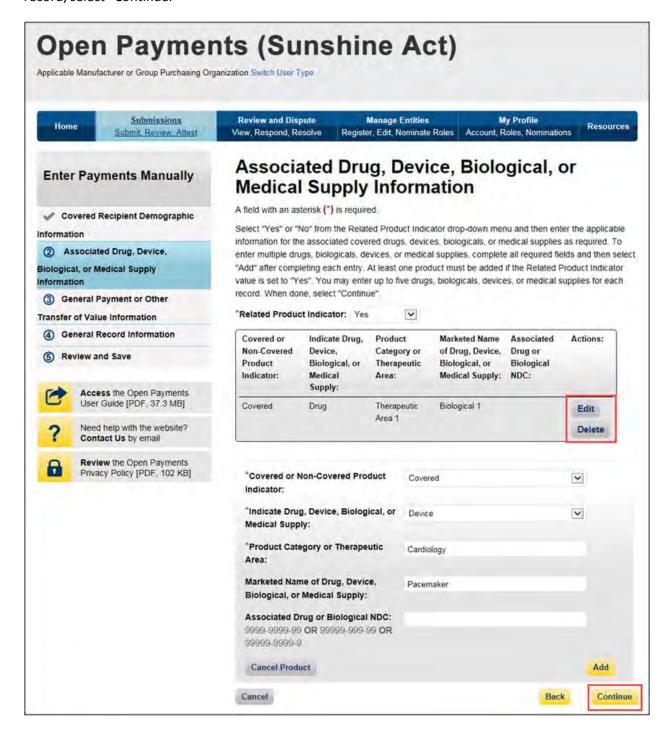


If you have another product to add to the record, select "Add" again to open up another set of data entry fields. A record may contain up to five products.





If you need to correct or delete the product information after adding it, select the "Edit" or "Delete" buttons in the table of saved products. Once you have saved all products (maximum five) into the record, select "Continue."



Once you have saved all products (maximum five) into the record, select "Continue."

For program years 2013-2015:

Select the appropriate value in the "Product Indicator" field:

- "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.

If you selected "None" or "Non-covered," you may select "Continue" and proceed to Step 6. If you selected "Covered or "Combination," enter the product information into the record using the guidance below.

Enter National Drug Codes (NDCs) for up to five covered drugs or biologicals to be included in this record. NDCs are unique identifiers with 12 characters and must be in one of the following formats:

- 9999-9999-99
- 99999-999-99
- 99999-9999-9

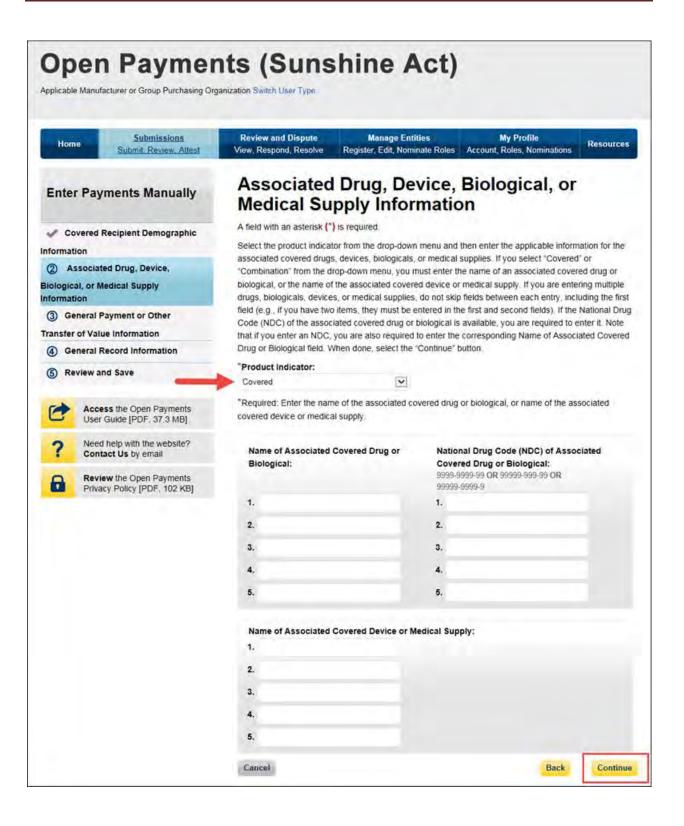
NDCs entered that do not match one of these three formats or contain all zeroes will not be accepted. NDCs can be found on the <u>U.S. Food and Drug Administration's website at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm</u>.

Enter the names of the drugs or biologicals associated with those NDCs. For every NDC entered, you **must** provide a corresponding "Name of Associated Covered Drug or Biological." If more than one NDC is provided, their order must match the order of the named covered drug or biological. For example, if an NDC code is entered in the first "NDC of Associated Covered Drug or Biological" field, the drug name must be entered in the first "Name of Associated Covered Drug or Biological" field.

If you are submitting information for covered devices or medical supplies, provide their names in the "Name of Associated Covered Device or Medical Supply" fields on the bottom of the page.

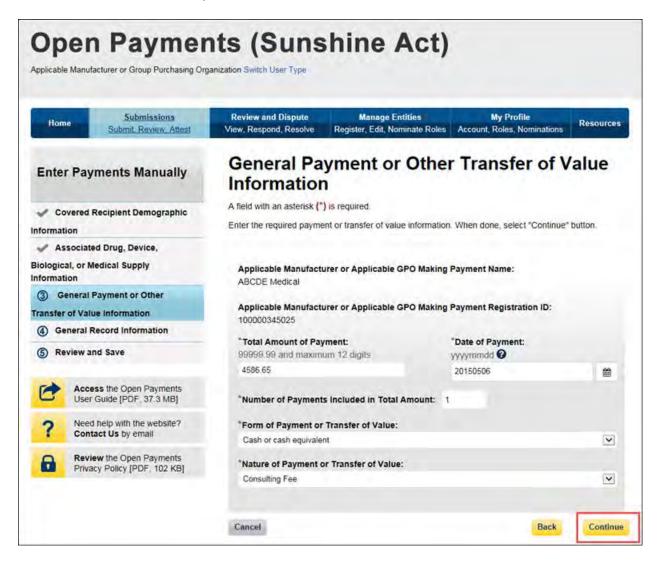
You may provide up to five drugs or biologicals and up to five devices or medical supplies.

Once all information is entered, select "Continue."



<u>Step 6:</u> Enter payment information in the required fields: total amount of payment, date of payment, the number of payments included in the total amount, the form of payment or other transfers of value, and the nature of payment or other transfers of value. Note that only positive dollar values are allowed when reporting payment amounts; negative dollar values and zeros are not permitted.

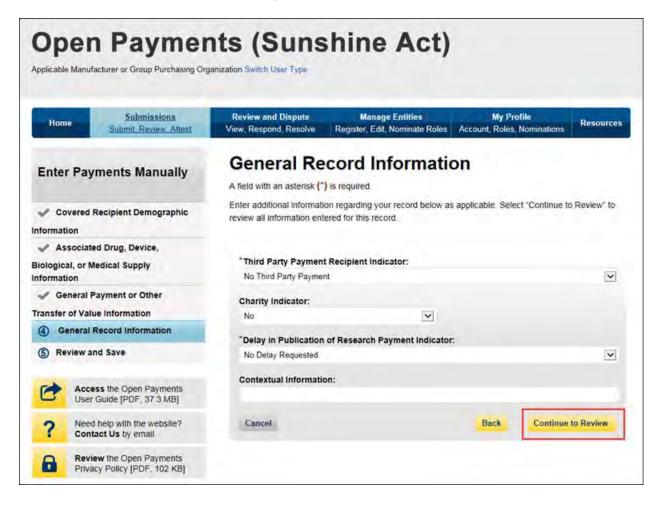
Once all information is entered, select "Continue."



Step 7: Enter general record information.

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. The "Contextual Information" text box is a free-form text field where you can enter any information you deem helpful or appropriate regarding the payment or other transfers of value. The text field has a limit of 500 characters. All special characters found on a standard U.S. keyboard can be used in the text box, not including ALT+NUMPAD ASCII Key characters.

Select the "Continue to Review" button to proceed.



<u>Step 8:</u> Review the payment information entered in the previous pages. If necessary, select the "Back" button at the bottom of the page to go back and edit information. Once the record is accurate, 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.



Take note that once the data has been uploaded to the system and undergone these checks, it still must be <u>submitted</u> as final into the Open Payments system. Manual data entry only uploads the record and checks it to ensure that it adheres to a valid data format and matching requirements. **You must complete the final submission and attestation process for the data to be considered reported.** See Section 4.10 for details on final submission and Section 4.14 for details on attestation.

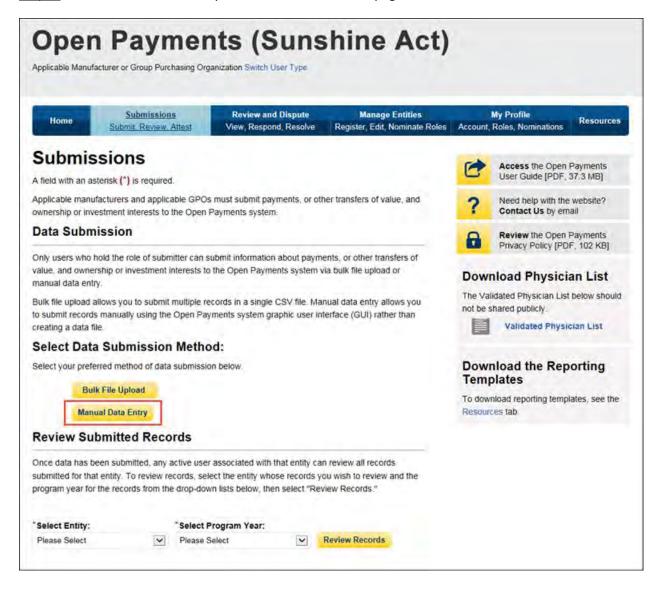
4.5b: Manual Entry of Research Payments

To enter research payment data manually, follow these steps:

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Submissions" tab from the home page.



Step 2: Select "Manual Data Entry" from the "Submissions" page.



<u>Step 3:</u> On the "Enter Records Manually" page, use the drop-down menus to select the Payment Category, Entity Name, and Program Year. You may enter the Home System Payment ID (if applicable) of the record you will submit. The Home System Payment ID is the identifier associated with the payment transaction in your home system. Select "Continue" to proceed.



<u>Step 4:</u> On the "Recipient Demographic Information" page, select the recipient type: covered recipient physician, covered recipient teaching hospital, non-covered recipient entity, or non-covered recipient individual. The next steps will differ depending on the covered recipient type selected.

<u>Step 4a:</u> **For teaching hospitals**: Enter information as requested on the page. Required fields are marked with asterisks.

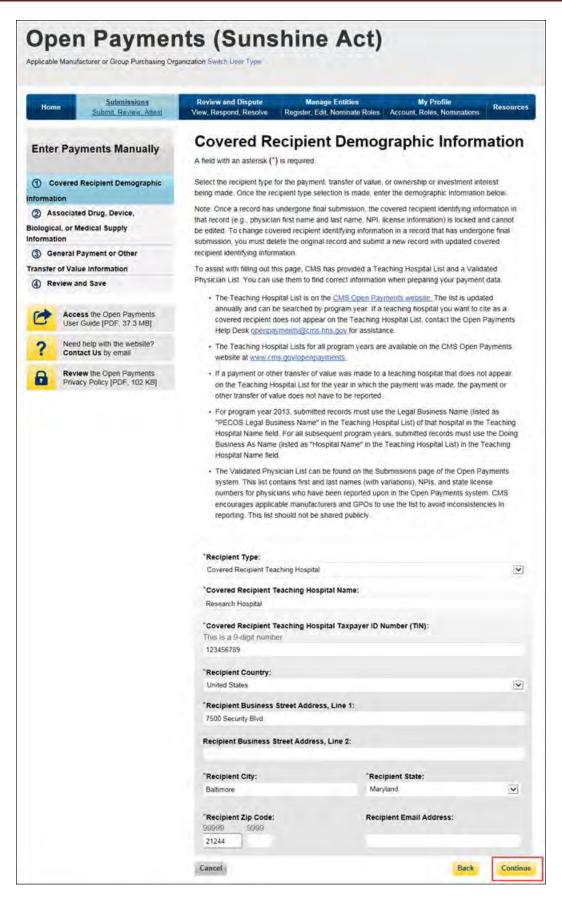
For complete and accurate identifying information for a teaching hospital, refer to the CMS Teaching Hospital List. This list, vetted and compiled by CMS, contains identifying information for teaching hospitals and is updated annually. Refer to the Teaching Hospital List of the same year as the program year of the record.

You can access the Teaching Hospital List by selecting the link on the "Covered Recipient Demographic Information" page to the CMS Open Payments website and from there going to the website's Resources page, or you can go directly to the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html Teaching Hospital List.

When entering record information, the name supplied in the "Teaching Hospital Name" field should match the name listed in the "Hospital Name" field of the Teaching Hospital List (also known as the "Doing Business As" (DBA) name), unless the record is for program year 2013, in which case the hospital's legal name from the 2013 Teaching Hospital List should be used.

The address should match the "NPPES Business Address" in the Teaching Hospital List.

When you have entered all of your information, select "Continue."



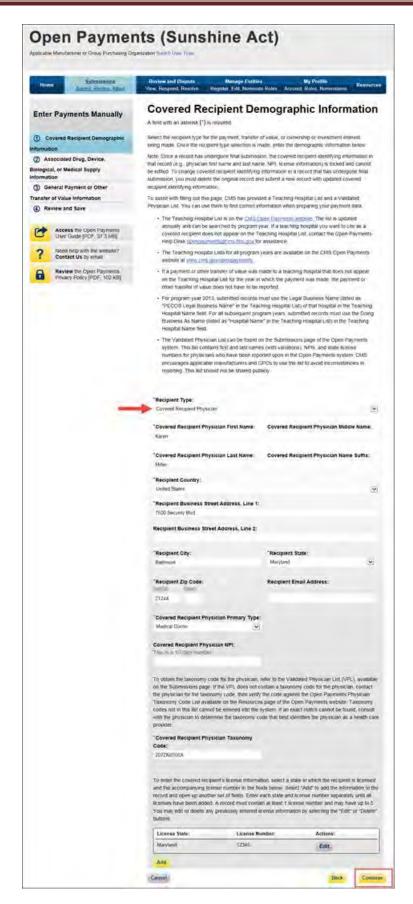
<u>Step 4b:</u> For *covered recipient physicians*, enter information as requested on the page below. Required fields are marked with asterisks. Consult the Validated Physician List, downloadable from the "Submissions" page, to confirm the identifying information for the physician.

To fill in the taxonomy code value, refer to the taxonomy code list linked to in <u>Appendix C</u> or on the Resources page of the Open Payments website

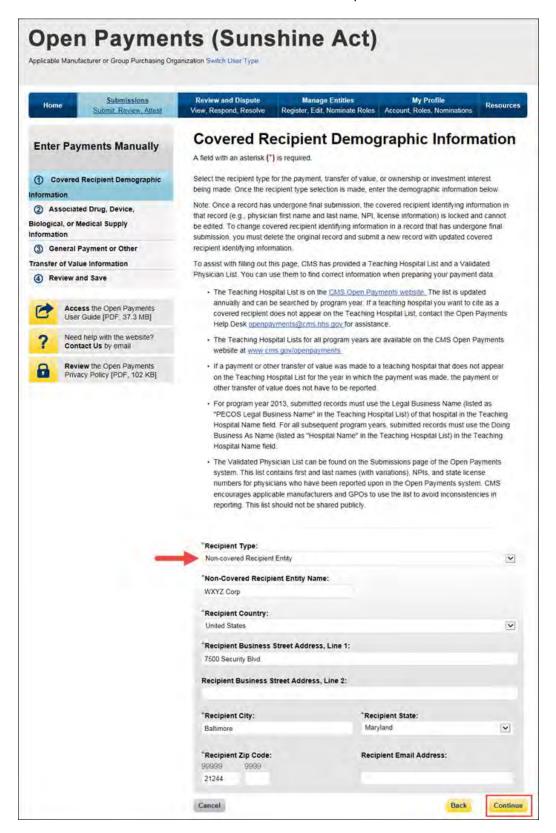
(https://www.cms.gov/OpenPayments/About/Resources.html) for a complete listing of the available taxonomy codes. Taxonomy codes not on the taxonomy code list should not be entered. If the physician's taxonomy code is not available, select the code that most closely represents the physician's specialty.

To add the physician's license information, select "Add License" and enter the state in which the license is held and the license number. The license number field may contain up to 25 characters, including special characters such as hyphens (-). When done, select "Add License." If you input data into the field and select "Continue" before selecting "Add License," the system will throw an error message. To proceed, either select "Add License" or clear the information from the license field. If the physician has licenses in more than one state, enter in one state and license number and then select "Add License." This will add the information to the record and open up another set of license fields. Repeat until all of the physician's state licenses have been added. You can enter up to five licenses.

Select the "Continue" button to proceed.



<u>Step 4c:</u> For *non-covered recipient entities*, enter information as requested on the page below. Required fields are marked with asterisks. Select the "Continue" button to proceed.



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



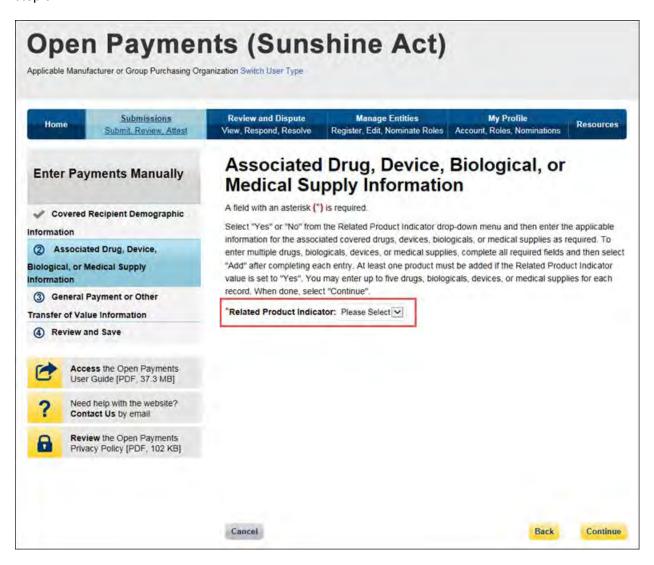
<u>Step 5:</u> Enter associated drugs, biologicals, devices, or medical supplies, if applicable, to the record. The process varies depending upon the program year of the record.

For program year 2016 and upcoming years:

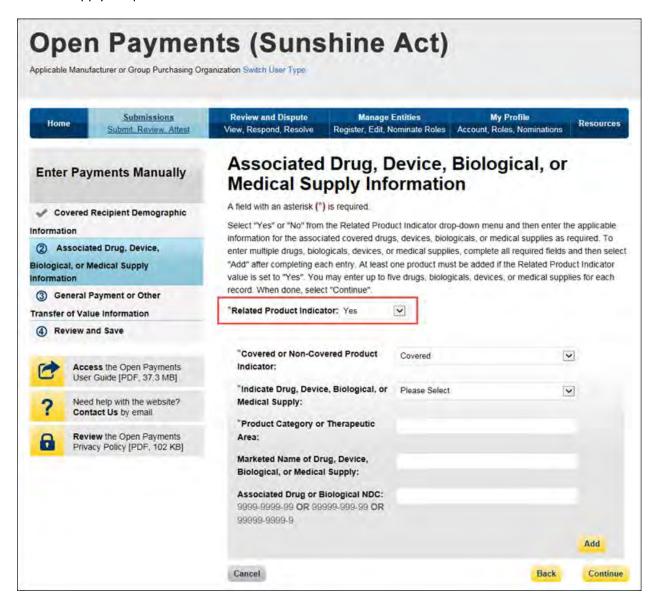
You can enter up to five drugs, biologicals, devices, or medical supplies per record. Begin by selecting the appropriate value in the "Related Product Indicator" drop-down list.

Select "Yes" if the payment record needs to include a drug, biological, device, or medical supply and follow the instructions for the rest of step 5 below.

If the payment did not include a drug, biological, device, or medical supply, select "No" and proceed to step 6.



If you selected "Yes," several fields will appear that will allow the entry of one drug, biological, device, or medical supply. Required fields are marked with an asterisk.



First select a value for the "Covered or Non-Covered Product Indicator."

- "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.

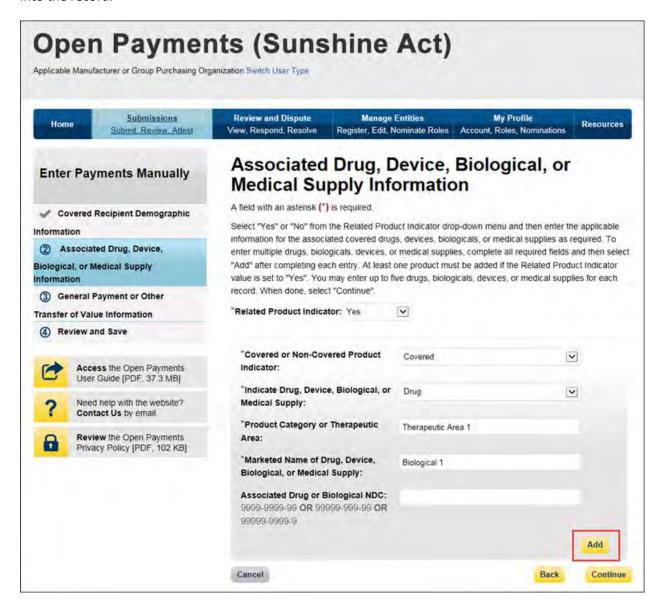
In the "Indicate Drug, Device, Biological, or Medical Supply" drop-down, select the appropriate value. Enter the appropriate information in the "Product Category or Therapeutic Area" text field and the marketed name of the drug, biological, device, or medical supply in the name field. If the product is a

drug or biological, enter the National Drug Codes (NDC) for the drug or biological in the NDC field. NDCs are unique identifiers with 12 characters and must be in one of the following formats:

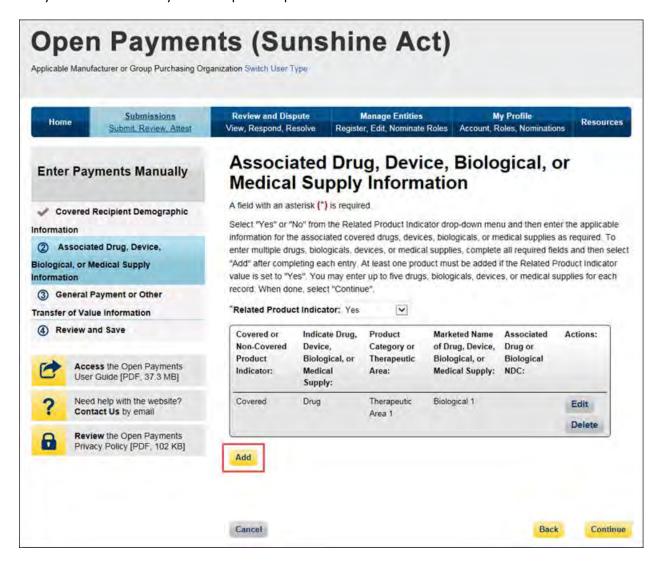
- 9999-9999-99
- 99999-999-99
- 99999-9999-9

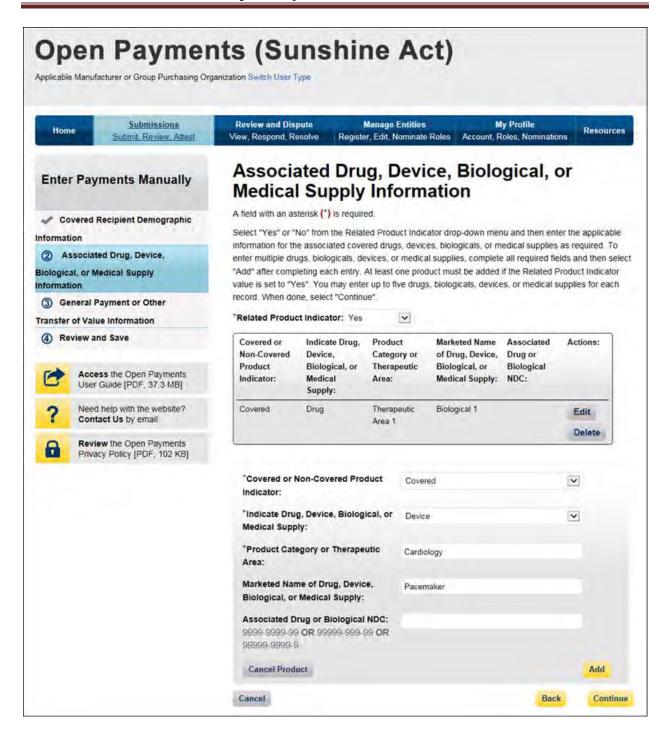
NDCs entered that do not match one of these three formats or contain all zeroes will not be accepted. NDCs can be found on the <u>U.S. Food and Drug Administration's website at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm</u>.

Once you have entered in the information for the product, select "Add." This will save the information into the record.



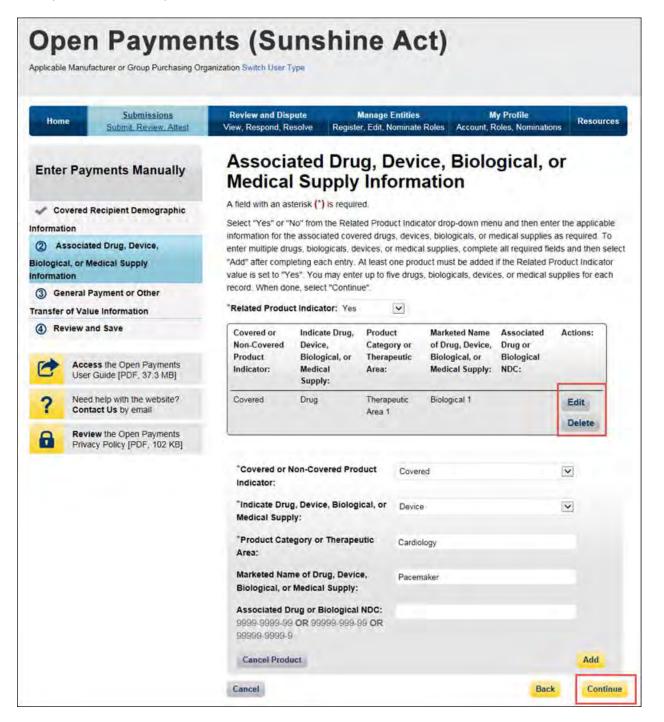
If you have another product to add to the record, select "Add" again to open up another set of data entry fields. A record may contain up to five products.





If you need to correct or delete the product information after adding it, select the "Edit" or "Delete" buttons in the table of saved products.

Once you have saved all products (maximum five) into the record, select "Continue."



For program years 2013-2015:

Select the appropriate value in the "Product Indicator" field:

- "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.

If you selected "None" or "Non-covered," you may select "Continue" and proceed to Step 6. If you selected "Covered or "Combination," enter the product information into the record using the guidance below.

Enter National Drug Codes (NDCs) for up to five covered drugs or biologicals to be included in this record. NDCs are unique identifiers with 12 characters and must be in one of the following formats:

- 9999-9999-99
- 99999-999-99
- 99999-9999-9

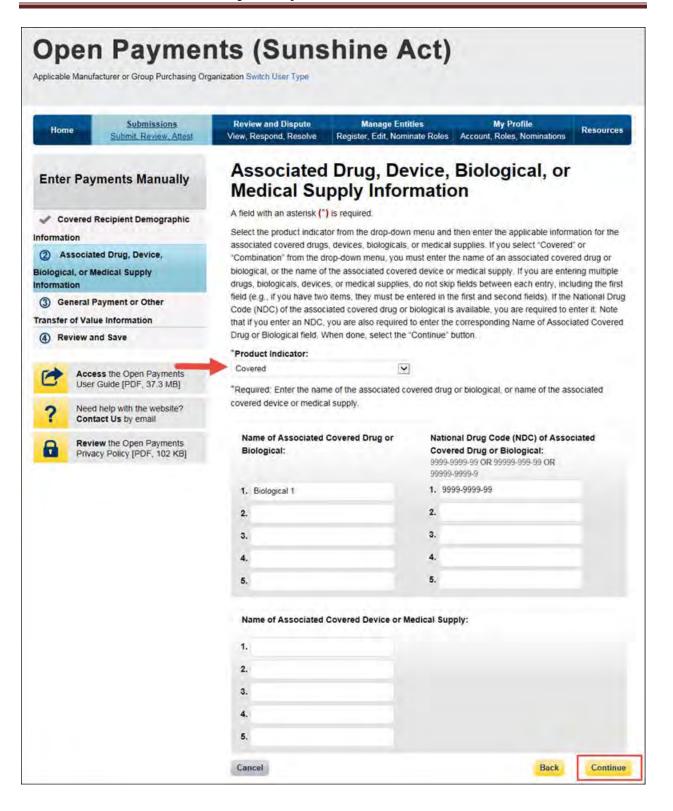
NDCs entered that do not match one of these three formats or contain all zeroes will not be accepted. NDCs can be found on the <u>U.S. Food and Drug Administration's website at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm</u>.

Enter the names of the drugs or biologicals associated with those NDCs. For every NDC entered, you **must** provide a corresponding "Name of Associated Covered Drug or Biological." If more than one NDC is provided, their order must match the order of the named covered drug or biological. For example, if an NDC code is entered in the first "NDC of Associated Covered Drug or Biological" field, the drug name must be entered in the first "Name of Associated Covered Drug or Biological" field.

If you are submitting information for covered devices or medical supplies, provide their names in the "Name of Associated Covered Device or Medical Supply" fields on the bottom of the page.

You may provide up to five drugs or biologicals and up to five devices or medical supplies.

Once all information is entered, select "Continue."



<u>Step 6:</u> Enter payment information in the required fields: total amount of payment, date of payment, 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 or zeros 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 page. See Section 4.11 for information on delays in publication.

If the record has one or more physician principal investigators associated with it, select "Yes" from the "Principal Investigator Covered Recipient Physician Indicator" drop-down box. The screen will expand to provide fields for entering identifying information for one principal investigator. Provide the required information for one covered recipient, then select "Add Principal Investigator" to add that individual to the record. If you select "Continue" before selecting "Add Principal Investigator," the Principal Investigator information will not be added to the record. Add up to five principal investigator covered recipients.

To fill in the taxonomy code value, refer to the taxonomy code list linked to in <u>Appendix C</u> or on the Resources page of the Open Payments website

(https://www.cms.gov/OpenPayments/About/Resources.html) for a complete listing of the available taxonomy codes. Taxonomy codes not on the taxonomy code list should not be entered. If the principal investigator's taxonomy code is not available, select the code that most closely represents the principal investigator's specialty.

To add a principal investigator's license information to a record, enter the state in which the license is held and the license number in the licensing fields. The license number field may contain up to 25 characters, including special characters such as hyphens (-). When done, select "Add." If you select "Add Principal Investigator" before selecting "Add," the license information will not be added to the record. If the principal investigator has licenses in more than one state, enter in one state and license number and then select "Add." This will add the information to the record and open up another set of license fields. Repeat until all of the principal investigator's state licenses have been added. You can enter up to five licenses.

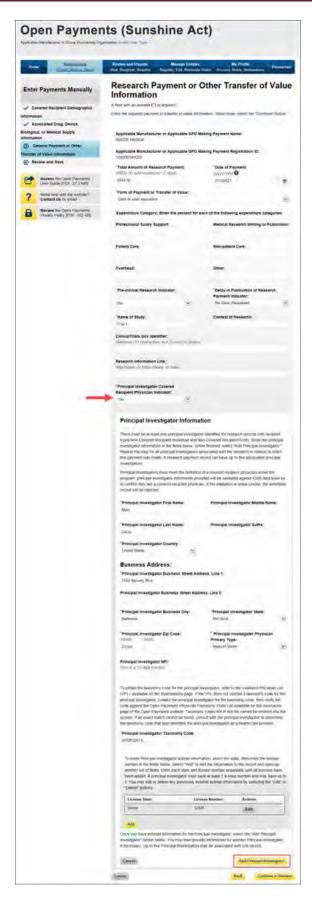
Note that a principal investigator's identifying information cannot be the same as the covered recipient physician's identifying information (i.e., the physician and principal investigator in a record cannot be the same individual).

The rules for principal investigator input varies based upon the type of recipient on the record (covered recipient physician, covered recipient teaching hospital, non-covered entity, or non-covered individual):

• If the recipient type is "Covered Recipient Physician" and the "Principal Investigator Covered Recipient Physician Indicator" is set to "Yes," then enter at least one covered Principal Investigator. The covered recipient physician should not also be listed as a principal investigator, nor should Principal Investigator information be repeated on a record.

- If the recipient type is "Covered Recipient Teaching Hospital" and the "Principal Investigator Covered Recipient Physician Indicator" is set to "Yes," then at least one covered recipient Principal Investigator is required to be entered.
- If the recipient type is "Non-Covered Entity" or "Non-Covered Individual," the "Principal Investigator Covered Recipient Physician Indicator" must be set to "Yes" and at least one covered recipient Principal Investigator must be entered.

Once all information is entered, select "Continue to Review."



<u>Step 7:</u> Review the payment information entered in the previous pages. Select the "Back" button at the bottom of the page to go back and edit information if necessary. If the information is correct, select "Save Record" to continue.



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



Take note that once the data has been uploaded to the system and undergone these checks, it still must be <u>submitted</u> as final into the Open Payments system. Manual data entry only uploads the record and checks it to ensure that it adheres to a valid data format and matching requirements. **You must complete the final submission and attestation process for the data to be considered reported.** See Section 4.10 for details on final submission and Section 4.14 for details on attestation.

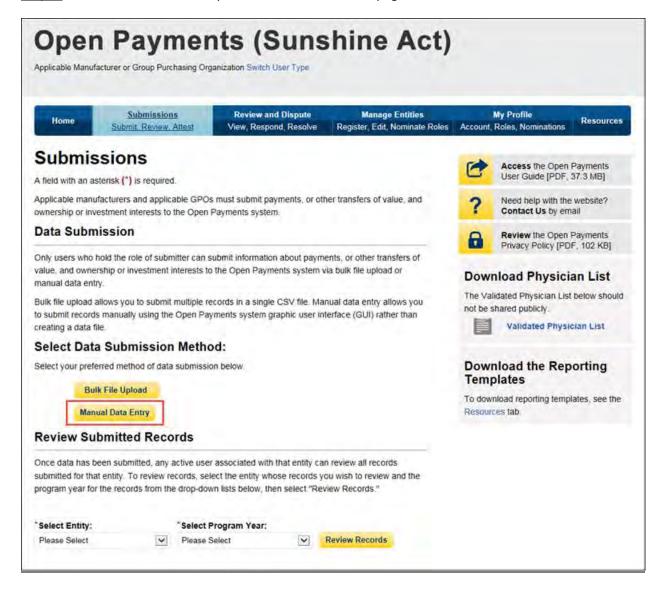
4.5c: Manual Entry of Ownership/Investment Interests Payments

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

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Submissions" tab from the home page.



Step 2: Select "Manual Data Entry" from the "Submissions" page.



<u>Step 3:</u> On the "Enter Records Manually" page, use the drop-down menus to select the Payment Category, Entity Name, and Program Year. You may enter the Home System Payment ID (if applicable) of the record you will submit. The Home System Payment ID is the identifier associated with the payment transaction in your home system. Select "Continue" to proceed.



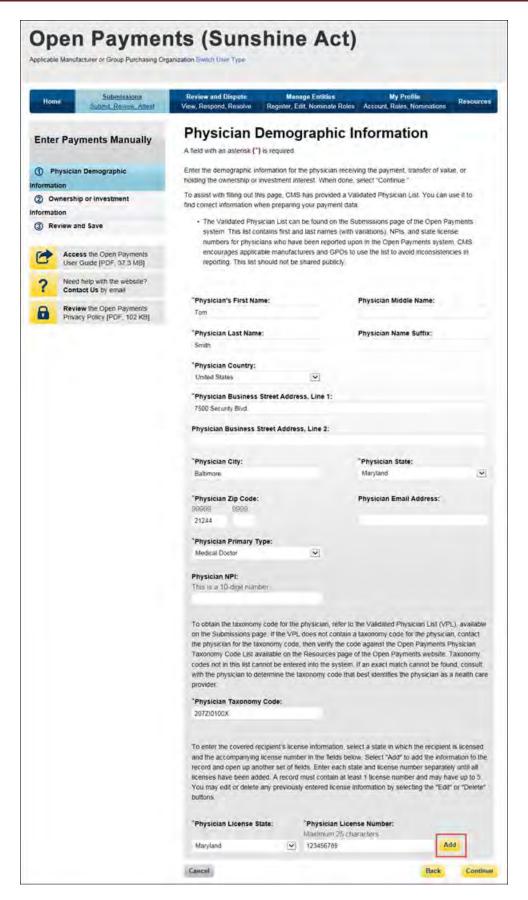
<u>Step 4:</u> Enter the Physician Demographic Information seen on the page below. Required fields are marked with asterisks. Consult the Validated Physician List (VPL), downloadable from the "Submissions" page, to confirm the identifying information for the physician.

To fill in the taxonomy code value, refer to the taxonomy code list linked to in <u>Appendix C</u> or on the Resources page of the Open Payments website

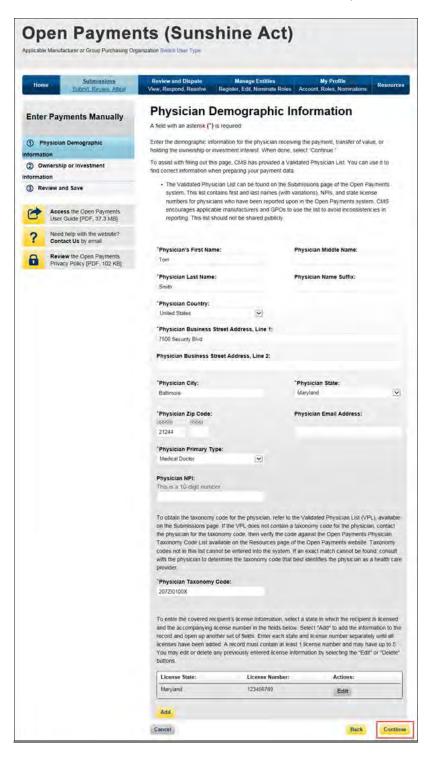
(https://www.cms.gov/OpenPayments/About/Resources.html) for a complete listing of the available taxonomy codes. Taxonomy codes not on the taxonomy code list should not be entered. If the physician's taxonomy code is not available, select the code that most closely represents the physician's specialty.

To add the physician's license information, select "Add License" and enter the state in which the license is held and the license number. The license number field may contain up to 25 characters, including special characters such as hyphens (-). When done, select "Add License." If you input data into the field and select "Continue" before selecting "Add License," the system will throw an error message. To proceed, either select "Add License" or clear the information from the license field. If the physician has licenses in more than one state, enter in one state and license number and then select "Add License." This will add the information to the record and open up another set of license fields. Repeat until all of the physician's state licenses have been added. You can enter up to five licenses.

Select the "Continue" button to proceed.

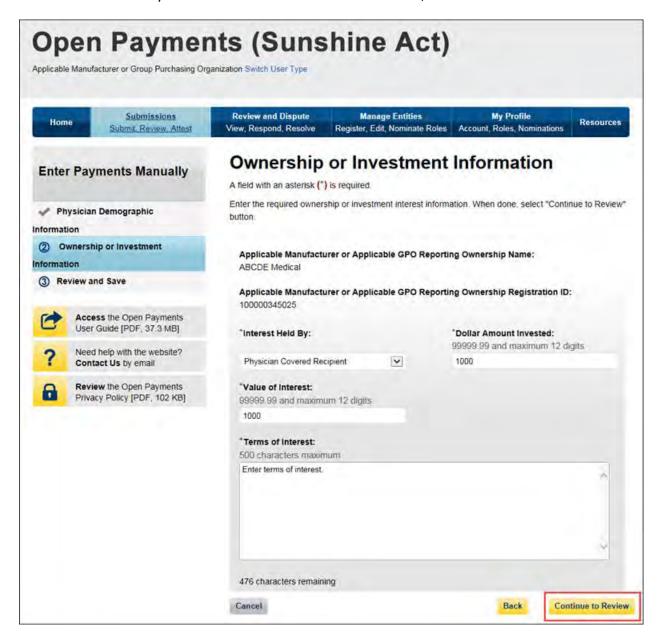


As mentioned above, selecting "Add" adds the physician license information to the record, shown in the picture below. To enter several licenses, enter in one state and license number and then select "Add" to add the information to the record. Repeat until all of the physician's state licenses have been added, up to a maximum of five. Select the "Continue" button once all information is provided.

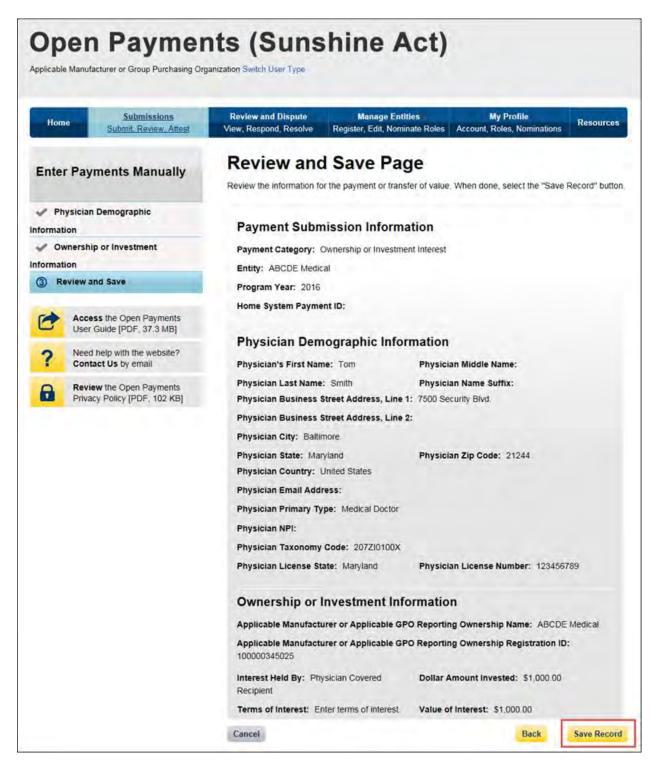


<u>Step 5:</u> Enter the ownership or investment interests information. Required fields are marked with asterisks.

Note that the total sum of the payment must exceed zero dollars. Correspondingly, either the "Dollar Amount Invested" or "Value of Interest" fields must have an amount greater than 0.00. The "Terms of Interest" field must contain a description of any applicable terms of the ownership or investment interests. When reporting the terms of any ownership or investment interests, provide the type of ownership or investment interests, 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. All special characters found on a standard U.S. keyboard can be used in the text box, not including ALT+NUMPAD ASCII Key characters. Once all information is entered, select "Continue to Review."



<u>Step 6:</u> Review the ownership or investment interests information entered in the previous pages. Select the "Back" button at the bottom of the page to go back and edit information if necessary. If the information is correct, select "Save Record" to continue.



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



Take note that once the data has been uploaded to the system and undergone these checks, it still must be <u>submitted</u> as final into the Open Payments system. Manual data entry only uploads the record and checks it to ensure that it adheres to a valid data format and matching requirements. **You must complete the final submission and attestation process for the data to be considered reported.** See Section 4.10 for details on final submission and Section 4.14 for details on attestation.

Section 4.6: Record Validation and Matching

Records submitted to the Open Payments system must pass several validation steps in order to become eligible for final submission and attestation. The steps are shown in Figure 4.2, below.

Figure 4.2: Validation Steps



Details on these types of validation are given below.

4.6a: Validation Step 1: File-Level Validation

Bulk files undergo validations before the records within the file are uploaded. If a file fails any of the file-level validations, no records from the file are uploaded to the Open Payments system. You will receive an email notifying you of the success or failure of the file upload based upon these validations. These emails are discussed in detail in Section 4.7a.

Bulk data files will not be accepted by the Open Payments system if any of the following errors are detected:

- The submitted file size is larger than 250 MB.
- The file is not in CSV or ZIP format.
- The file header row is not present.
- Columns are missing in the data file.
- The sample file used to create the submitted file and payment category of the file selected at upload do not match.
- The Applicable Manufacturer ID or Applicable GPO Registration ID included in the file's records does not match the Applicable Manufacturer or Applicable GPO Registration ID in the reporting entity's profile.
- The payment category selected in the dropdown menu on the Upload Payments page of the Open Payments system does not match the payment category of the submitted file.
- A value other than "Y" or "N" was entered for the Consolidated Report Indicator.
- The Consolidated Report Indicator value is not the same for all of the records in the file.
- The Applicable Manufacturer or Applicable GPO Making Payment Registration ID did not match the Applicable Manufacturer or Applicable GPO Registration ID and the Consolidated Report Indicator value was set to "N".
- The submitting user did not hold the submitter role with the reporting entity corresponding to the Applicable Manufacturer or Applicable GPO Making Payment Registration ID or Applicable Manufacturer Applicable GPO Registration ID in the record.
- The Applicable Manufacturer or Applicable GPO Making Payment Registration ID provided in the record does not exist in the Open Payments system.
- The Resubmission File Indicator in the uploaded file does not match the value selected for the Resubmission File Indicator drop-down menu on the Upload Payments page of the Open Payments system.

- The payment date in a record does not correspond to the Program Year selected on the Upload Payments page of the Open Payments system.
- The submitted template does not match the Program Year selected on the Upload Payments page of the Open Payments system.
- The Applicable Manufacturer or Applicable GPO Making Payment Registration ID is not included; this value is required for General Payment and Research Payment records.
- The Applicable Manufacturer or Applicable GPO Reporting Ownership Registration ID is not included; this value is required for Ownership/Investment records.
- The Resubmitted Payment Record ID has an invalid format or length.
- An invalid value was provided for the Delay in Publication of Research Payment Indicator.
- The required fields for update of delay in publication are not populated for all records in the file.
- The required fields for deletion are not populated for all records in the file.
- The required fields for new submission are not populated for all records in the file.
- The required fields for resubmission are not populated for all records in the file.
- A service within the Open Payments system was down and the file could not be processed.

4.6b: Validation Steps 2 and 3: Record-Level Validations

Step 2 validations are performed only on records submitted via bulk file upload before the records are saved into the Open Payments system.

Step 3 validations are performed on records submitted via bulk file upload after the record is saved. Records submitted manually undergo step 3 validations during the record entry process.

In both steps, individual records are checked to determine their validity, including whether:

- All required fields are populated;
- The information in each field meets the formatting requirements of that field; and
- If the record is submitted to change an existing record (i.e., the record is a resubmission or is intended to delete or renew the delay in publication of an existing record), an original version of the record exists within the Open Payments system.

Record field requirements are detailed in the Submission Data Mapping Documents, which are available on the Resources page of the Open Payments website

(<u>https://www.cms.gov/OpenPayments/About/Resources.html</u>). Refer to the Submission Data Mapping Document that corresponds to the record's program year.

4.6c: Validation Step 4: Record Matching

After a record passes record-level validations, the Open Payments system attempts to match the covered recipient information in the record (e.g., Physician First Name, Teaching Hospital Address, etc.) with a valid covered recipient using existing CMS resources and information. If the information in the record cannot be matched, the record will fail matching validation.

Section 4.7 Identifying Errors

The Open Payments system notifies users of errors in records via several means.

4.7a: Identifying Errors – Bulk File Upload

Errors in files or records submitted via the bulk file upload process are communicated to submitters via notification emails.

Determining the Step Where the Error Occurred

You can determine at what step the file or records failed based upon the format of the notification email.

- **Step 1 failure**: Email describes a file validation failure, the reason for the failure, and, if applicable, the line number of the submitted data file where the failure occurred.
- **Step 2 failure:** Email lists the reasons for record rejections, the number of records in the file that failed for each reason, and identifies up to a set number of records for each rejection reason.
- **Step 3 or 4 failure**: Email explains that records were rejected, provides instructions for locating the Error Log.

Note that if a bulk file submission makes it past Step 1, Steps 2-4 check records individually. Therefore, a bulk file might include records that fail at Step 2, records that fail at Step 3, records that fail at Step 4 and records that upload successfully.

If Errors Occur During File Validation (Step 1):

If your file fails initial validation (Step 1), the entire file will be rejected. No records in the file will be saved in the Open Payments system.

The notification email will state the reason for the failure, and, if applicable, the line number of the file where the failure occurred. Step 1 validations stop upon finding one error.

You will need to correct the error and reload the file to continue with processing. Refer to Section 4.8, "Correcting Records," for more information and further instructions.

If Errors Occur During Record Validation – Pre-Upload (Step 2)

Records that fail pre-upload validation checks (Step 2) will not be saved in the Open Payments system.

The notification email will state the reasons for record failures, the number of records from your file that failed for each reason, and up to a set number of Record ID numbers of records that failed for each reason.

The email will identify whether the number of records rejected exceeds the visible amount. If more records are rejected for a reason than can be displayed, contact the Open Payments Help Desk for the complete list of records rejected for that reason.

Records with Step 2 errors are not loaded into the Open Payments system and therefore are not available for review or correction within the Open Payments system, nor will they appear in an error log. You will need to correct record errors and resubmit the records. Refer to Section 4.8, "Correcting Records," for more information and further instructions.

If Errors Occur During Record Validation – Post-Upload (Step 3) or Matching Validation (Step 4)

Records that fail Steps 3 or 4 will be saved within the Open Payments system and can be reviewed and edited within the system.

The notification email for record failure of Steps 3 or 4 contains instructions on locating and downloading an Error Log that lists and details errors.

You may also identify records that failed Steps 3 and 4 by searching within the Open Payments system. To do so, follow the steps below:

<u>Step 1:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar.

<u>Step 2:</u> On the "Review Submitted Records" section, select the entity and program year for the records you wish to review, then select "Review Records."

<u>Step 3:</u> On the "Review Records" page, find the payment category (general, research, or ownership/investment) of the record(s) you wish to review, then select "View All." All records submitted for the reporting entity for that payment category and program year will display on the selected Payment Category page.

<u>Step 4:</u> Use the filters for "Record Status" to search for records in a "Failed Validation" and/or "Failed Matching" statuses.

- "Failed Validation" means that the data in at least one field in the record does not match the required formatting for that field.
- "Failed Matching" means that the covered recipient information in the record, including
 principal investigator information, cannot be matched to a valid covered recipient physician or
 teaching hospital.

You can download the record information returned by your search into a CSV file by selecting the "Download Zip File" link on the Payment Category page. The filters applied on the page will be applied

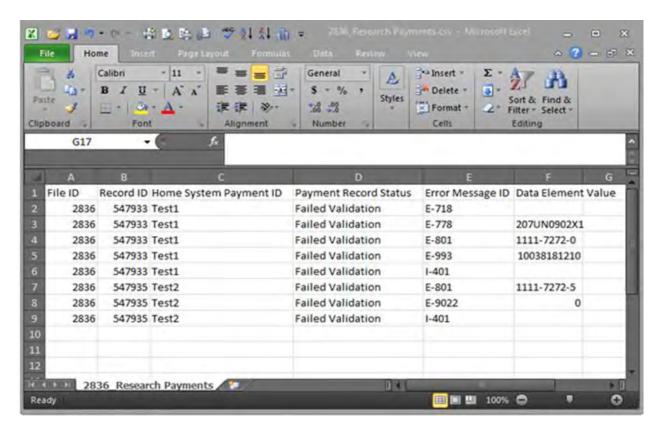
to the download. Downloaded data files cannot exceed the acceptable limit of 400,000 records. If your record volume exceeds the record limit, filter your search results by File ID to create smaller subsets of records and download them in multiple files. Note: the filter for Teaching Hospital CCN should not be used for downloading failed records, as it only returns records that have been successfully validated and matched. It will not return records with a status of "Failed Validation" or "Failed Matching."

To download an Error Log for records that failed Steps 3 or 4 and interpret the error codes it contains:

<u>Step 1:</u> Go to the table at the bottom of the Payment Category page, which will now be filtered for failed records per the process above. Select the hyperlink in the "File ID" column of a record you wish to examine. This will take you to the "File ID" page. (Note: the File ID page does not change based on any resubmissions or deletions made using manual or bulk file upload. The page is fixed during file upload.)

<u>Step 2:</u> On the "File ID" page, select the "Error Log" hyperlink at the bottom of the page to download the error log.

<u>Step 3:</u> Find the error code displayed in the "Error Message ID" column of the error log. A sample Error Log is shown below. The codes listed in the "Error Message ID" column are error codes. To clarify errors for data elements that have multiple fields and therefore may contain multiple values, such as physician license, the error log file column "Data Element Value" displays the specific value that produced the error.



<u>Step 4:</u> Once you have determined the error codes for each record, consult the Error Code Key, which is available on the Resources page of the Open Payments website at https://www.cms.gov/openpayments/About/Resources.html. The Error Code Key lists error IDs along with a description regarding the relevant data element name, an error description, and steps to avoid and correct the error.

To see errors on individual records in the Open Payments System

If a record fails steps 3 or 4, you can also see details of the failure in the individual record in the Open Payments system.

<u>Step 1</u>: Go to the table at the bottom of the Payment Category page. Filter the records as needed to locate the failed record to be examined.

<u>Step 2</u>: Select the hyperlink in the "Record ID" column for that record or select the "View" hyperlink under the "Actions" column. This will take you to the record's "Record ID" page.

<u>Step 3:</u> On the "Record ID" page, error messages for the record will be displayed at the top of the page. Error messages associated with data elements that can contain multiple values, such as physician license, will identify the specific value that produced the error in parentheses after the error message.

You will need to correct record errors and resubmit the records. Refer to Section 4.8, Correcting Records, for details.

4.7b: Identifying Manual Entry Errors

Records entered manually do not undergo Step 1 or Step 2 validations. Step 3 validations are applied during the manual data entry process, and any failures of Step 3 will trigger on-screen error messages. Manual entry of a record cannot be completed until all Step 3 errors are resolved.

Once a manually entered record has been uploaded, it undergoes Step 4 validations. Records that fail Step 4 validations will **not** trigger a notification email alerting you to their failure. Instead, you must go into the Open Payments system and search for records to determine whether any errors were encountered during this process.

To search the Open Payments system to find which records failed Step 4, follow the steps below:

- 1. Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar.
- 2. On the "Review Submitted Records" section, select the entity and program year for the records you wish to review, then select "Review Records."
- 3. On the "Review Records" page, find the payment category (general, research, or ownership/investment) of the record(s) you wish to review, then select "View All." All records submitted for the reporting entity for that payment category and program year will display on the selected Payment Category page.

4. Use the filters for "Record Status" to search for records in a "Failed Matching" status.

You can download the record information returned by your search into a CSV file by selecting the "Download Zip File" link on the Payment Category page. The filters applied on the page will be applied to the download. Downloaded data files cannot exceed the acceptable limit of 400,000 records. If your record volume exceeds the record limit, filter your search results by applying search criteria to create smaller subsets of records and download them in multiple files. Note: the filter for Teaching Hospital CCN should not be used for downloading failed records, as it only returns records that have been successfully validated and matched. It will not return records with a status of "Failed Validation" or "Failed Matching."

To see details of the failure in the individual record in the Open Payments system, follow the steps below:

- 1. Go to the table at the bottom of the Payment Category page, which will now be filtered for failed records per the process above. Select the hyperlink in the "Record ID" column for the record you wish to view or select the "View" hyperlink under the "Actions" column. This will take you to the record's "Record ID" page.
- 2. On the "Record ID" page, error messages related to this record will be visible.

You will need to correct record errors and resubmit the records. Refer to Section 4.8, Correcting Records, for details.

Section 4.8: Correcting Records

Records containing errors must be corrected and re-submitted until the records are free from errors. Once free from errors, you can complete the submission process for these records. Records can be corrected via bulk file upload or manual editing in the Open Payments system.

Note: Fields that identify the record's covered recipient or principal investigators cannot be changed once a record is in a "Ready for Attestation" or "Attested" status. If fields need to be changed in a record that is in a "Ready for Attestation" or "Attested" status, the original record must be deleted and then re-submitted as a new record. The attester is encouraged to use the assumptions statement to denote records that have been deleted and then re-submitted, including when those records were re-submitted after the submission deadline. Refer to section 4.14 for details about the assumptions statement. The relevant fields that identify the record's covered recipient or principal investigators are as follows:

- For physicians (including principal investigators): First Name, Last Name, NPI, License State, and License Number.
- For teaching hospitals: Teaching Hospital Name, the hospital address fields, and Taxpayer Identification Number.

Changing a record may affect the publication of that record, depending on when the changes are made. Refer to Chapter 8 of the Open Payments User Guide or the Data Dictionary and Methodology document for details.

4.8a: Correcting Records via Bulk File Upload

To correct records via bulk file upload:

<u>Step 1:</u> Create a new bulk data file containing the rejected or failed records with the identified errors corrected. In these corrected records, set the Resubmission File Indicator as explained below. Note that all records in a bulk file must have the same value for Resubmission File Indicator.

- If the file failed in steps 1 or 2, the Resubmission File Indicator for the records does not need to be changed from the original submission.
- If the record(s) in the file failed in steps 3 or 4, the record(s) must undergo resubmission or deletion and new records submitted in their place.
 - For resubmissions, each corrected record must have its "Resubmission File Indicator" value set to "Y" and the original record's Record ID provided in the updated record's "Resubmitted Payment Record ID" field.
 - o If the failed record must be deleted and replaced due to changes in identifying information (per the boldfaced text in the "Correcting Records" section above), consult the quick reference guide "Record Deletion" for instructions. Replacement records will be new submissions and should have a "Resubmission File Indicator" value of "N".

<u>Step 2:</u> Submit the record through the bulk file upload process. Instructions are available in Section 4.4, Bulk File Upload. After the bulk file is uploaded, the records must undergo final submission and attestation. Refer to Section 4.10, Final Submission and Section 4.14, Attestation and Assumptions.

4.8b: Correcting Records Manually

You can correct records manually, one at a time. To correct an individual record manually, follow these steps.

- Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/
 and select the "Submissions" tab on the toolbar. In the "Review Submitted Records" section, select the reporting entity whose record you wish to view and the program year for that record, and then select "Review Records."
- On the "Review Records" page, find the payment category (General, Research, or Ownership/Investment) of the record you wish to correct, and select the button labeled "View All."

- 3. Locate the desired record in the data table at the bottom of the "Payment Category" page. You can use the filtering tools on the page to help find a relevant record. Once you have found the record, select the "Edit" hyperlink in the "Actions" column for that record.
- 4. Update the record information and select "Submit."
- 5. The edited records must undergo final submission and attestation. Instructions are available in Section 4.14, Final Submission and Attestation.

Section 4.9: Deleting Records

Records submitted to the Open Payments system by applicable manufacturers and applicable group purchasing organizations may require deletion as part of validation, matching, or the review and dispute process. You can delete records individually through the graphic user interface or in bulk via bulk file. You may also delete a previously submitted bulk file, thereby deleting all records that had been submitted in that file.

The record deletion process varies depending upon the status of the records to be deleted. Records that had not yet been attested to will be immediately removed from the Open Payments system. Records that had been previously attested to will be placed in a "Marked for Deletion" status rather than immediately deleted. To complete the deletion of records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year, which includes attesting to the deletion of previously attested records. Until they are attested, and therefore removed from the system, records in "Marked for Deletion" status remain visible to covered recipients and are eligible for publication.

Records that are deleted through any of the methods described below cannot be recovered or viewed.

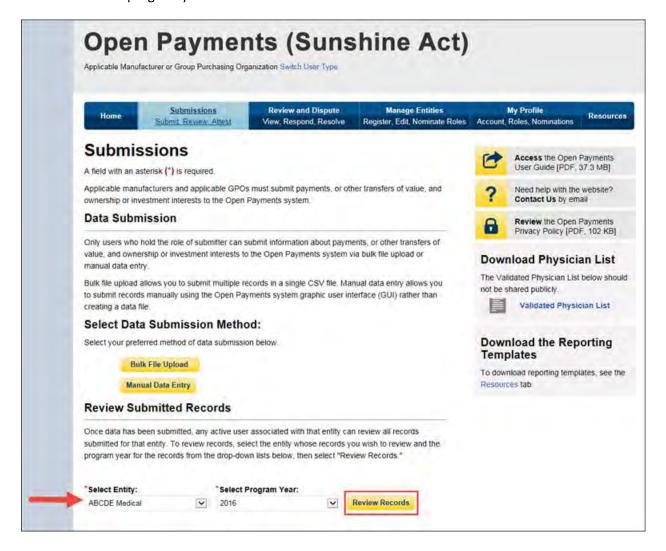
4.9a: Deleting a Bulk File

The process outlined below will delete all unattested records in a previously submitted bulk file and mark for deletion all attested records contained in the file.

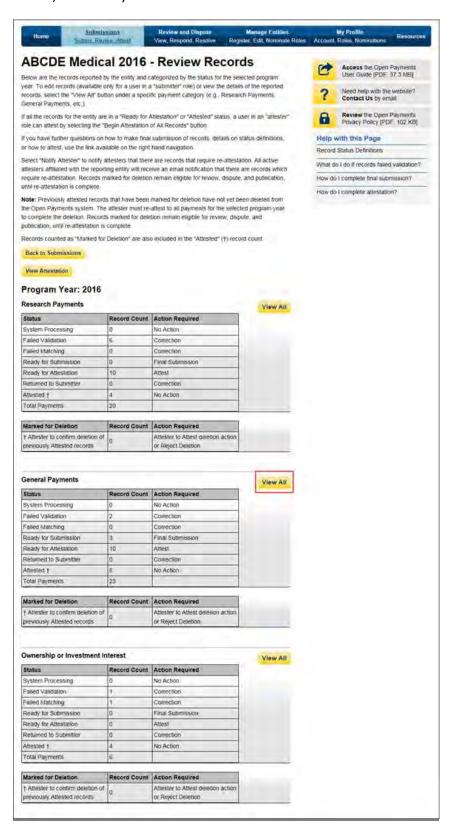
<u>Step 1:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar.



<u>Step 2:</u> On the "Review Submitted Records" menu, select the reporting entity whose records you want to delete and the program year for those records. Select "Review Records."



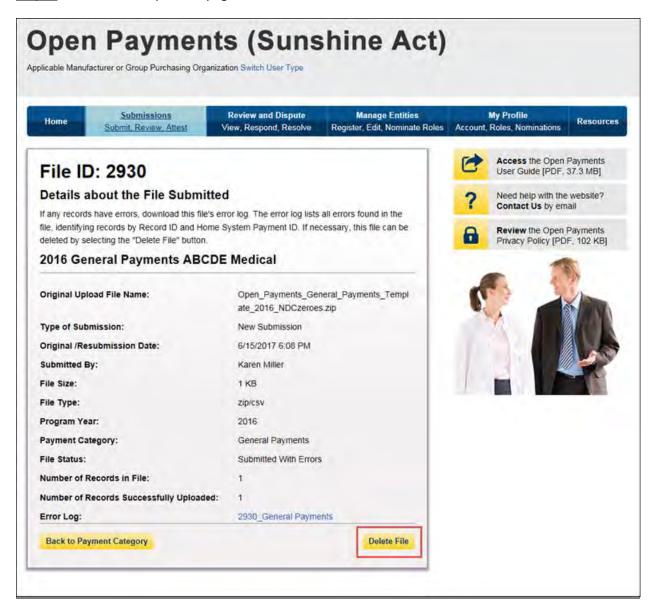
<u>Step 3:</u> On the "Review Records" page, find the payment category (General, Research, or Ownership/Investment) of the file you wish to delete and select the button labeled "View All."



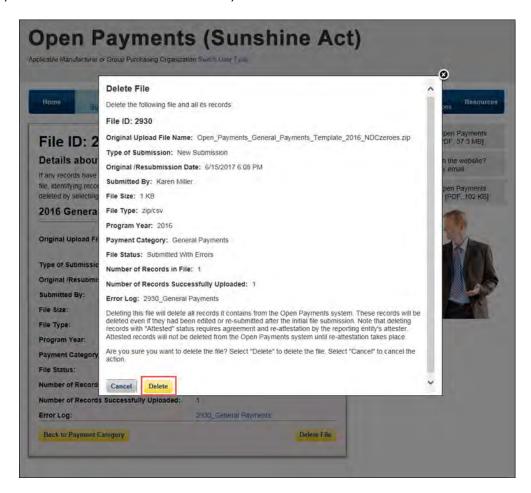
<u>Step 4:</u> At the bottom of the "Payment Category" page is a data table. Find one record from the file you wish to delete. Select the hyperlink in that record's "File ID" column.



Step 5: On the "File Properties" page, select "Delete File."



<u>Step 6:</u> An on-screen message will appear to confirm you want to delete the file. To proceed with deletion, select the "Delete" button. To cancel, select "Cancel."



If any records from this bulk file had been previously attested to, the previously attested records will not be immediately deleted but marked for deletion. To delete records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year.

4.9b: Deleting Records via Bulk File Upload

Records can be deleted through the creation and submission of a bulk file that instructs the Open Payments system to delete the records referenced. The process is outlined below.

<u>Step 1:</u> Create a bulk file for the record(s) you wish to delete. Set the "Resubmission File Indicator" for these record(s) to "D" and provide information for all of the required fields. Note that only the following fields are required for bulk file records intended for deletions:

- Applicable Manufacturer or Applicable GPO Registration ID;
- Consolidated Report Indicator;
- Resubmission File Indicator (must be "D" to delete records);

- Applicable Manufacturer or Applicable GPO Making Payment Registration ID;
- Resubmitted Payment Record ID; and
- Date of Payment (General and Research payment records only).

Information included in other fields will be ignored by the system.

<u>Step 2:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar. Select "Bulk File Upload."

<u>Step 3:</u> From the drop-down menus, select the appropriate Payment Category, Reporting Entity, and Program Year. For the Resubmission File Indicator value, select "Delete."

If the file is rejected, you will receive an email with an explanation on the reason for failure. Refer to Section 4.7 on identifying errors and Section 4.8 on record error correction.

Upon successful processing of this bulk file, the records it includes that have not yet been attested to will be deleted. Records included in this bulk file that had been previously attested to will be marked for deletion but remain in the system. To complete the deletion process for records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year.

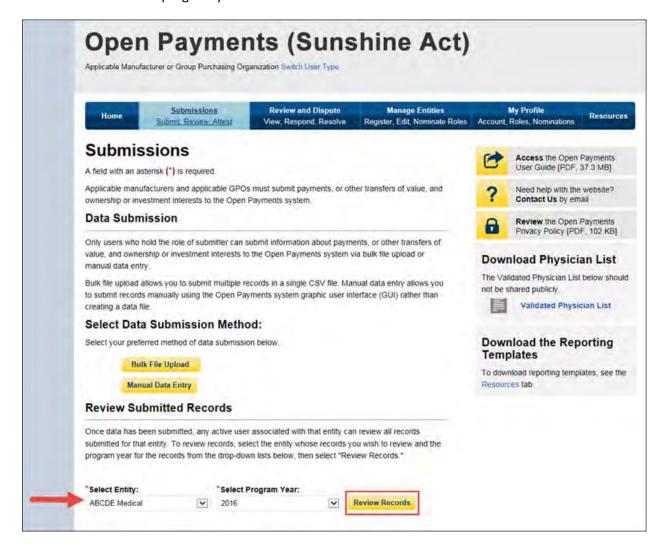
4.9c: Deleting a Record Manually

The process below will delete an individual unattested record and mark for deletion an individual attested record.

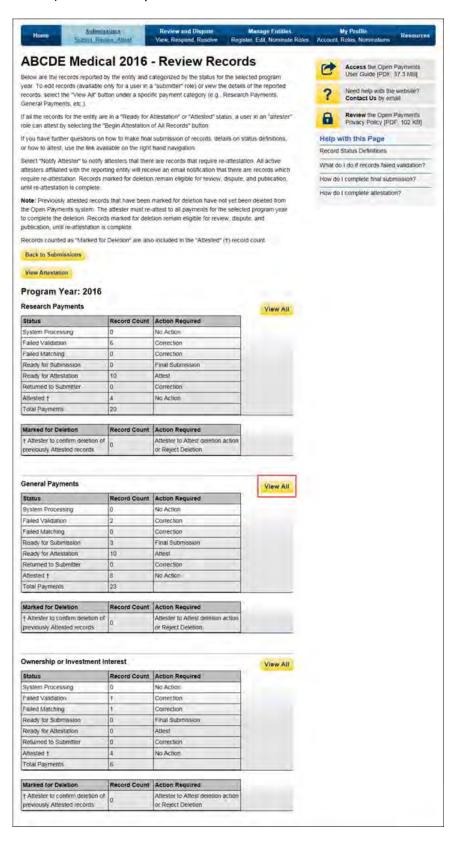
<u>Step 1:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar.



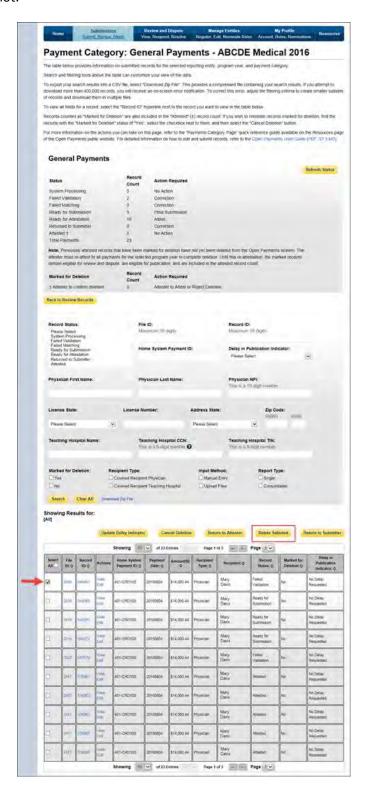
<u>Step 2:</u> Under the "Review Submitted Records" heading, select the reporting entity whose record you want to delete and the program year for those records. Select "Review Records."



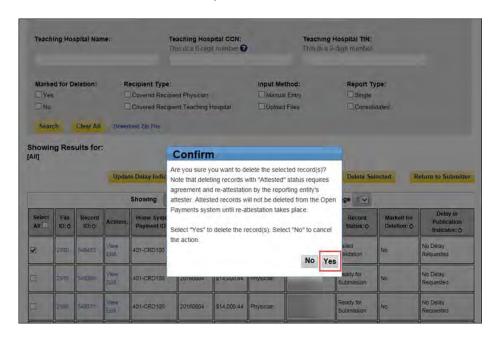
<u>Step 3:</u> On the "Review Records" page, find the payment category (General, Research, or Ownership/Investment) of the record you wish to delete and select the button labeled "View All."



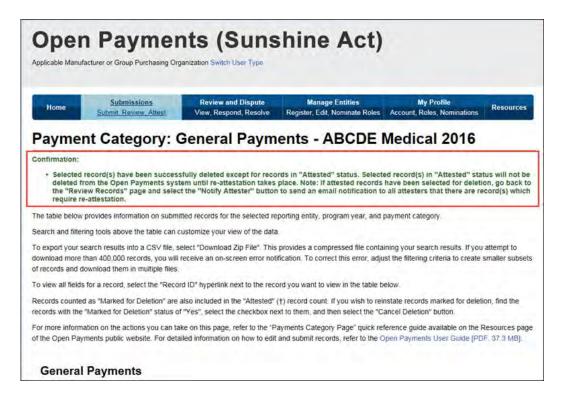
<u>Step 4:</u> At the bottom of the "Payment Category" page is a data table. To delete a record, select that record in the data table by selecting the corresponding checkbox and select the "Delete Selected" button. A confirmation message will be displayed prompting the user to confirm if they would like to delete the record or not.



<u>Step 5:</u> An on-screen message will appear to confirm you want to delete the file. To proceed with deletion, select the "Delete" button. To cancel, select "Cancel."



You will receive an onscreen notification of the deletion.



If the record had been previously attested to, it will not be immediately deleted but marked for deletion. To delete records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year.

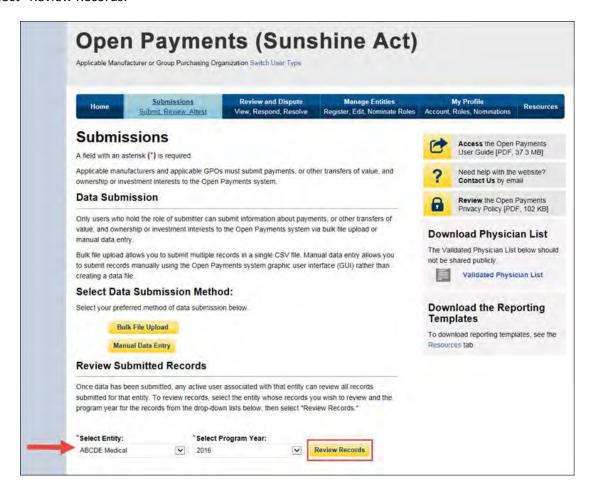
4.9d: Viewing Records Marked for Deletion

To find records that have been marked for deletion, follow the steps below.

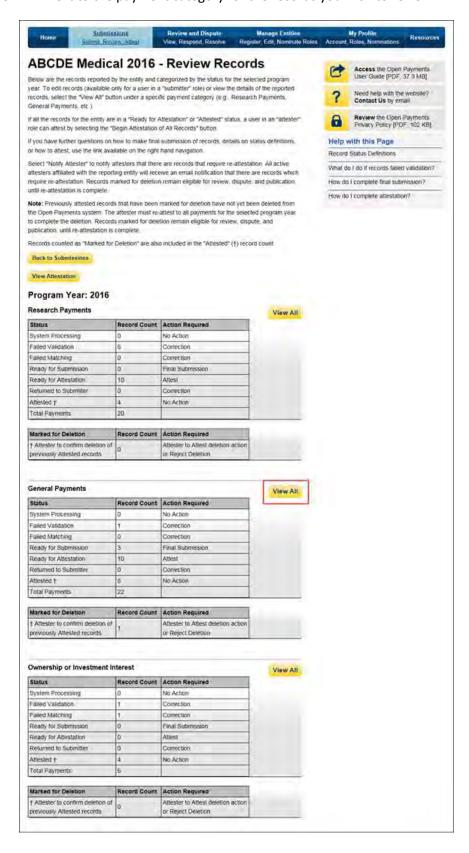
<u>Step 1:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab.



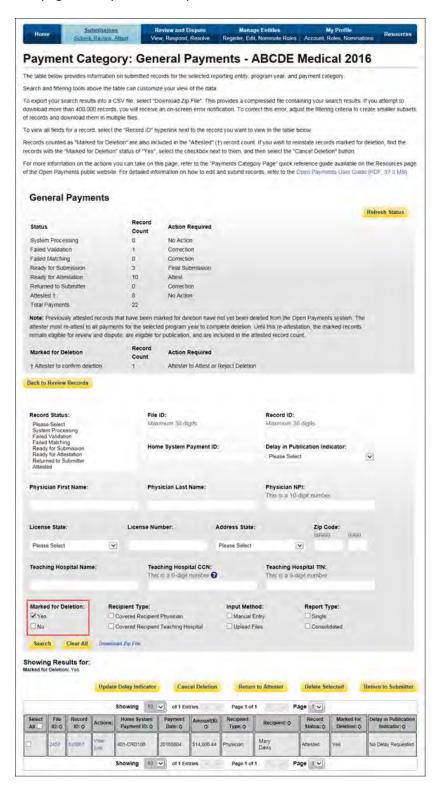
<u>Step 2:</u> From the "Submissions" tab, use the drop-down lists under the "Review Submitted Records" heading to select the reporting entity and program year for which you want to perform attestation and select "Review Records."



Step 3: Select "View All" next to the payment category for the records you wish to review.



<u>Step 4:</u> On the following page, in the Record Status filter box, check the box for "Yes" under the heading "Marked for Deletion." Select "Search." This will display all the records "Marked for Deletion." Return to the "Review Records" page when you are ready to attest.



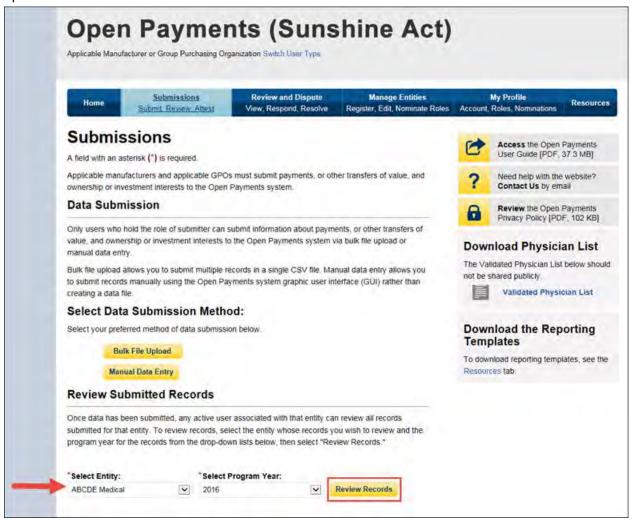
Section 4.10: Final Submission of Data

Final submission of data occurs after data has been uploaded and each record is error free. To perform final data submission, follow these steps.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials. Navigate to the Open Payments home page and select the "Submissions" tab.



<u>Step 2:</u> Select the entity and program year from the drop-down list for which the payments were uploaded and select "Review Records."



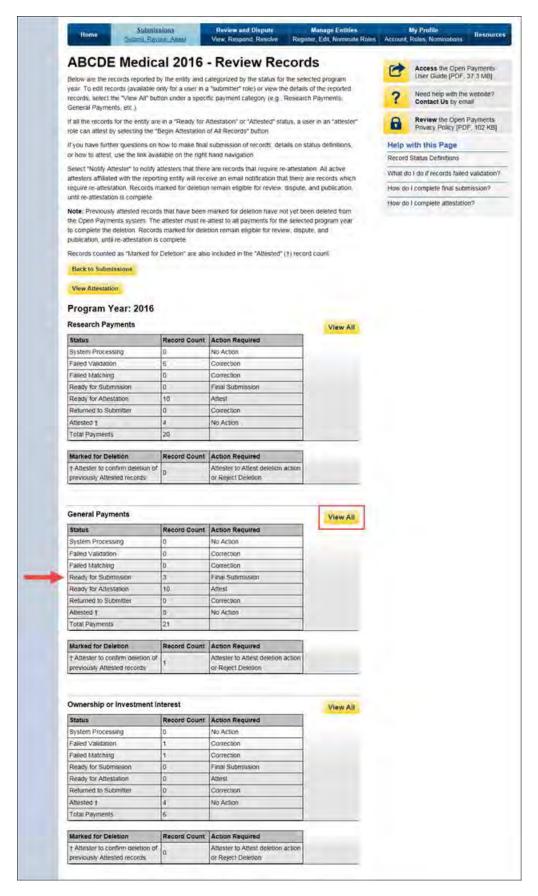
<u>Step 3:</u> On the "Review Records" page, you will see a summary of all records that have been submitted for that entity. The three payment types will be in separate boxes. In each box is a series of statuses and the number of records currently in that status for the entity. Note that the numbers displayed are for all records submitted for the entity to date for that program year. The statuses are the following:

- System Processing: Records being processed by the system for field validation checks.
- Failed Validation: Records which did not pass field validation checks.
- **Failed Matching:** Records which did not pass data matching checks. See Section 4.6 for information on data matching.
- **Ready for Submission:** Records which have passed field validation and data matching and are ready for final submission.
- Ready for Attestation: Records which have been successfully submitted and are ready for attestation.
- **Returned to Submitter:** Records returned to the submitter by the attester because the records contain errors and require correction.
- Attested: Records which have been attested to as accurate by the attester.

Below the statuses is **Total Payments**, which is the total number of records in the Open Payments system for that reporting entity and payment type.

Also visible is a count of the total number of records that have been **Marked for Deletion.** These are records that have been previously attested to and have been selected for deletion. They will continue to be counted with the other records until records for that program year are re-attested to, which will delete the records marked for deletion.

Select the payment category for which you wish to perform final submission and select "View All" to proceed.



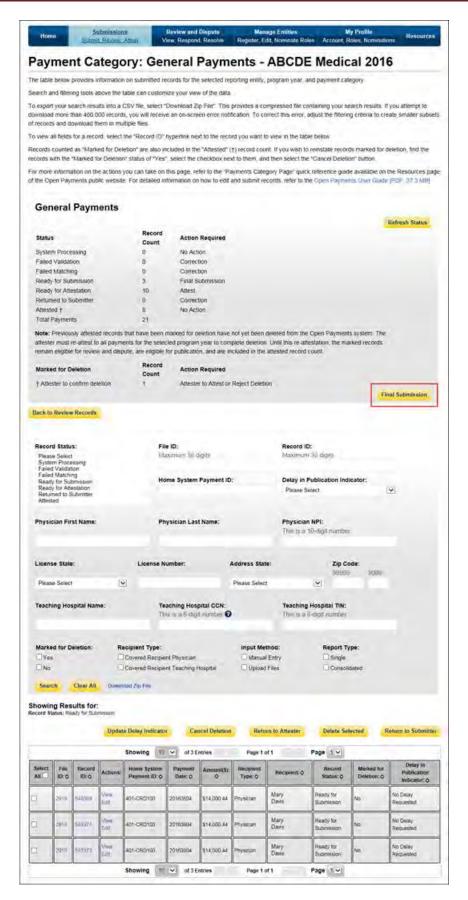
<u>Step 4:</u> The "Payment Category Page" displays all records submitted for the selected payment category and program year along with their processing status. To proceed with final submission, select "Final Submission."

The "Final Submission" button will only be visible once all records are in "Ready for Submission" status. If this button is not visible, review the status column on the left side of the page. If any records are in the statuses listed below, you cannot perform final submission for that payment type.

- System Processing Records that the Open Payments system is still processing and validating. Failed Validation - Records that did not pass field validation checks.
- Failed Matching Records that were not successfully matched to a valid covered recipient.
- Returned to Submitter Records in this status have been returned to the submitter by the attester for correction(s).

Records in "System Processing" status will change to another status automatically when processing completes. For guidance on correcting records that failed validation or matching validation, refer to Sections 4.7 and 4.8.

You can download the record information returned by searches on this page to a CSV file by selecting the "Download" link on the page. The download file will contain all of the columns of data displayed on the Payment Category page. Filters applied on the page will be applied to the download. Downloaded data files cannot exceed the acceptable limit of 400,000 records. If your record volume exceeds the record limit, apply filtering criteria to create smaller subsets of records and download them in multiple files. Note: the filter for Teaching Hospital CCN should not be used for downloading failed records, as it only returns records that have been successfully validated and matched. It will not return records with a status of "Failed Validation" or "Failed Matching."



<u>Step 5:</u> The following page will allow you to review summary details of your submission. If those details are correct, select "Submit as Final Submission."

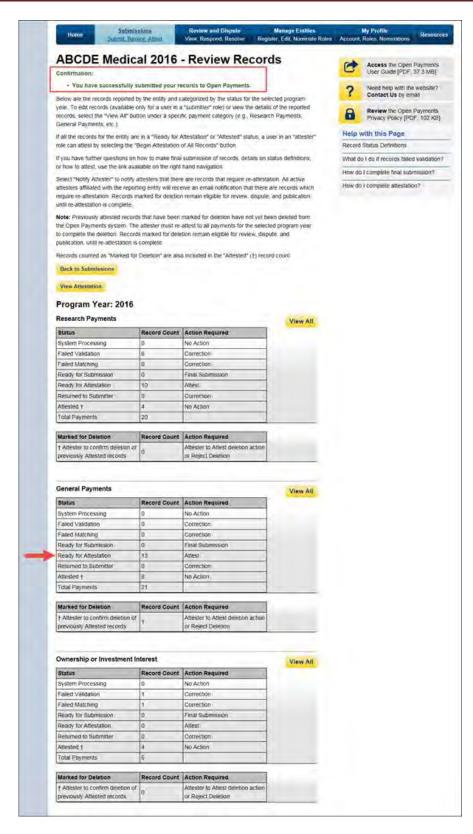


An email notification will automatically be sent to the attester informing them that there are records ready for attestation if, upon your selecting "Submit as Final Submission:"

- All records across all payment categories are in "Ready for Attestation" status and;
- No records for that program year have previously undergone attestation.

If any records for the program year have already undergone attestation and re-attestation is required, select the "Notify Attester" button once all records are ready for the attester to review. This button sends an email notification to the attester informing them that there are records ready for attestation. Re-attestation is required when any previously attested data is changed, including any data fields, delay in publication indicator, or if previously attested records are deleted. The "Notify Attester" button will only be enabled if there are records in "Attested" or "Ready for Attestation" status.

After final submission, an onscreen notification will appear on the "Review Records" page. The table for the payment category will show records in "Ready for Attestation" status.



Repeat the final submission process for all three payment categories. Once all records are in "Ready for Attestation" status, follow the instructions in Section 4.14 to complete attestation.

Section 4.11: Delay in Publication

Certain general or research payments or other transfers of value made to a covered recipient by an applicable manufacturer or applicable GPO may be delayed from publication. All payments or other transfers of value that are related to research, as defined in the Open Payments Final Rule, 42 C.F.R. § 403.902, and are made pursuant to a written research agreement for research related to new products, will be granted a delay in publication if one is requested. The Final Rule is available at https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf.

However, payments or other transfers of value related to research for new applications of products already on the market will be treated differently due to the statutory distinction between new products and new applications of existing products. Pursuant to the statute, payments related to research on new applications of existing products will be granted a delay only if the research does not meet the definition of "clinical investigation."

A delay in publication can only be requested up to a period of four years from date of payment. After four years have elapsed, the delayed records will be published.

Applicable manufacturers and applicable GPOs must request the delay in publication annually (up to four years) on records that have indicated a request for a delay in publication in a previous program year (if that designation is still applicable for that record). If the request for delay in publication is not renewed by the submission closing date for that program year, the record will be published.

Applicable manufacturers and applicable GPOs that do **not** request a delay in publication of a payment or other transfer of value should indicate within the record that no delay is requested. In addition, when a delay in publication is requested or renewed for a new program year, re-attestation of the record(s) must be completed by the submission closing date for that program year.

Records that have been delayed in publication can be reviewed by covered recipients and may be disputed.

4.11a: Eligibility for Delay in Publication

Records are eligible for a delay in publication if they relate to one of the following:

- Research or development of a new drug, device, biological, or medical supply.
- Research or development of a new application of an existing drug, device, biological, or medical supply.
- Clinical investigations regarding a new drug, device, biological, or medical supply.

4.11b: Initially Requesting a Delay in Publication

If you are manually submitting a record, you can request a delay in publication for that record using the "Delay in Publication of Research Payment Indicator" drop-down list, selecting either "R&D on New Product" or "Clinical Investigation on New Product" as appropriate.

- For general payment records, the delay in publication indicator is found on the "General Record Information" page.
- For research payment records, the delay in publication indicator is found on the "Research Payment or Other Transfer of Value Information" page.
- Ownership/investment records cannot be delayed.

For a general payment record, ensure that the name of the research study is displayed in the "Contextual Information" field. This is a free-form text field where you can also enter any additional information you deem helpful or appropriate information regarding the payment or other transfer of value.

If you are submitting a record via bulk file, you can request a delay in publication for that record by populating the record's "Delay in Publication of Research Payment Indicator" field. Enter a value of '1' to request a delay because the record relates to research and development on a new product or '2' to request a delay because the record relates to clinical investigation on a new product.

If the record is a general payment record, provide the name of the research study in the "Contextual Information" field as well as any additional information about the payment that might be helpful.

If the record is a research payment record that is not pre-clinical research, populate the fields "Name of Study." In the "Context of Research" field, you may provide any additional information about the payment that might be helpful.

4.11c: Updating a Delay in Publication

You may request that your payment records have their publication delayed for up to four years after the date of payment. The request for a delay must be renewed each year. If this request is not renewed each year by the end of the data submission period, the record will be automatically flagged for publication in the next publication cycle.

Records eligible for a renewal in delay of publication are marked with one of two Delay in Publication Indicator statuses during the submission period: "Pending Renewal – R&D on New Product" or "Pending Renewal – Clinical Investigation on New Product."

If these records do not have their delays in publication renewed by the end of the submission period, their Delay in Publication Indicator status will change to "Delay Not Renewed – R&D on New Product" or "Delay Not Renewed – Clinical Investigation on New Product." Records with "Delay Not Renewed" status will be eligible for publication in the next publication cycle.

You may also request that records previously delayed for publication be published. Those records will have their Delay in Publication status updated to "No Delay Requested" and become eligible for publication in the next publication cycle.

After renewing delay in publication flags via manual editing or bulk file upload, <u>all</u> records for that program year must undergo final submission and be attested to again for the delay to be accepted. Refer to Section 4.10 for guidance on final submission and Section 4.14 for guidance on attestation.

Instructions on finding records eligible for delay in publication renewals and the renewal process follow.

4.11c(1): Finding Records Eligible for a Renewal in Delay in Publication

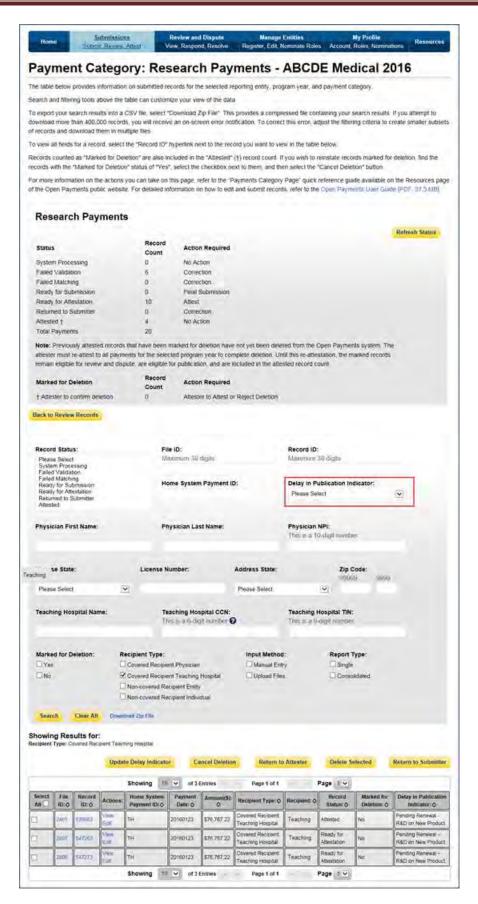
To find which records previously delayed for publication are eligible for delay in publication renewal, follow the steps below.

<u>Step 1:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/. Select the "Submissions" tab on the menu bar.

<u>Step 2:</u> Under the "Review Submitted Records" section on the "Submissions" home page, select the entity whose records you wish to review and the program year for those records. Select "Review Records."

<u>Step 3:</u> On the "Review Records" page, find the payment category of the record you wish to review and select the button labeled "View All." Note: Delays in publication can only be requested for general and research payment records.

<u>Step 4:</u> Search for the records eligible for renewal on the payment category page (i.e., Research Payments page or General Payments page) by using the "Delay in Publication Indicator" filter above the data table to search for records with a Delay in Publication status of either "Pending Renewal – R&D on New Product" or "Pending Renewal – C.I. on New Product." You may also select any other search filter(s) as appropriate.



4.11c(2): Updating a Delay In Publication Indicator via Bulk File Upload

Users can update Delay in Publication of existing records(s) via bulk file upload through two methods: by setting the "Resubmission File Indicator" field to Resubmit ("Y") or Renew Delay in Publication ("R").

- To update the delay in publication field only, you can set the "Resubmission File Indicator" field to "R". Records renewed via this process will not be revalidated nor sent through the matching process again. Note there are fewer fields required for files submitted via this process.
 - This process can only be performed on records in "Ready for Submission", "Ready for Attestation," or "Attested" record status.
 - O This process cannot be used to change the delay in publication indicator value from "3= No Delay Requested" to "1= R&D on New Product" or "2= Clinical Investigation on New Product." To change the delay in publication indicator value from 3 to 1 or 2, you must perform a full resubmission ("Resubmission File Indicator" is set to "Y").
- The process where the "Resubmission File Indicator" field in each record set to "Y" is a full resubmission. The record must include all required fields. Records renewed via this process will undergo revalidation and the matching process. This process can be performed on records in any record status.

4.11c(2)a: Update Delay in Publication Indicator via Resubmission File Indicator Set to "R"

To update by setting the "Resubmission File Indicator" field in each record to "R", follow these steps.

<u>Step 1:</u> Create a bulk file for the record(s) you wish to update, with the "Resubmission File Indicator" set to "R." Note that all records in the bulk file must have the same "Resubmission File Indicator" value.

Only the following fields are required. Information in other fields will be ignored by the system.

- Applicable Manufacturer or Applicable GPO Registration ID;
- Consolidated Report Indicator;
- Resubmission File Indicator (must be "R" for this process);
- Applicable Manufacturer or Applicable GPO Making Payment Registration ID;
- Resubmitted Payment Record ID (the "Record ID" assigned to the original record by the Open Payments system);
- Date of Payment; and
- Delay in Publication of Research Payment Indicator.
 - To renew a delay in publication: Set the indicator to '1' if you are requesting a delay because the record relates to research and development on a new product, or '2' if you are requesting a delay because the record relates to clinical investigation on a new product.

 To indicate a delay is no longer requested: Set the indicator to '3,' which indicates no delay is requested.

<u>Step 2:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar. Select "Bulk File Upload."

<u>Step 3:</u> On the "Upload Records" page, select the Payment Category, Reporting Entity, and Program Year for the bulk file. For the Resubmission File Indicator dropdown, select "Renew Delay in Publication." Select the appropriate file to upload, then select "Submit File to Open Payments."

You will receive email notifications regarding your file and record processing statuses. If the records upload successfully, the Delay in Publication Indicator and the Last Modified Date and Time will be updated for the record(s) and the record(s) will be placed in "Ready for Submission" status. If the records do not upload successfully, you will receive an email identifying the issue(s). Review the email to determine the issues, correct the records, and resubmit. For more details, refer to Sections 4.6 and 4.7.

<u>Step 4:</u> To complete the submission process, proceed with final submission and re-attestation of the records for that program year. Refer to Section 4.10 for instructions on final submission and Section 4.14 for instructions on the attestation process.

4.11c(2)b: Update Delay in Publication Indicator via Resubmission File Indicator Set to "Y"

The process below can be performed to update most data elements on the record, including the Delay in Publication indicator. Records updated via this process will go through the entire matching and validation process upon resubmission, and are not restricted to records in certain record statuses.

<u>Step 1:</u> Create a bulk file for the record(s) you wish to update. The record must include all fields required by the Submission Data Mapping Document. In addition:

- The "Resubmission File Indicator" for all records must be set to "Y."
- The Resubmitted Payment Record ID must be the "Record ID" assigned to the original record by the Open Payments system.
- Provide a value for the "Delay in Publication of Research Payment Indicator" field.
 - To Renew a Delay in Publication: Set the value to '1' if you are requesting a delay because the record relates to research and development on a new product, or '2' if you are requesting a delay because the record relates to clinical investigation on a new product.
 - To Indicate a Delay is No Longer Requested: Set the value to '3,' which indicates no delay is requested.
- For a general payment record, if you are selecting a value of '1' or '2', ensure that the name of the research study is displayed in the "Contextual Information" field, as well as any additional information you deem helpful regarding the payment or other transfer of value. "Contextual Information" is not required if you select a value of '3.'

<u>Step 2:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar. Select "Bulk File Upload."

<u>Step 3:</u> On the "Upload Records" page, select the Payment Category, Reporting Entity, and Program Year for the bulk file. For the Resubmission File Indicator dropdown, select "Resubmission." Select the appropriate file to upload, then select "Submit File to Open Payments."

You will receive email notifications regarding your file and record processing statuses. If the records do not upload successfully, you will receive an email identifying the issue(s). For more details on record correction, refer to Sections 4.6 and 4.7. If the records uploaded successfully, proceed to step 4.

<u>Step 4:</u> To complete the submission process, proceed with final submission and re-attestation of the records for that program year. Refer to Section 4.10 for instructions on final submission and Section 4.14 for instructions on the attestation process.

4.11c(3): Updating the Delay in Publication Indicator via Manual Data Entry

Users can update Delay in Publication of existing records(s) via manual data entry through two methods:

- Using the edit functionality; and
- Using the Delay in Publication Update button.

Both methods are explained below.

4.11c(3)a: Updating the Delay in Publication Indicator via Manual Data Entry – Using Edit Functionality To manually update the delay in publication status of a general or research payment record using the edit functionality, follow the steps below. Note: Records updated via this process will go through the entire matching and validation process.

<u>Step 1:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar. On the "Review Submitted Records" menu, select the reporting entity whose record you wish to view and the program year for that record, and then select "Review Records."

<u>Step 2:</u> On the "Review Records" page, find the payment category (General or Research) of the record you wish to update and select the button labeled "View All."

<u>Step 3:</u> Locate the record you wish to update in the data table, using the filtering tools if necessary. Select "Edit" from the "Actions" column for that record.

<u>Step 4:</u> If it is a general payment record, navigate to the record's "General Record Information" page. If it is a research payment record, navigate to the "Research Payment or Other Transfer of Value Information" page.

 To Renew a Delay in Publication: From the "Delay in Publication of Research Payment Indicator" drop-down, select either "R&D on New Product" or "Clinical Investigation on New Product." For

a general payment record, ensure that the name of the research study is displayed in the "Contextual Information" field, as well as any additional information you deem helpful or appropriate regarding the payment or other transfer of value.

• <u>To Indicate No Delay is Requested</u>: Select "No Delay Requested" from the "Delay in Publication of Research Payment Indicator" drop-down. The record will then be eligible for publication in the next publication cycle.

<u>Step 5:</u> Select "Continue to Review," then "Save Record" to save the changes.

<u>Step 6: Complete</u> the submission process by putting the record through final submission and re-attesting to the records for that program year. Refer to Section 4.10 for instructions on the final submission and Section 4.14 for instructions on the attestation process.

Note: Records updated via this process will go through the entire matching and validation process.

4.11c(3)b: Updating the Delay in Publication Indicator via Manual Data Entry – Using Delay in Publication Update Functionality

You can update the delay of publication of general and research payment record(s) from the Payment Category page using the "Update Delay Indicator" button. Note: records updated through this process do not undergo re-validation and re-matching.

To use this process, the records must be in the "Ready for Submission", "Ready for Attestation", or "Attested" status. To manually update the delay in publication status of records in other statuses, you must use the process described in Section 4.11c(3)a above.

Also, this process cannot be used to update a Delay in Publication Indicator value of "No Delay Requested" to "R&D on New Product" or "Clinical Investigation on New Product." To manually update a record in that manner, you must use the process described in the Section 4.11c(3)a above.

<u>Step 1:</u> Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar. On the "Review Submitted Records" menu, select the reporting entity whose record you wish to view and the program year for that record, and then select "Review Records."

<u>Step 2:</u> On the "Review Records" page, find the payment category (General or Research) of the records you wish to update and select the button labeled "View All."

<u>Step 3:</u> Locate and select the records you wish to update in the data table, using the filtering tools if necessary.

Step 4: Select the "Update Delay Indicator" button.

<u>Step 5:</u> The Update Delay in Publication Indicator page will be displayed. From the drop-down menu "Delay in Publication Indicator", select one of three options:

- R&D on New Product;
- Clinical Investigation on New Product; or
- No Delay Requested.

Records updated through this process do not undergo re-validation and re-matching. The status of the records will be updated to "Ready for Submission".

<u>Step 6:</u> Complete the submission process by putting the file through final submission and re-attesting to the records for that program year. Refer to Section 4.10 for instructions on the final submission and Section 4.14 for instructions on the attestation process.

4.11d: Delay in Publication – Publication Impact

The publication impact of Delay in Publication statuses is as follows:

- Records with a Delay in Publication status of "Delay Requested" will not be published in the next publication cycle.
- Records with a Delay in Publication status of "No Delay Requested" will be published in the next publication cycle.
- If no action is taken on records with a Delay in Publication status of "Pending Renewal" by the end of the submission period, the records will be eligible for publication. These records will be published in the next publication cycle.
- Research or general payment records will be published in the fifth year after the date of payment regardless of requests for delay in publication.

Section 4.12: Consolidated Reporting

One reporting entity, under common ownership with other reporting entities, may submit and attest to data in the Open Payments system on behalf of those other reporting entities. This process is called consolidated reporting. Consolidated reporting can be performed only via bulk file upload and is not available through manual entry.

Each individual entity contributing to the consolidated report is required to register in the Open Payments system separately.

The individual user who submits the consolidated report must hold the user role of submitter for all reporting entities included in the consolidated report. The individual user who attests to the consolidated report must hold the user role of attester for all entities included in the consolidated report. Note: the attester must hold an "officer" position (e.g., Chief Executive Officer, Chief Financial Officer, etc.) with the entity that submits the report but does not need hold such a position within all of the entities included in the report.

Within the Open Payments system, payment records are affiliated with the individual entities that made the payment, not the entities that submitted the records. Similarly, payment information submitted in consolidated reports will be published as though the information had been submitted by the individual entities. The information will not be published under the submitting entity's name.

Each record's "Record ID" page provides the name of the entity that made the payment and the name of the entity that submitted the payment record. Similarly, "Covered Recipient Demographic Information" pages include the name of the entity that made the payment and the name of the entity that submitted the payment record.

4.12a: Performing Consolidated Reporting

To perform consolidated reporting, create separate bulk file(s) for the payment types (general, research, or ownership/investment) that contain payment data from all of the reporting entities included in the consolidated report. For each record:

- Set the "Consolidated Indicator" field in each record within the file to "Y."
- Provide the name and Open Payments registration ID for the entity <u>submitting</u> the consolidated report in the fields "Applicable Manufacturer or Applicable GPO Name" and "Applicable Manufacturer or Applicable GPO Registration ID."
- Provide the name and Open Payments registration ID for the entity that <u>made the individual</u> <u>payment or other transfer of value</u> in the fields "Applicable Manufacturer or Applicable GPO Making Payment Name" and "Applicable Manufacturer or Applicable GPO Making Payment Registration ID." This may be the same as the entity submitting the file.

The entity names and registration IDs in the records must match exactly those provided during Open Payments registration.

Once the records are complete, submit the bulk file(s) normally. Note that each entity's records must be attested to separately. Attesting to the records of one of the reporting entities does not attest to all records for all reporting entities in that consolidated report.

The following is an example of how a consolidated report works:

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. Within the bulk data file, each record lists Entity A's information in the "Applicable Manufacturer or Applicable GPO Name" and "Applicable Manufacturer or Applicable GPO Registration ID" fields. The "Applicable Manufacturer or Applicable GPO Making Payment Name" and "Applicable Manufacturer or Applicable GPO Making Payment Registration ID" fields for each record contains the information for the entity that made that particular payment (Entity A, B, or C).

The submitter of the file must hold 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. to attest to records from all three entities.

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. When the data is published, the records for Entity A, Entity B, and Entity C will be listed under their own names.

Section 4.13: 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 the Open Payments system on behalf of a reporting entity. A specific individual within the third party must be identified as the submitter, not the third party 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 User Guide for validating and submitting data.

Section 4.14: Attestation and Assumptions

Data attestation is how reporting 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. The attester will be able to attest to the accuracy, completeness, and timeliness of the data. This applies to all resubmissions as well.

Attestation completes the submission process. Records are not considered fully submitted until attestation is performed upon them. Records attested to after the submission closing date for that respective program year will be flagged as late.

Attestation is conducted for all records for that program year, across all three payment types.

Therefore, all records for the program year must be in "Ready for Attestation" or "Attested" status for attestation to be performed (i.e., the records have successfully undergone final submission or have been attested to previously).

If the attester believes any of the records are in error, he or she may decline to attest to the records and return selected data to the submitter for correction and review. To do so, the attester selects the records to be returned to the submitter and then selects the "Return to Submitter" button. The submitter must perform the corrective actions requested by the attester or indicate that no action is required. The payment record(s) must then be re-submitted for attestation. Once the submitter has made the corrections or has determined no corrections are necessary, the submitter selects the "Return to Attester" button to notify the attester that records are again ready for attestation.

The attester has the option of submitting an assumptions statement during the attestation process. Assumptions explain the reasonable assumptions made, methodologies used, and unusual circumstances that may have occurred when reporting payments, other transfers of value, or ownership or investment interests. Assumptions will be documented in 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) and can be edited later.

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.

4.14a: Attestation Statements in the Open Payments System

Below are the attestation statements presented to attesters in the Open Payments system. Attesters are required to confirm these statements by selecting the checkboxes next to each applicable statement. The first two statements must be selected to proceed with the attestation process. The other statements should be selected as applicable.

Note that if a reporting entity is deleting one or more previously attested records, the entity will be required to re-attest and confirm the deletion of the record(s). Entities deleting records as part of the attestation are encouraged to select the sixth attestation statement in addition to the first two.

The text in the Open Payments system reads as follows:

- 1. I attest that I am a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer for the reporting applicable manufacturer or applicable GPO with the authority to attest to the information submitted in the Open Payments system.
- 2. I attest that the information reported is timely, accurate, and complete to the best of my knowledge and belief.
- I attest 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 C.F.R. § 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, biologicals, or medical supplies. Therefore, my entity is only required to report payments or other transfers 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 Food and Drug Administration 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 attest 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 transfers 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 attest that my entity is submitting a consolidated report because it is under common ownership, as defined by 42 C.F.R. § 403.902, with a separate entity or entities that are also applicable manufacturers.
- 6. I am attesting to the action that my entity has deleted one or more records, which have previously been attested, and I am re-attesting that my entity's information reported is accurate and complete to the best of my knowledge and belief.

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. See Section 4.12 for more information on consolidated reporting.

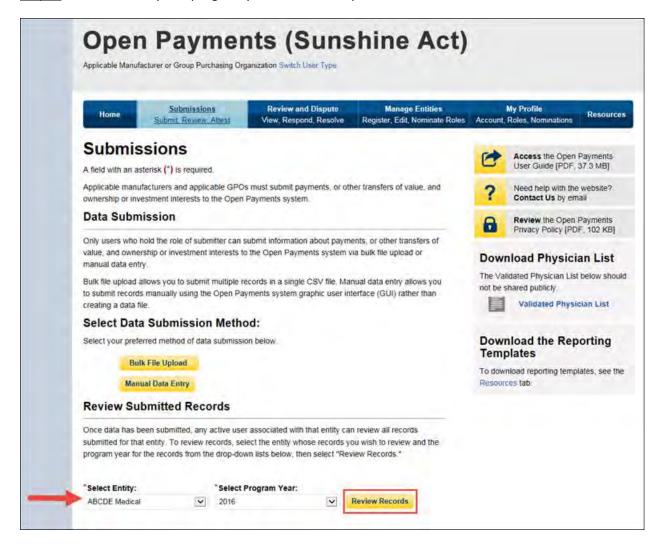
4.14b: Attesting to Data in the Open Payments System

The following instructions show the step-by-step pages for the attestation process. Remember that all records must be in "Ready for Attestation" status (or "Attested" status in the case of re-attestation) to complete these steps.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "Submissions" tab on the Open Payments system home page.



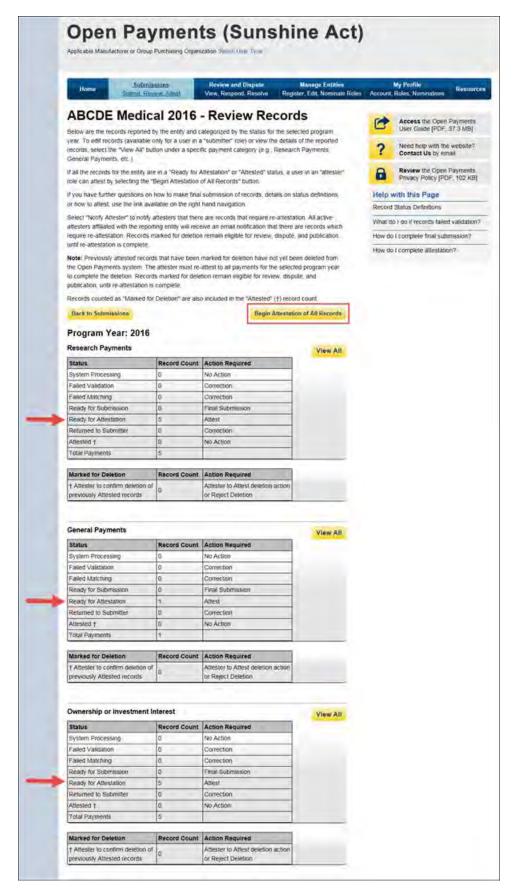
Step 2: Select the entity and program year from the drop-down lists and then select "Review Records."



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

If the "Begin Attestation of All Records" button is not visible, check that there are records for that program year in "Ready for Attestation" or "Attested" status. If there are not, contact a submitter for the reporting entity and alert him or her that records need to be advanced to "Ready for Attestation" status (i.e., undergo final submission) before attestation can begin.

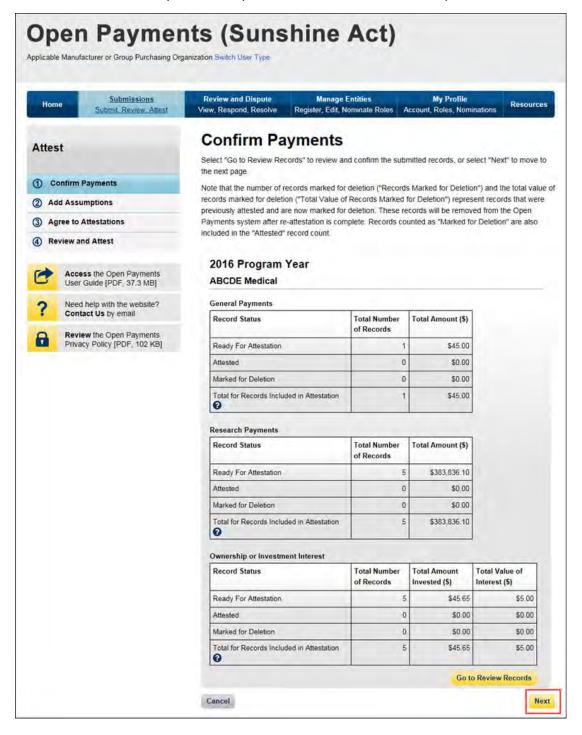
To view records in "Marked for Deletion" status, select "View All" next to the payment category for the records you wish to examine. On the following page, in the Record Status filter box, check the box for "Yes" under the heading "Marked for Deletion." Select "Search." Return to the "Review Records" page when you are ready to attest.



Step 4: Review the payment information on this page.

Select the "Go to Review Records" button to view details on the records being attested.

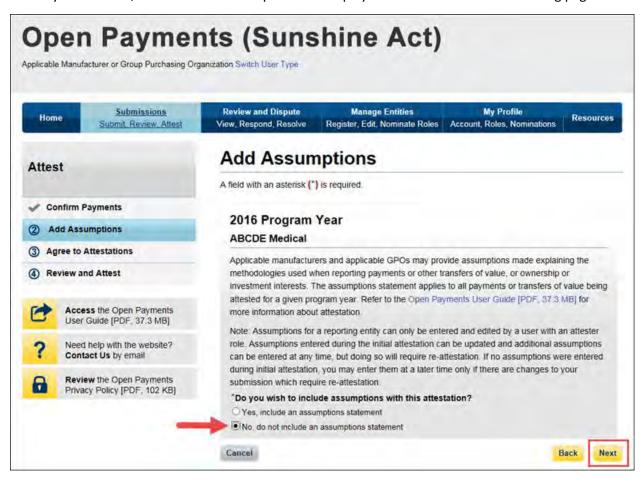
Select the "Next" button when you are ready to continue with the attestation process.

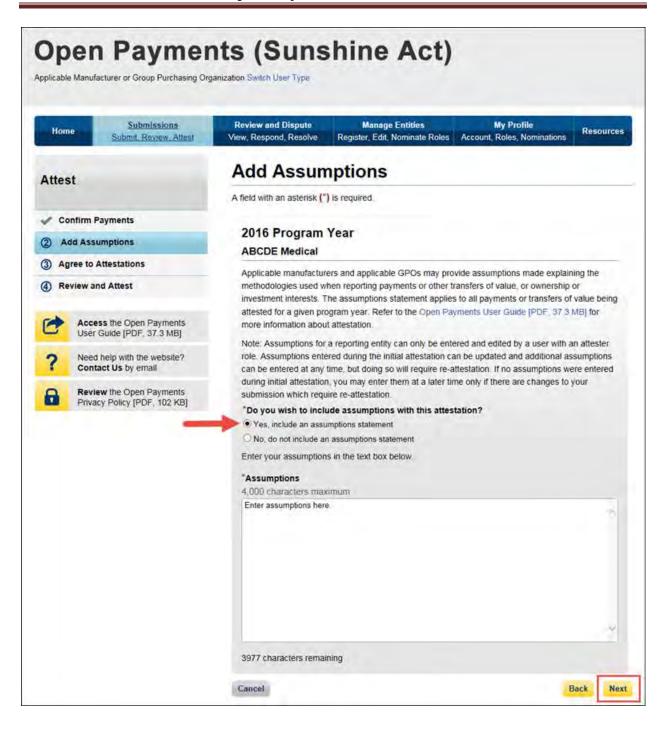


<u>Step 5:</u> Next, the option to add assumptions associated with these records is presented. Select "No" if you will not provide assumptions. Select "Yes" if you will provide assumptions. If you select "Yes," a free-form text field will appear. If assumptions have previously been entered for these records, those assumptions will be in the text box and can be edited.

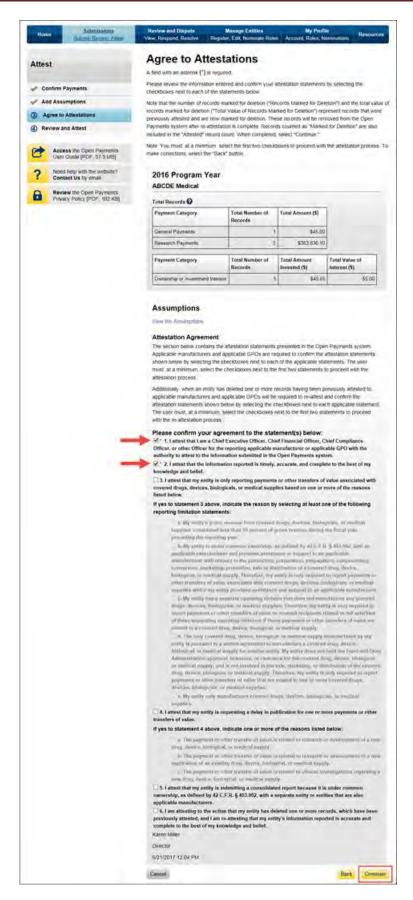
Type or paste your assumptions into this field, which has a 4,000-character limit. The text field allows all special characters found on a standard U.S. keyboard, not including ALT+NUMPAD ASCII Key characters. This text field can be edited later.

When you are done, select "Next." Both options are displayed below and onto the following page.

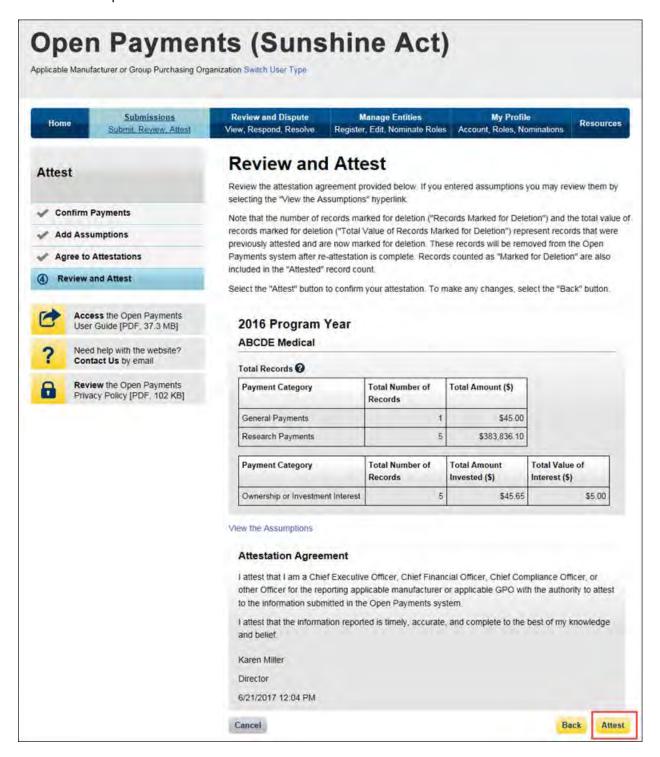




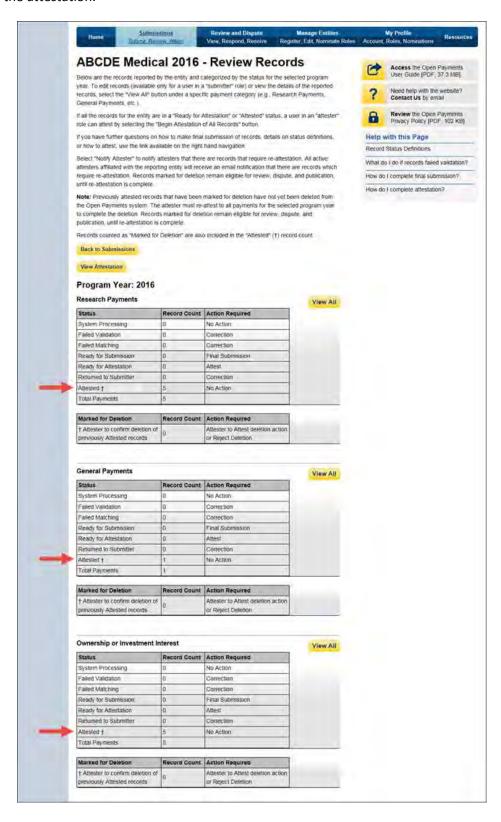
<u>Step 6:</u> Read and agree to the attestations shown on the page below. You **must** agree to attestation statements 1 and 2 to complete the attestation process. Attestation statements 3 through 5 should be reviewed and selected only if they apply to your reporting entity and the payments being attested to. If you are attesting to the deletion of records, it is strongly encouraged you agree to statement 6. The text of these statements is provided earlier in this section. Once the appropriate attestations have been chosen, select "Continue."



<u>Step 7:</u> 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 all attester(s) notifying them of the success of the attestation.



Review and Dispute For Industry

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

This chapter provides information on the review, dispute, and correction process for applicable manufacturers and applicable GPOs.

This chapter is divided into the following sections:

- **Review, Dispute, and Correction Overview** provides information on the review and dispute process within the Open Payments system.
- Acknowledging Disputes and Resolving Disputes with No Change provides information on how
 applicable manufacturers and applicable GPOs can acknowledge and resolve disputes initiated
 by physicians, teaching hospitals, and principal investigators. The "resolved, no change" action
 acknowledges that the applicable manufacturer or applicable GPO and the physician, teaching
 hospital, or principal investigator have resolved the dispute in accordance with the guidance in
 the Final Rule, and no changes to the data were needed.
- Correction and Resolution of Disputed Data provides information on how applicable manufacturers and applicable GPOs can make corrections to disputed data to resolve disputes.

Section 5.1: Review, Dispute, and Correction Overview

When an applicable manufacturer or applicable GPO has submitted records regarding payments, other transfers of value, or physician ownership or investment interests to the Open Payments system, the physicians and teaching hospitals identified in records have an opportunity to review those records. If a physician or teaching hospital finds discrepancies with the submitted data, they can initiate a dispute. Applicable manufacturers and applicable GPOs can then work with the disputing party to resolve the dispute.

Note: a physician principal investigator may only dispute his or her association with a research payment record and his or her own personal identifying information.

Records that have been delayed in publication can be reviewed and disputed by the covered recipients identified in the record.

Dispute resolution takes place outside of the Open Payments system. Nevertheless, the status of the dispute resolution should be captured within the Open Payments system. **CMS will not mediate**

disputes between physicians, physician principal investigators, teaching hospitals, and reporting entities. Reporting entities should work with the disputing party directly to resolve disputes. Only users who hold the role of submitter with the applicable manufacturer or applicable GPO will be able to perform activities related to review, dispute, and correction of record(s).

The process is outlined in **Figure 5.1**, below.

Figure 5.1: Review, Dispute, and Correction Process

Review Activities	Dispute Activities	Correction Activities
 Physicians, teaching hospitals, and physician principal investigators may review data submitted about them before it is published. 	Physicians, teaching hospitals, and physician principal investigators dispute information reported about them or their institutions if they find inaccuracies.	 Applicable manufacturers and applicable GPOs work with the disputing party to correct disputed data, or agree that no change to data is necessary to resolve the dispute.
	 Physician principal investigators may only dispute their association with a research payment record and their personal identifying information they may not dispute other information, such as the amount. 	Applicable manufacturers and applicable GPOs re-submit and attest to corrected records, if necessary.

5.1a: Review, Dispute and Correction Period

Each program year has a scheduled review, dispute, and correction period. This period begins with a 45-day period for physicians, teaching hospitals, and physician principal investigators to review, dispute, and work with the reporting entity to resolve the dispute or disputes. Immediately following the initial 45-day period is an additional 15-day correction period for reporting entities to make final corrections to records and resolve any active disputes. Records that are flagged for delay in publication by the reporting entity are still eligible for review and dispute by physicians, teaching hospitals, and physician principal investigators.

Note that although there is a distinct review, dispute, and correction period, these activities can be performed throughout the year. The designated review and dispute period only affects when and how the dispute is displayed in the initial data publication and subsequent data refresh. For details on data publication, and how the timing of disputes and corrections impacts how the data is published, see Chapter 8.

If you cannot resolve a dispute with a physician, teaching hospital, or physician principal investigator within the 60-day review, dispute, and correction period for a program year, all parties should continue

to seek a resolution until the dispute is resolved. Once the dispute is resolved and any necessary corrections are made, the data will be updated in a subsequent publication based on when the corrections were made in the Open Payments system.

When a dispute resolution results in changes to or deletion of a record, applicable manufacturers and applicable GPOs must re-submit the record with the revisions to the Open Payments system. Then, the revised record must be re-attested to by the applicable manufacturer or applicable GPO to be considered fully submitted.

5.1b: Review and Dispute Statuses

Records in the review and dispute process will have one of the following review and dispute statuses:

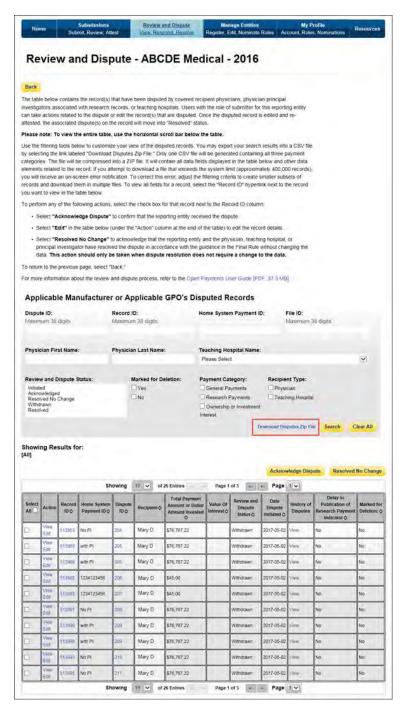
- Initiated: Indicates that a physician, teaching hospital, or physician principal investigator has initiated a dispute against a record submitted by an applicable manufacturer or applicable GPO.
- Acknowledged: Indicates that an applicable manufacturer or applicable GPO has received and acknowledged a dispute initiated against them by a physician, teaching hospital, or physician principal investigator.
- Resolved, No Change: Indicates that the applicable manufacturer or applicable GPO and the
 physician, teaching hospital, or physician principal investigator have resolved the dispute in
 accordance with the guidance in the Final Rule and no changes were made to the disputed
 record.
- Withdrawn: Indicates that a physician, teaching hospital, or physician principal investigator 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 re-submitted and re-attested to by the applicable manufacturer or applicable GPO.

This chapter explains how applicable manufacturers and applicable GPOs acknowledge, resolve with no change, and resolve disputes with corrections in the Open Payments system. Chapter Nine, "Review and Dispute for Physicians, Teaching Hospitals, and Principal Investigators," explains how physicians, teaching hospitals, and physician principal investigators initiate and withdraw disputes.

Email notifications are sent to alert applicable manufacturers, applicable GPOs, physicians, teaching hospitals, and physician principal investigators of review and dispute activities in the Open Payments system. These emails contain only the information necessary to locate the record in the Open Payments system and do not contain contact information for any of the parties involved in the dispute. Users will need to access the dispute in the system to determine the dispute details. The Reporting Entity Contact Information for disputes included in your entity's profile is available on the "Record ID" page of each individual record.

5.1c: Exporting Disputed Data

The Open Payments system now allows users to download disputed data into a separate CSV file. Records are exported into a pipe ("|") delimited CSV file by selecting the link labeled "Download Disputes" from your entity's "Review and Dispute" page. The file will be compressed into a ZIP file. It will contain all data fields displayed in the table and other data elements related to the dispute. Downloaded data files cannot exceed the acceptable limit of 20,000 records. If your record volume exceeds the record limit, apply filtering criteria to create smaller subsets of records and download them in multiple files. To download, select the "Download Disputes Zip File" hyperlink.



Section 5.2: Acknowledging Disputes and Resolving Disputes with No Change

Applicable manufacturers and applicable GPOs have the option to acknowledge disputes initiated by physicians, teaching hospitals, and physician principal investigators. This status does not indicate agreement or acceptance of the dispute by the reporting entity and is only meant to serve as a notification to the physician, teaching hospital, or physician principal investigator that the dispute has been received by the reporting entity.

When the dispute status is changed to "Acknowledged" or "Resolved, No Change," the physician, teaching hospital, or physician principal investigator will receive an email notification of the status update. This email notification may help reduce the chance of a physician, teaching hospital, or physician principal investigator disputing a record multiple times, as they will receive notification that the dispute review process is underway.

When a record undergoes revision to address a dispute, that record will not be visible to the physician, teaching hospital, or physician principal investigators identified in it, until the record is re-attested. (Note that this does not occur on records whose disputes were resolved without changes to the data.) The record will return to the view of the physician, teaching hospital, or physician principal investigators only after the record regains "attested" status. The acknowledgement email can serve as a receipt, confirming to the disputing party that the record exists and the dispute received.

The five steps of the process are given in **Figure 5.2** below.

Figure 5.2: Acknowledging Disputes and Resolving Disputes with No Change Process



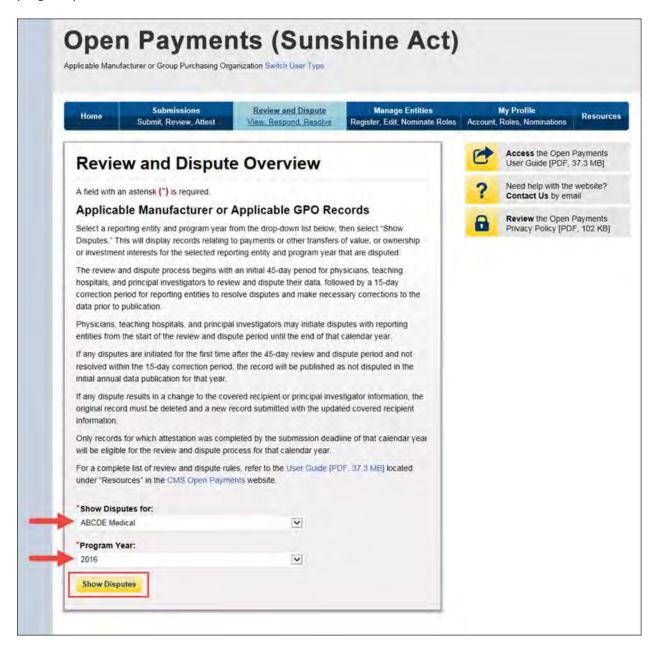
The specific steps to acknowledge a dispute and to set a disputed record to the status of "Resolved, No Change," are given below.

5.2a: Acknowledging a Dispute

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.



<u>Step 2:</u> Select the reporting entity name and the 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 in that program year.



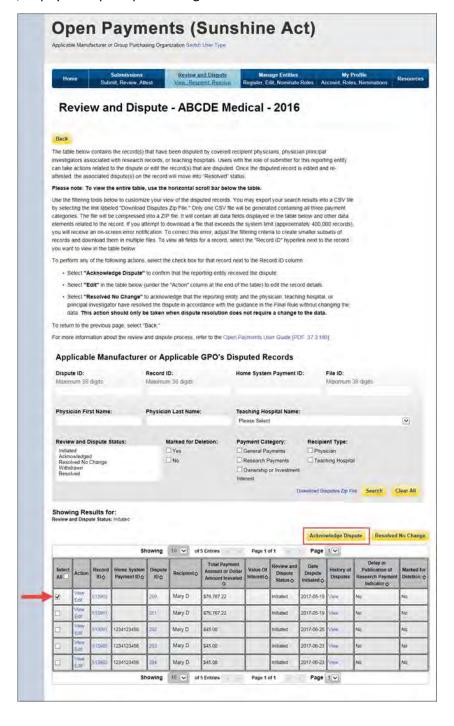
<u>Step 3:</u> On the Review and Dispute page, you will see a list of all data disputes that were initiated by physicians, teaching hospitals, and physician principal investigators.

If you wish, you may filter the records by using the search criteria options that are shown. You do not need to filter the results in order to proceed. For instructions on how to export this data, see Section 5.1c. To view all fields for an individual record, select the "Record ID" hyperlink in the record's row in the table. To view details about a disputed record, select "View" under the "Actions" column. Review the information on the Record ID page. When finished, select "Back."

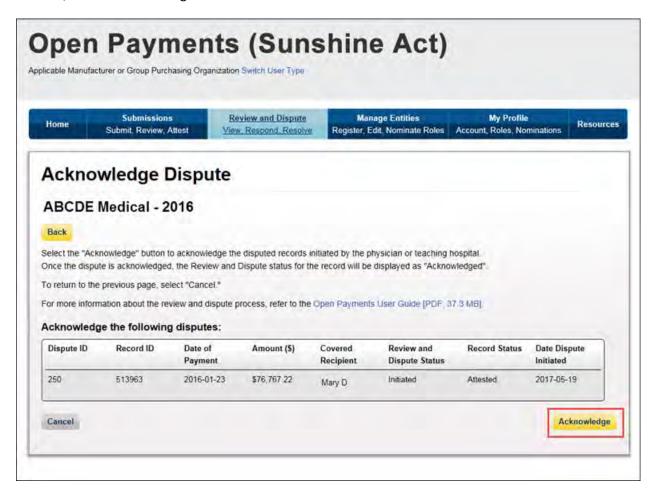


<u>Step 4:</u> Select the checkboxes next to the disputed record(s) you wish to acknowledge. Once you have selected the appropriate record(s), select "Acknowledge Dispute." You may only acknowledge disputes with a review and dispute status of "Initiated."

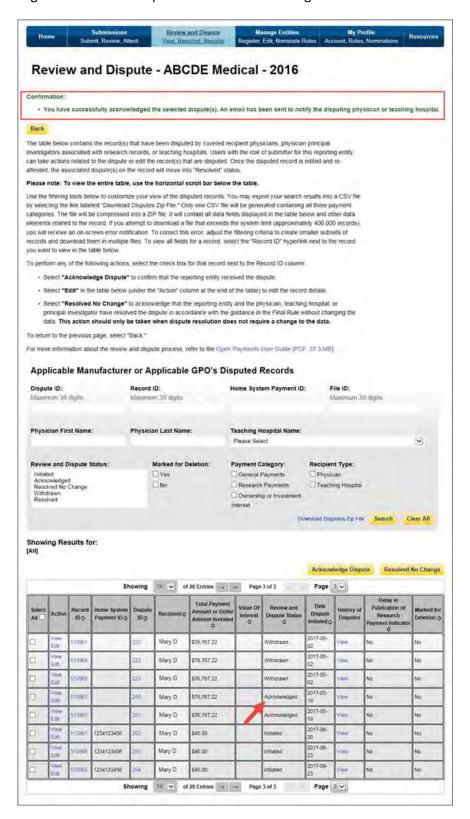
If you wish to view the detailed history for a record's dispute, select "View" under the "History of Disputes" column. This will display the History of Disputes page for that record, which displays information for the record and any comments regarding the dispute entered by the disputing physician, teaching hospital, or physician principal investigator.



<u>Step 5:</u> Review the disputed record information as displayed on the Acknowledge Dispute page. When finished, select "Acknowledge."



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



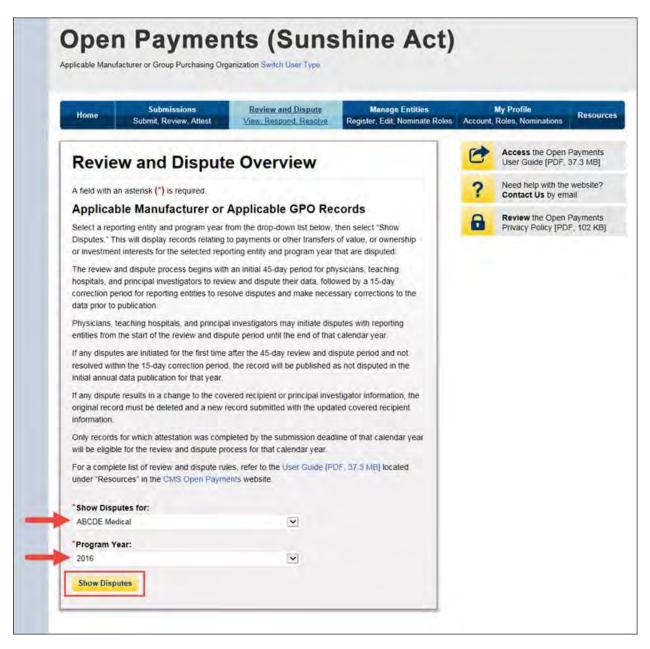
5.2b: Resolved, No Change Disputes

The "Resolved, No Change" status means that the applicable manufacturer or applicable GPO and the physician, teaching hospital, or physician principal investigator have resolved the dispute in accordance with the guidance in the Final Rule, and the record in the Open Payments system does not require correction.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.



<u>Step 2:</u> Select the reporting entity name and the 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 in that program year.



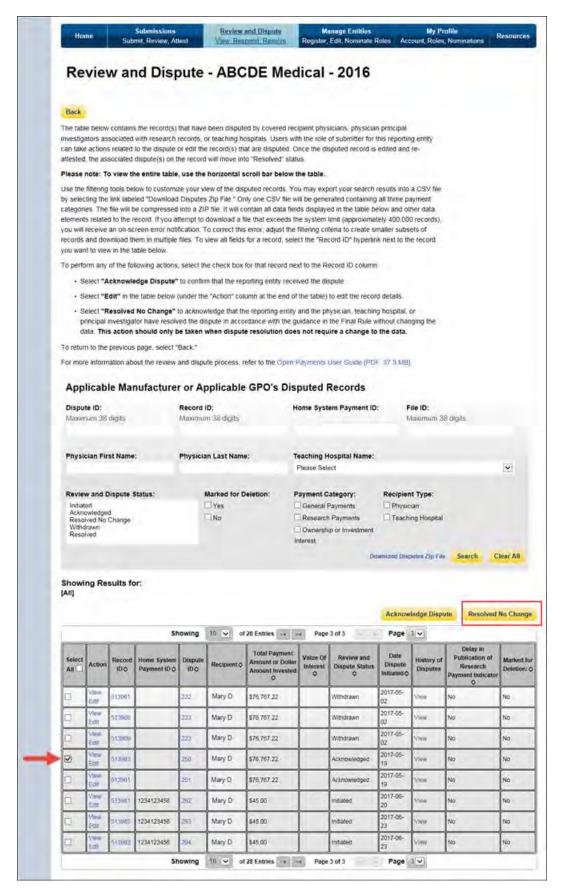
<u>Step 3:</u> On the Review and Dispute page, you will see a list of all data disputes that were initiated by physicians, teaching hospitals, and physician principal investigators. If you wish, you may filter the records by using the search criteria options that are shown. You do not need to filter the results to proceed. For instructions on how to export this data, see Section 5.1c.

To view all fields for an individual record, select the "Record ID" hyperlink in the record's row in the table. To view details about a disputed record, select "View" under the "Action" column.

Select the checkboxes next to the disputed 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 if you and the disputing physician, teaching hospital, or physician principal investigator have resolved the dispute in accordance with the guidance in the Final Rule.

If you wish to view the detailed history for a record's dispute, select "View" under the "History of Disputes" column. This will display the History of Disputes page for that record, which shows information for the record and any comments regarding the dispute entered by the disputing physician, teaching hospital, or physician principal investigator.

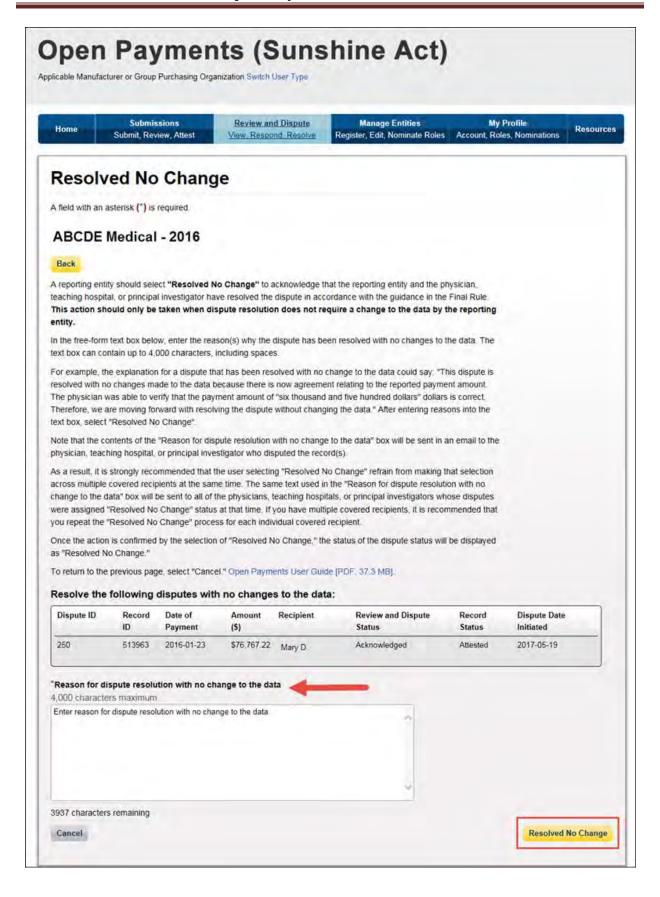


<u>Step 4:</u> Review the disputed record information as displayed on the "Resolved, No Change" page. In the text box, you must enter the reason the dispute was resolved without changes made to the data. The text box can contain up to 4,000 characters, including spaces. All special characters found on a standard U.S. keyboard can be used, not including ALT+NUMPAD ASCII Key characters.

An email notification will be sent to the physician, teaching hospital, or physician principal investigator informing them that their dispute has been resolved with no changes made to the data. The email will include the explanation provided in the "Reason for dispute resolution with no change to the data" box. If disputes on multiple records are resolved without changes in the same action (e.g., multiple records are selected and then the "Resolved No Change" button is selected), the explanation provided in the "Reason for dispute resolution with no change to the data" text will be sent to all of the covered recipients included in the disputes marked as "Resolved No Change."

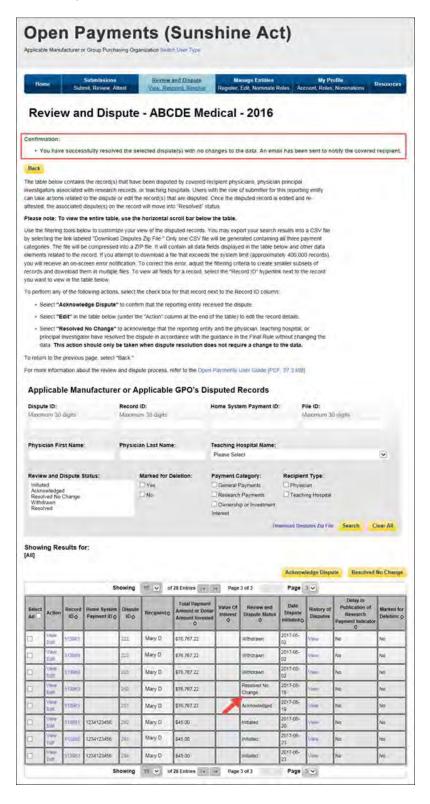
If the reasons for dispute resolution vary for each record disputed, perform the actions above separately for each dispute to ensure the correct reasons are provided to the correct disputing physicians, teaching hospitals, or physician principal investigators; otherwise, the disputing covered recipient may see an explanation that was meant for a different covered recipient.

When you have entered in the information you wish to include in the text box, select "Resolved No Change."



The following confirmation message will be displayed on the page.

Note that the physician, teaching hospital, or physician principal investigator may initiate a new dispute for the same record if the dispute has not been resolved to their satisfaction.



Section 5.3: Correction, Resolution, and Deletion of Submitted Payment Data

Once a dispute is initiated by a physician, teaching hospital, or physician principal investigator, the reporting entity should work directly with the disputing party to correct the disputed data. CMS will not mediate disputes between physicians, teaching hospitals, physician principal investigators, and reporting entities.

If a correction to a record is needed to resolve a dispute, the corrected record must be re-submitted and then re-attested to. If the re-submission is made via bulk file upload, the "Record ID" for the record(s) must be included in the re-submission. If the re-submission is made manually, the record(s) should be located in the Open Payments system and edited using the edit function. See Section 5.3a below for more information.

After re-attestation to the corrected records is complete, the physician, teaching hospital, or physician principal investigator will receive an email notification that the record(s) has been edited and the dispute resolved.

The five steps of the correction and resolution process are given in Figure 5.3 below.

Figure 5.3: Correction and Resolution Process



Note: If the dispute resolution changes any of the fields that identify the covered recipient, the original record must be <u>deleted</u> and <u>resubmitted as a new record</u>.

- For physicians (including principal investigators), these identifying fields are First Name, Last Name, NPI, License State, and License Number.
- For teaching hospitals, these identifying fields are Teaching Hospital Name, the hospital address fields, and Taxpayer Identification Number.

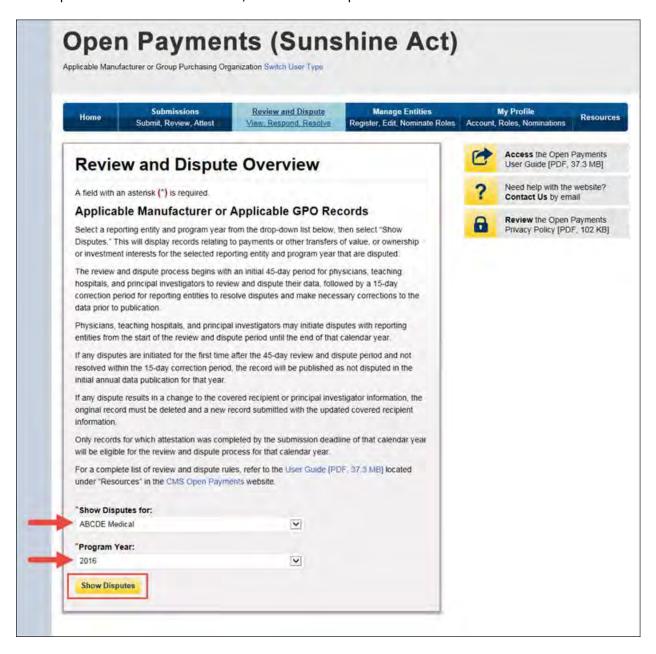
Deletion and resubmission may affect the publication timing of the record. Refer to Chapter 8 for publication rules.

5.3a: Edit Information and Resubmit Record

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.



<u>Step 2:</u> Select the reporting entity name and the program year for which you wish to view disputes from the drop-down menus. When finished, select "Show Disputes."



<u>Step 3:</u> On the Review and Dispute page, you will see a list of all data disputes that were initiated by physicians, teaching hospitals, and physician principal investigators.

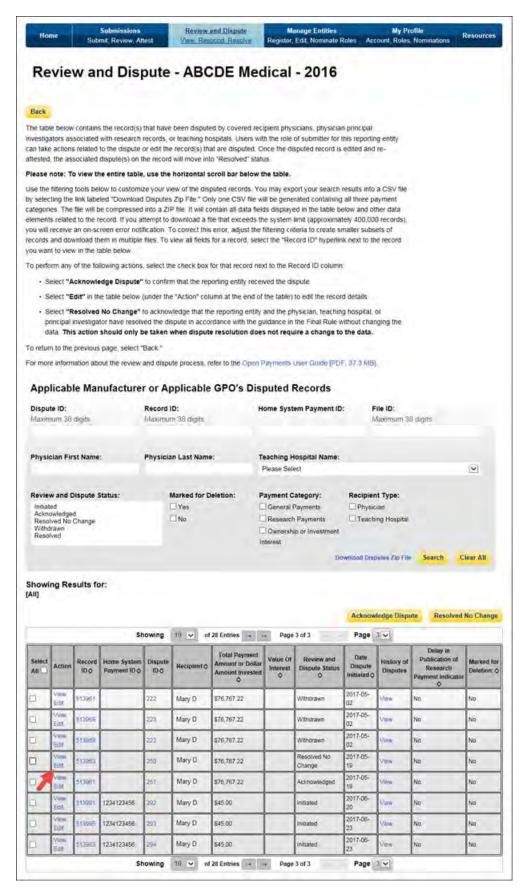
If you wish, you may filter the records by using the search criteria options that are shown. You do not need to filter the results in order to proceed. To view details about a disputed record, select "View" under the "Actions" column. For dispute resolution, a useful filter would be to filter for records with a "Review and Dispute Status" of "Acknowledged" and/or "Initiated," as you can only update and/or correct record(s) with a review and dispute status of "Initiated" or "Acknowledged." For instructions on how to export this data, see Section 5.1c.

To manually edit a record, select "Edit" under the "Actions" column and edit the appropriate fields. For instructions on how to manually edit a record, see Section 4.8b. To manually delete a record, follow the instructions in Section 4.9c.

To edit a record via bulk file upload, create a bulk data file that contains the records to be corrected. In each record in this bulk file, you must set the "Resubmission Indicator" to "Y" and enter the original Record ID created by the Open Payments system in the "Resubmitted Payment Record ID" field. This is necessary for the system to accept the record as a re-submission and not create a new record. Once you have prepared the re-submission file, submit the file per the standard file submission process. For detailed instructions on how to submit a bulk data file, see Section 4.4.

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."

Once the record has been changed, it must be re-attested to before it is made available to the covered recipient, and the dispute is considered resolved. See Section 5.3b.



5.3b: Re-Submission and Re-Attestation

Entities submitting corrected data must both re-submit 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.

It is strongly recommended that you do not delete the original record and replace it with a new one, unless the dispute resolution changes any of the fields that identify the covered recipient in that record. In such cases, the original record **must** be deleted and resubmitted as a new record.

If a record is deleted and replaced after the submission closing date, the Open Payments system will treat the record as a newly arriving late record rather than a correction. The new records will not be included in the current publication cycle and will be identified as eligible for review and dispute for a future publication. Once a record is deleted, it will no longer be visible to the physicians, teaching hospitals, or physician principal investigators identified in it. A record marked for deletion but not yet deleted is still visible to the physicians, teaching hospitals, or physician principal investigators identified in it.

The attester will need to re-attest to the accuracy of all re-submitted or deleted 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 select the "Return to Attester" button to notify the attester that records are ready for attestation. For more detailed instructions on attestation of data, see Section 4.14.

For detailed instructions on submitting data, see Chapter 4. For details on how data resubmission affects publication dates, see Chapter 8.

PART IV: PHYSICIANS AND TEACHING HOSPITALS

Open Payments Registration For Physicians and Teaching Hospitals

Chapter 6: 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:

- **Two-Step Registration Process** provides an overview of the Registration process. Registration includes user registration in EIDM, as well as user registration in the Open Payments system.
- **EIDM Registration** provides an overview of the first step in registration, how to register for EIDM and request access to the Open Payments system.
- Registration in the Open Payments System provides walkthroughs of various scenarios for registering a physician or a teaching hospital in the Open Payments system.
- Open Payments Users and User Roles 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.
- **Nominations** contain information on how to nominate other individuals for roles associated with physicians and teaching hospitals.
- **Updating Profile Information in the Open Payments System** contains information on how physicians, physician authorized representatives, and users affiliated with teaching hospitals can update their profiles in the Open Payments system.

Section 6.1: Two-Step 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.

Registration for Open Payments is a two-step process. First, users must register in EIDM to obtain EIDM credentials and request access to the Open Payments system. Once the user has obtained EIDM credentials, he or she will be able to register in the Open Payments system.

Section 6.2: Enterprise Identity Management (EIDM) Registration and Open Payments Access

Enterprise Identity Management (EIDM) is an identity management and services system that (1) serves as an identity proofing tool to verify a person's identity; and (2) provides users with access to various CMS applications. Registering in EIDM provides users with log in 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 users to log in to the CMS Enterprise Portal and request access to various CMS applications, including the Open Payments system.

EIDM can be accessed and the registration process can begin on the CMS Enterprise Portal at https:/portal.cms.gov. A complete EIDM Operations Document and a list of EIDM FAQs are available on the CMS website at https://www.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 any CMS application(s) available through EIDM. 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.

NOTE FOR INDIVIDUALS WITH FOREIGN ADDRESSES: Individuals with addresses outside of the United States can enter their foreign address during registration. However, identity proofing will take place manually. Contact the Open Payments Help Desk at openpayments@cms.hhs.gov for assistance with this manual proofing process.

For step-by-step instructions on how to register in CMS's Enterprise Portal, refer to Section 3.2 of this User Guide.

Section 6.3: Registering in the Open Payments System

A physician must register him- or herself in the Open Payments system and undergo a vetting process to be fully registered in the Open Payments system. See Section 6.3c for more on physician vetting. Physician registration has five steps, as shown in **Figure 6.1** below. Details on these steps are included later in this chapter.

Figure 6.1: Physician Registration Process



Figures 6.2 and **6.3** detail the fields which are required and optional when creating physician and user profiles. It is important to have this information on-hand prior to beginning the registration process.

Figure 6.2: Required and Optional Fields for Physician Profiles

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

^{**}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 the Open Payments system, 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 6.3: Required and Optional Fields for Individual User Profiles

Fields	Required or Optional
First Name	Required
Middle Name	Optional
Last Name	Required
Name Suffix	Optional
Job Title (for Physician)	Optional
Job Title (for Authorized Representative)	Required
Business Address	Required
Business Phone Number	Required
Business Email Address	Required

Teaching hospitals are pre-populated into the Open Payments system based on the Open Payments
Teaching Hospital List, which is maintained by CMS and updated annually. Teaching hospitals do not
need to be vetted after registration and are approved immediately in the Open Payments system after
registration with a status of "vetted." Note that no vetting occurs beyond that done to create the annual
Teaching Hospital List. CMS makes the current and past Teaching Hospital Lists available on the
Resources page of the CMS Open Payments website at

https://www.cms.gov/OpenPayments/About/Resources.html. Teaching hospitals not on the lists will not have payments or other transfers of value reported about them.

Teaching hospitals must register using the hospital's "Doing Business As" name rather than its legal name, unless you are registering the teaching hospital for program year 2013. (For directions on registering a teaching hospital for a prior program year, see Section 6.3f.) In the Teaching Hospital List, the "Doing Business As" name is under the heading of "Hospital Name." The address should be the "NPPES Business Address."

Teaching hospital registration has five steps, as shown in **Figure 6.4** below. Details on these steps are included later in this chapter.

Figure 6.4: Teaching Hospital Registration Process



Figures 6.5 and **6.6** 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 6.5: Required and Optional Fields for Teaching Hospital Profiles

Fields	Required or Optional?
State Where Teaching Hospital is Located	Required
Teaching Hospital Doing Business As Name	Required
Teaching Hospital Business Address	Required
Taxpayer Identification Number (TIN)	Required

Figure 6.6: Required and Optional Fields for Individual User Profiles

Fields	Required or Optional?
First Name	Required
Middle Name	Optional
Last Name	Required
Suffix	Optional
Job Title	Required
Business Address	Required
Business Phone Number	Required
Business Email Address	Required
City Name	Required
State	Required
Zip Code	Required

The list of required information for registration for both physicians and teaching hospitals is also available in the quick reference guide "Required Fields for Registration," which can be downloaded from the Resources page of the Open Payments website

(https://www.cms.gov/openpayments/About/Resources.html).

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 30 minutes of inactivity and it does not have an auto-save feature.** If the system times out, your updates will not be saved.

Important notes on Open Payments physician and teaching hospital registration:

- If your teaching hospital was registered in a previous year, it does not need to be registered again.
- Registration must be completed in one session.
- Never use the navigation buttons on your browser toolbar. Only use the navigation buttons (i.e., "Back" button) within the Open Payments system itself.
- If you do not know your 10-digit NPI number, you can find it on the NPI Registry, located at https://npiregistry.cms.hhs.gov/.
- If you cannot find your DEA number, contact the DEA Office of Diversion Control. Their website is https://www.deadiversion.usdoj.gov.

6.3a: Registering as a Physician (First Time System Users)

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

Note: If you are a physician who works in a teaching hospital and wish to see data related to you in your capacity as a physician, select the "Physician" option when registering. If you are a physician who works in a teaching hospital and wish to represent that teaching hospital as an authorized official or authorized representative, follow the instructions in Section 6.3d for registering a teaching hospital.

Note that if you select the "Teaching Hospital" option when registering, you will only be able to view payments made to the teaching hospital you are associating yourself with. If you wish to see data related to you as a physician, register a second time and select the "Physician" option. Users may be registered for both options and can alternate between physician and teaching hospital profiles using the "Switch User" functionality described in Section 6.3g.

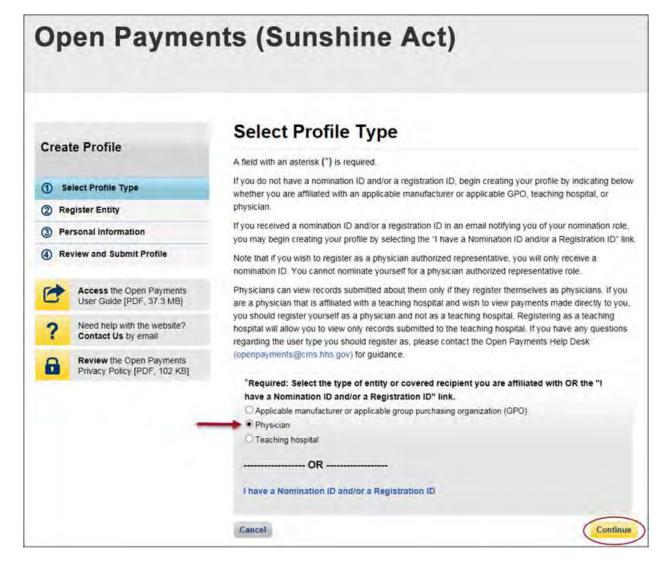
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.



<u>Step 2:</u> The on-screen text contains important information regarding creating the physician profile. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile" at the bottom of the page when you are ready to continue.



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

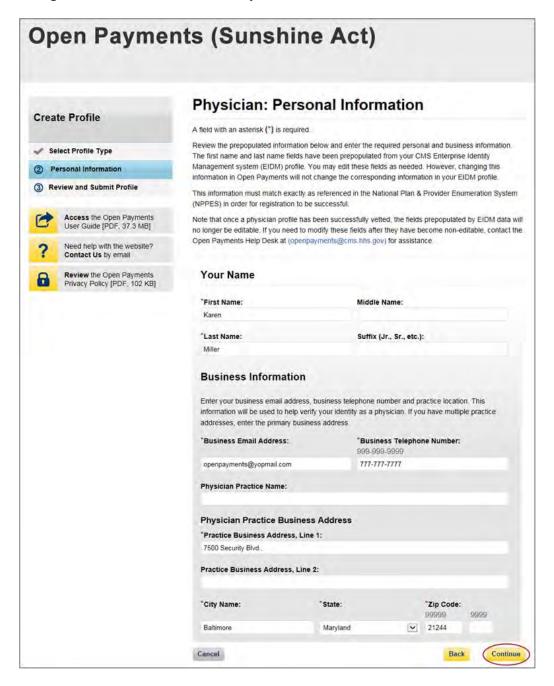


<u>Step 4:</u> Enter your personal information. All required fields will be marked with an asterisk (*). You will not be able to proceed with registration until all of the required fields have been entered.

If you are registered with the National Plan and Provider Enumeration System (NPPES), ensure that you enter your name exactly as it is in NPPES.

When you are done, select "Continue."

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

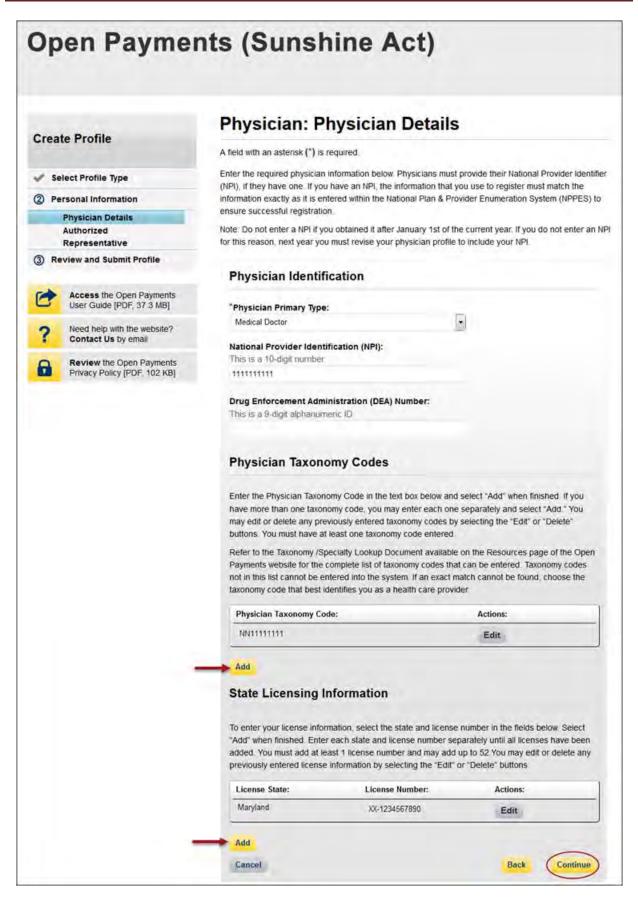


Step 5: Enter your physician details. All required fields will be marked with an asterisk (*).

Note that while the National Provider Identifier (NPI) and Drug Enforcement Administration (DEA) Number fields are not marked as required, they must be entered if you have them. If you do not have these identifiers, you can still proceed with registration.

Refer to the taxonomy code list linked to in <u>Appendix C</u> or on the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html) for a complete listing of the available taxonomy codes. Taxonomy codes not on the taxonomy code list should not be entered. As you begin entering information into the Taxonomy Code field, the system will provide a list of codes to help guide your entry. If your taxonomy code is not available, select the code that most closely represents your specialty. Select "Add" after entering each taxonomy code to add it to your profile.

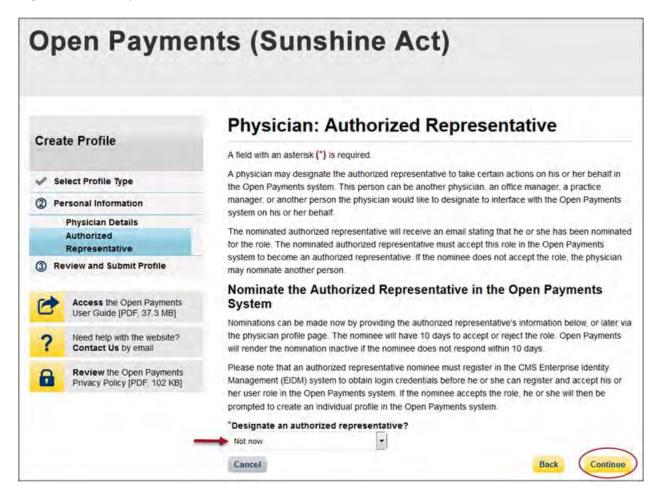
To add your licensing information, select "Add License" and enter the state in which the license is held and the license number. The license number field may contain up to 25 characters, including special characters such as hyphens(-). You are required to enter at least one license. When you are done, select "Add License." If you input data into the field and select "Continue" before selecting "Add License," the system will throw an error message. To proceed, either select "Add License" or clear the information from the license field. If you have licenses in more than one state, enter in the first state and license number and then select "Add License." Repeat until all of your state licenses have been added. You can enter up to 52 licenses. When you are finished, select "Continue."



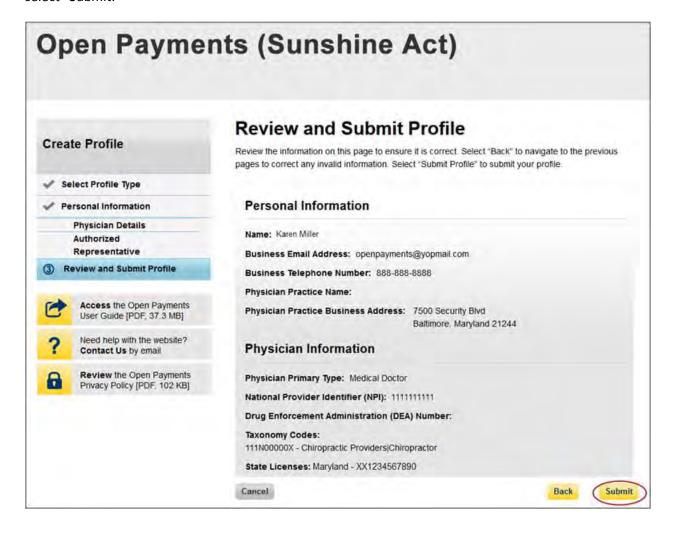
<u>Step 6:</u> At this point in registration, you may nominate an individual to serve as your authorized representative within the Open Payments system. By default, "Designate an Authorized Representative" will be selected. **A physician cannot be his or her own authorized representative.**

To designate an authorized representative, enter the required information. You will also be asked to select the access level for the authorized representative. Authorized representative access levels are explained in depth in Section 6.4a. The access levels are also summarized on the page. When you are finished, select "Continue."

You do not need to designate an authorized representative during initial registration and may do so at a later time. If you choose not to designate an authorized representative at this time, select "Not Now" and then select "Continue." For instructions on how to nominate an authorized representative after registration is complete, see Section 6.5a.



<u>Step 7:</u> Review the information entered. Select the "Back" button at the bottom of the page 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.



6.3b: Registering as a Physician for a User with another Role (Returning System Users)

If you are registering a physician and you are already affiliated with a reporting entity or teaching hospital in the Open Payments system, follow the steps below.

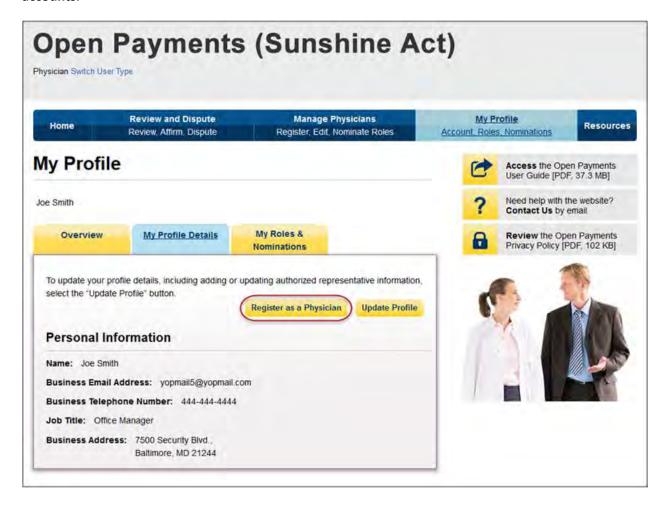
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "My Profile" tab from the menu bar on the Open Payments home page.



<u>Step 2:</u> From the "My Profile Overview" tab, select the "My Profile Details" tab. 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.

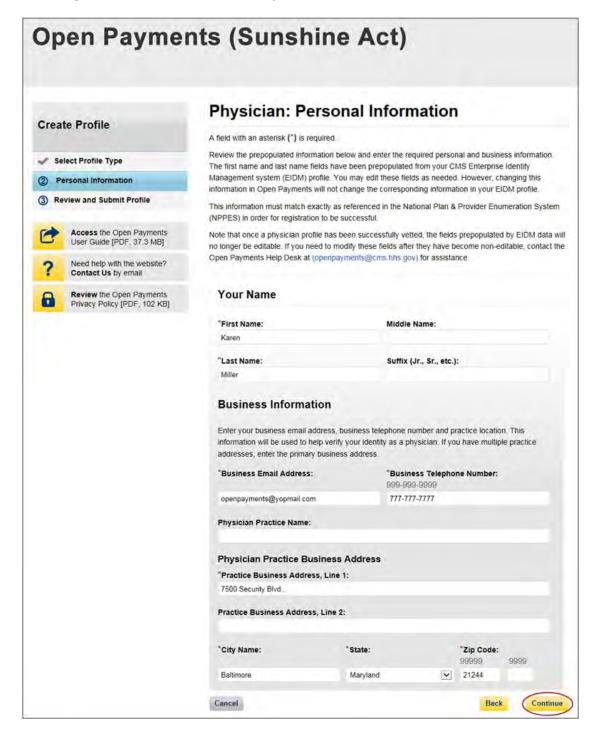
To proceed in registering as a physician, select "Register as a Physician."

Note: Changes made here will not automatically update your profile information in your other CMS accounts.



<u>Step 3:</u> Enter your personal information. All required fields will be marked with an asterisk (*). You will not be able to proceed with registration until all of the required fields have been entered. If you are registered with the National Plan and Provider Enumeration System (NPPES), ensure that you enter your name exactly as it is in NPPES. When you are done, select "Continue."

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

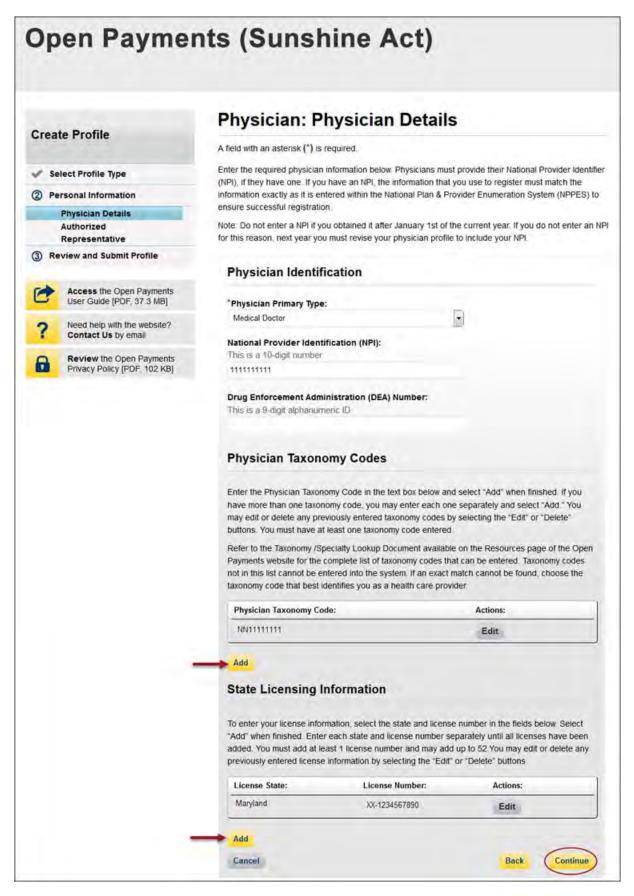


<u>Step 4:</u> Enter your physician details. All required fields will be marked with an asterisk (*). You will not be able to proceed with registration until all of the required fields have been entered. The National Provider Identifier (NPI) and Drug Enforcement Administration (DEA) Number must be entered if you have them. If you do not have these identifiers, you can still proceed with registration.

If you have an NPI, enter it exactly as it is listed in NPPES for the current calendar year. Do not enter an NPI if you obtained it after January 1st of the current year. If you do not enter an NPI for this reason, next year you must revise your physician profile to include your NPI.

Refer to the taxonomy code list linked to in <u>Appendix C</u> or on the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html) for a complete listing of the available taxonomy codes. Taxonomy codes not on the taxonomy code list should not be entered. As you begin entering information into the Taxonomy Code field, the system will provide a list of codes to help guide your entry. If your taxonomy code is not available, select the code that most closely represents your specialty. Select "Add" after entering each taxonomy code to add it to your profile.

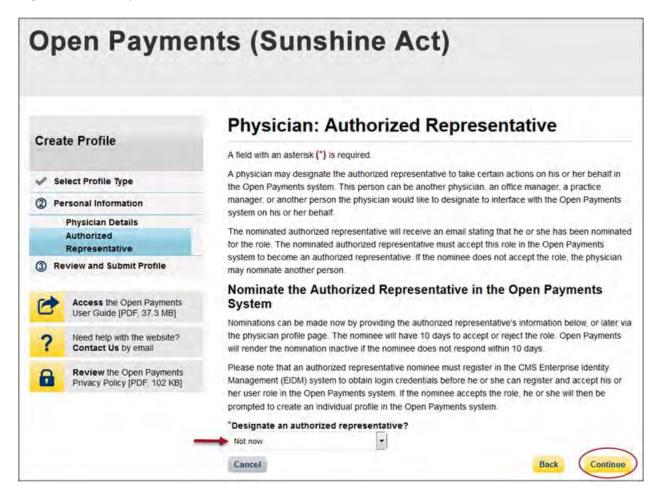
To add your licensing information, select "Add License" and enter the state in which the license is held, and the license number. The license number field may contain up to 25 characters, including special characters such as hyphens(-). You are required to enter at least one license. When you are done, select "Add License." If you select "Continue" before selecting "Add License," the license information will not be added to the record. If you have licenses in more than one state, enter in the first state and license number and then select "Add License." Repeat until all of your state licenses have been added. You can enter up to 52 licenses. When you are finished, select "Continue."



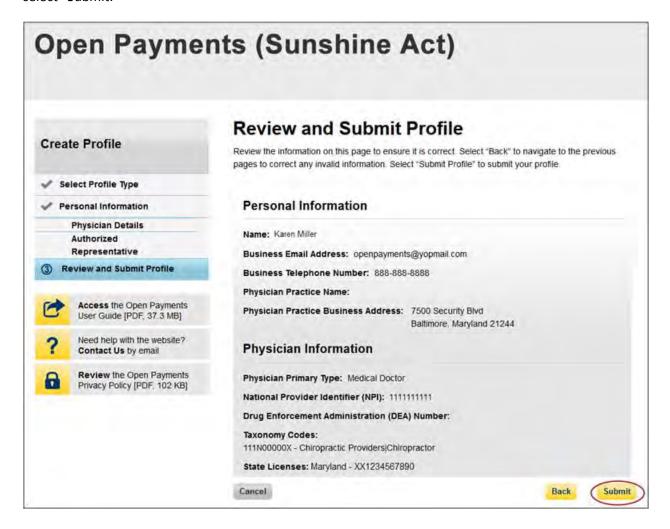
<u>Step 5:</u> At this point in registration, you may nominate an individual to serve as your authorized representative within the Open Payments system. By default, "Designate an Authorized Representative" will be selected. **A physician cannot be his or her own authorized representative.**

To designate an authorized representative, enter the required information. You will also be asked to select the access level for the authorized representative. Authorized representative access levels are explained in depth in Section 6.4a. The access levels are also summarized on the page. When you are finished, select "Continue."

You do not need to designate an authorized representative during initial registration and may do so at a later time. If you choose not to designate an authorized representative at this time, select "Not Now" and then select "Continue." For instructions on how to nominate an authorized representative after registration is complete, see Section 6.5a.



<u>Step 6:</u> Review the information entered. Select the "Back" button at the bottom of the page 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 with further instructions will be sent to that individual.



6.3c: 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 physician has submitted his or her profile to the Open Payments system. **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 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 physician's first and last name, NPI, state license information, and primary type (if no NPI is provided). 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 enter valid license information. If incorrect license information is entered, the physician will 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.

If the physician does not successfully pass vetting despite all of the information provided in the physician profile being correct to the best of his or her knowledge, or the physician requires assistance with

successfully vetting their profile, contact the Open Payments Help Desk (<u>openpayments@cms.hhs.gov</u>) or call 1-855-326-8366.

The automatic vetting process normally takes less than 24 hours, though it could take longer depending upon the completeness of the information provided by the user and the number of physicians undergoing vetting at the same time.

Once vetting is successful, you will not be able to change the name or NPI referenced in your profile. If edits to either of these fields is required after successful vetting, contact the Open Payments Help Desk at openpayments@cms.hhs.gov for assistance. CMS encourages physicians to register and begin the vetting process as early as possible to allow sufficient time for vetting to be completed.

Note: If a physician profile is modified, the profile will undergo vetting again.

6.3d: Registering a Teaching Hospital (First Time System User)

If you are a first-time user registering a teaching hospital in the Open Payments system, follow the steps below. By registering a teaching hospital, you must take the role of authorized official for the teaching hospital in the Open Payments system. See Section 6.4b for information on user roles for teaching hospitals.

Note that a physician who is employed by a teaching hospital should not register him- or herself with the option "Teaching Hospital" unless he or she will represent the teaching hospital regarding the data reported by applicable manufacturers and applicable GPOs. Physicians who select the "Teaching Hospital" option when registering will only be able to view payments made to the teaching hospital they are affiliated with. If you wish to see data related to you as a physician, register a second time and select the "Physician" option. Users may be registered for both options.

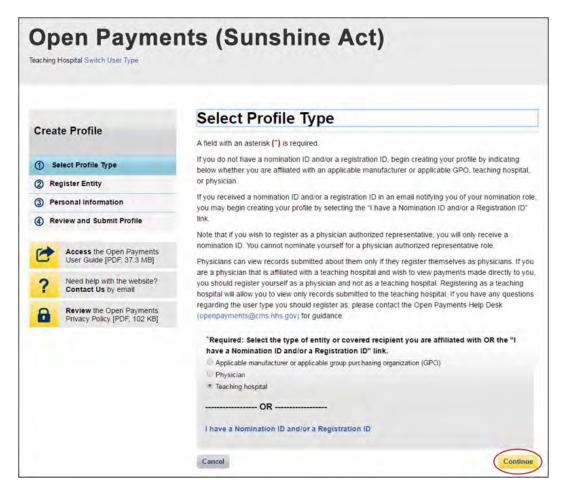
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.



<u>Step 2:</u> The on-screen text contains important information regarding creating the individual profile. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile" at the bottom of the page when you are ready to continue.



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



<u>Step 4:</u> 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."

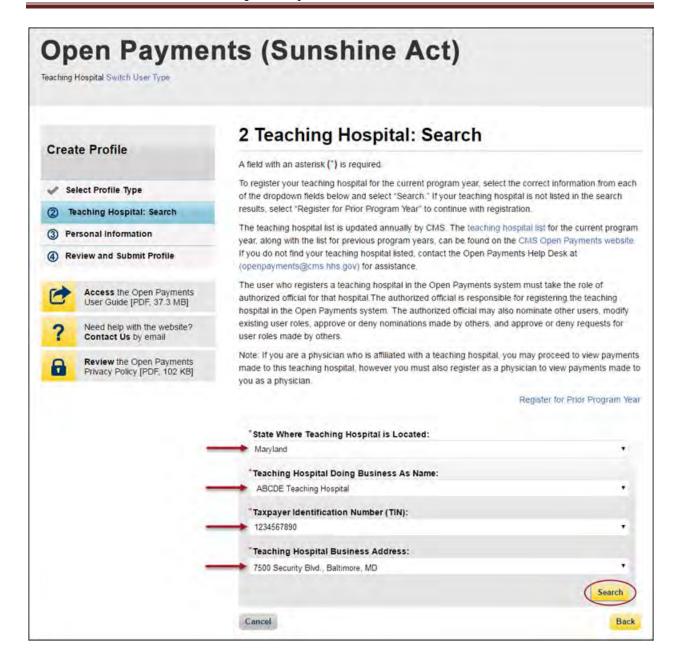
If your teaching hospital is not found, select "Register for Prior Program Year" to search for your teaching hospital in a previous program year. If you can find your teaching hospital only in a prior program year, you may select the teaching hospital and proceed with registration. For instructions on registering a teaching hospital for a prior program year, see Section 6.3f.

If your teaching hospital cannot be found in any program year, contact the Open Payments Help Desk at openpayments@cms.hhs.gov for assistance.

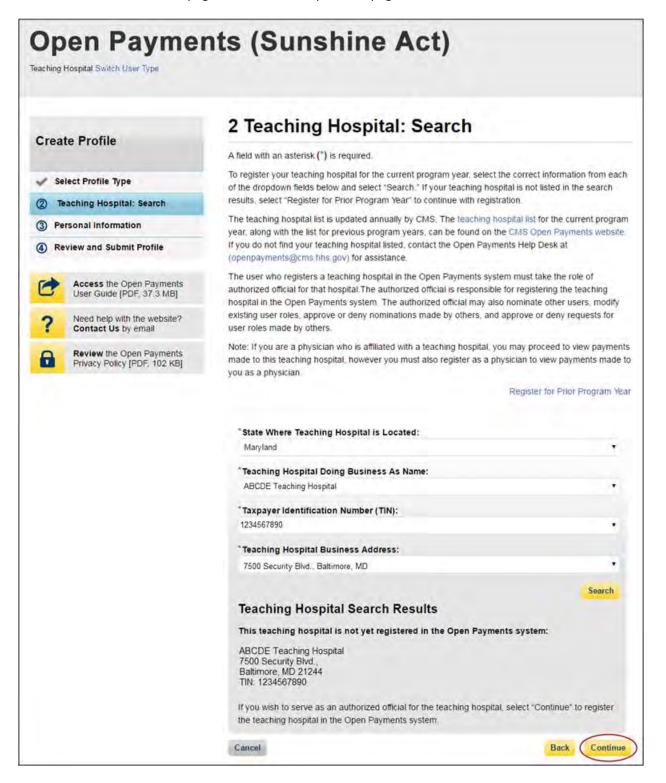
The name of the hospital selected during registration must be the hospital's "Doing Business As" name. In the CMS Teaching Hospital List, the "Doing Business As" name is under the heading of "Hospital Name." (Note that this differs if you register the teaching hospital for program year 2013 only. Refer to Section 6.3f for detailed information on registering a teaching hospital for a prior program year.)

The hospital address selected must be the address listed in the CMS Teaching Hospital List as the hospital's "NPPES Business Address."

Teaching hospitals are pre-populated into the Open Payments system based on the Open Payments Teaching Hospital List. Teaching hospitals not on this list or prior program year lists will not have payments or other transfers of value reported about them.



<u>Step 5:</u> Review the information displayed on the page. Select "Continue" if the information displayed is the teaching hospital you wish to register. If this is not the correct teaching hospital, select the "Back" button at the bottom of the page to return to the previous page and re-enter the information.

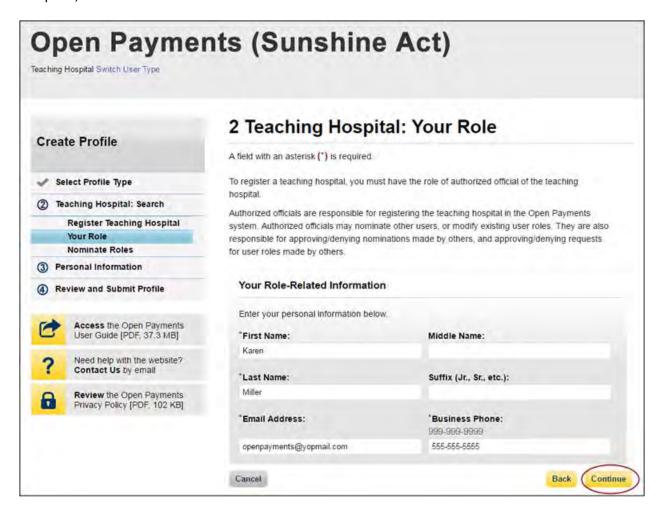


Step 6: Review the information displayed on the page. When complete, select "Continue."

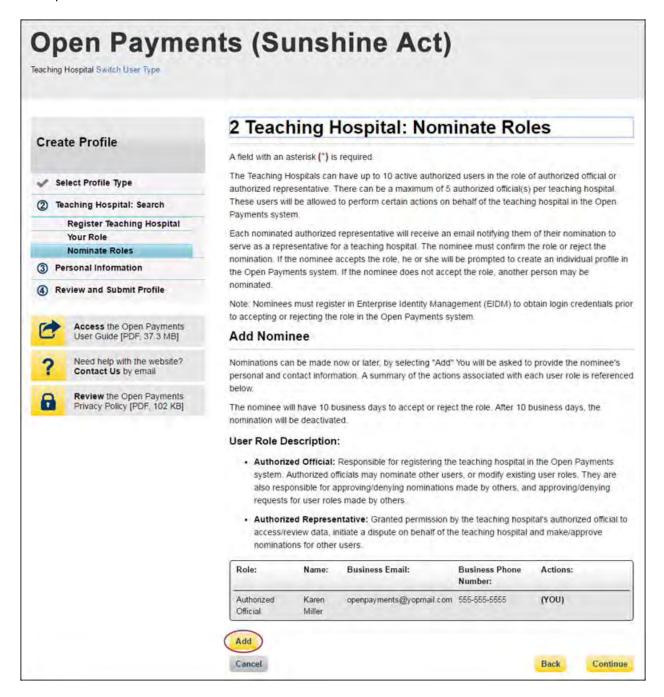


<u>Step 7:</u> Review the information generated by the system related to your role. You must select the role of "Authorized Official" for yourself to proceed with registration. Information on teaching hospital user roles is available in Section 6.4b.

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 (*). You will not be able to proceed with registration until all of the required fields have been entered. When complete, select "Continue."



<u>Step 8:</u> You may choose to nominate additional users to fill the authorized official or authorized representative roles. To do so, select "Add" to nominate any additional individual(s). If you choose not to add nominees at this time, select "Continue" without adding any nominee information and proceed to Step 9.

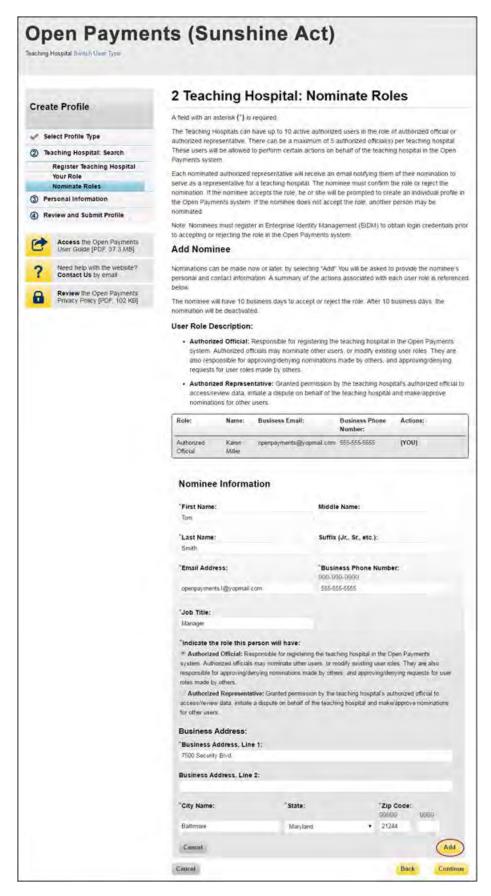


<u>Step 8a</u>: If you selected "Add," enter the required information for one individual and select either "Authorized Official" or "Authorized Representative" to nominate the individual for the selected role. Information on teaching hospital user roles is available in Section 6.4b. When you have entered the information, select "Add." This will add the nominee information to the teaching hospital's profile, as well as open another set of information fields to enter an additional nominee.

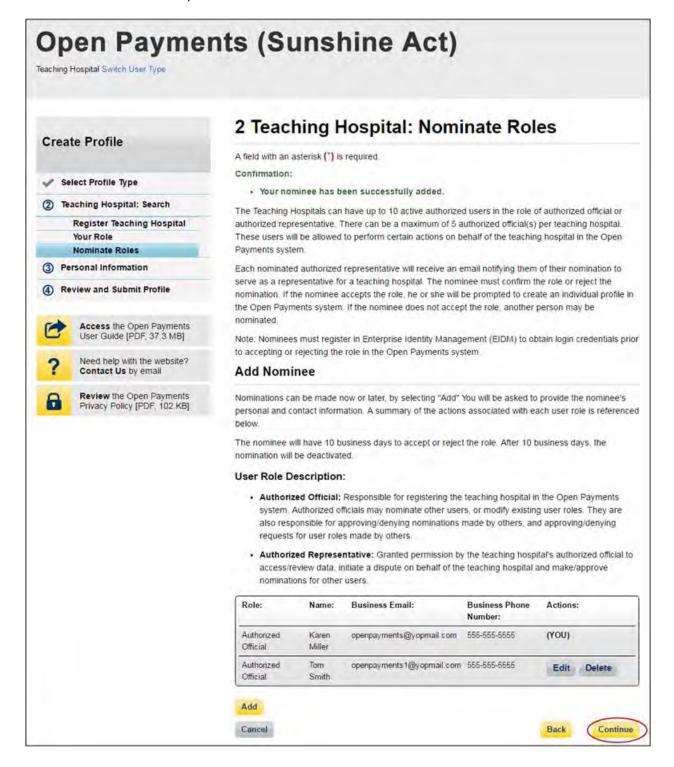
Repeat the process until you have entered all of the individuals you wish to nominate. A teaching hospital may have up to 10 unique active users, 5 of whom can hold the role of authorized official. When you have added all of the individuals you wish to nominate, select "Continue."

Each nominated individual will receive an email notifying them of their nomination. The nominee must confirm or reject the role within 10 calendar days.

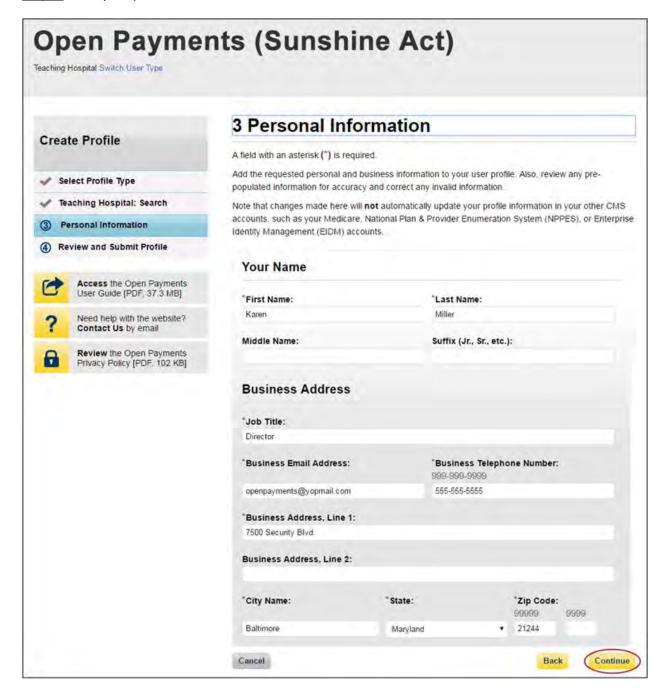
You do not have to nominate additional individuals during initial registration. You can nominate individuals later by updating your teaching hospital profile within the "Manage Teaching Hospitals" tab.



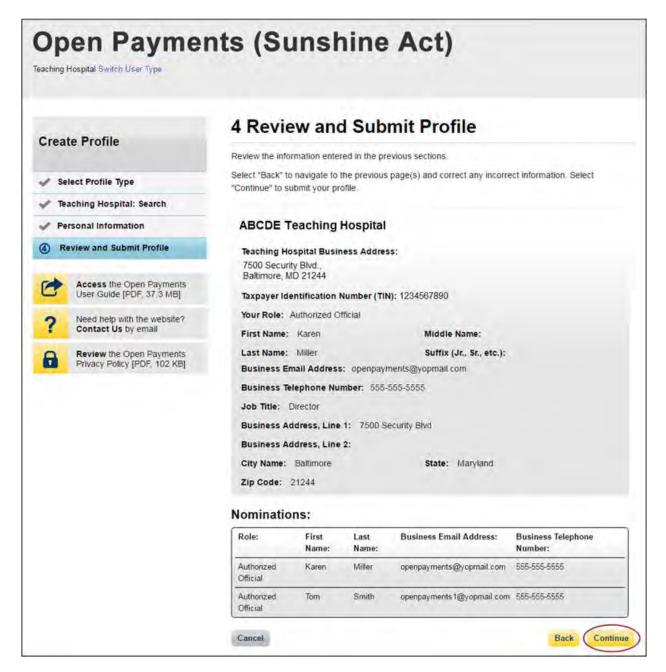
If you entered any nominees, you will see the nominee information displayed on the page. Confirm the information and when complete select "Continue."



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



<u>Step 10:</u> Review your profile information on the "Review and Submit Profile" page. Select the "Back" button at the bottom of the page 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 have immediate access to the teaching hospital data. If you nominated additional individuals for user roles, an email notification is sent to the nominees that will instruct them on their next steps.



6.3e: Registering a Teaching Hospital (Returning System Users)

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

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "Manage Teaching Hospitals" tab.



Step 2: From the "Manage Teaching Hospitals" tab, select, "Register New Teaching Hospital."



<u>Step 3:</u> Search for the teaching hospital by selecting the appropriate state, teaching hospital name, teaching hospital business address, and Taxpayer Identification Number (TIN) from the drop-downs and select "Search."

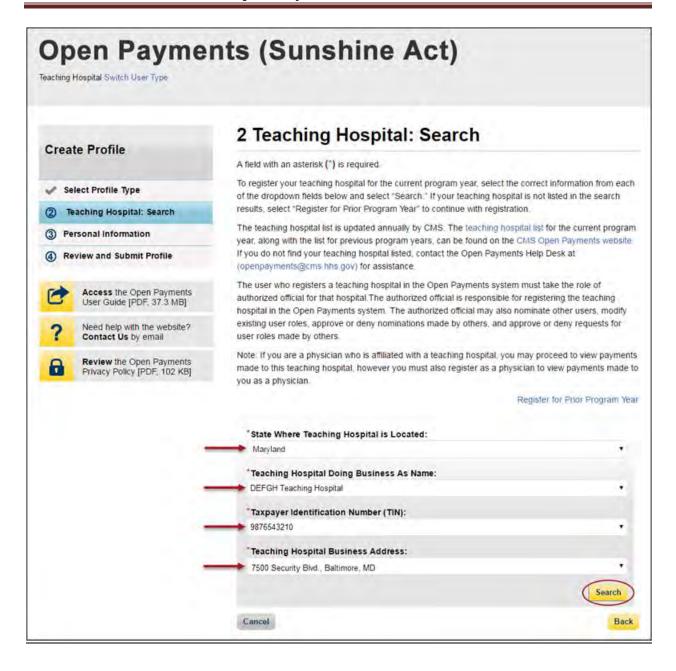
If your teaching hospital is not found, select "Register for Prior Program Year" to search for your teaching hospital in a previous program year. If you can find your teaching hospital only in a prior program year, you may select the teaching hospital and proceed with registration. For instructions on registering a teaching hospital for a prior program year, see Section 6.3f.

If your teaching hospital cannot be found in any program year, contact the Open Payments Help Desk at openpayments@cms.hhs.gov for assistance.

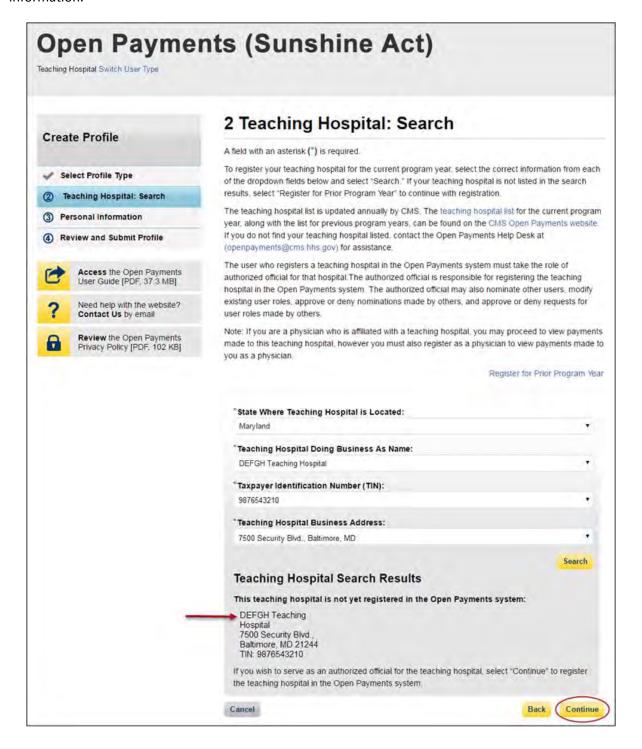
The name of the hospital selected during registration must be the hospital's "Doing Business As" name. In the CMS Teaching Hospital List, the "Doing Business As" name is under the heading of "Hospital Name." (Note that this differs if you register the teaching hospital for program year 2013 only. Refer to Section 6.3f for detailed information on registering a teaching hospital for a prior program year.)

The hospital address selected must be the address listed in the CMS Teaching Hospital List as the hospital's "NPPES Business Address."

Teaching hospitals are pre-populated into the Open Payments system based on the 2015 Open Payments Teaching Hospital List. Teaching hospitals not on this list or prior program year lists will not have payments or other transfers of value reported about them.



<u>Step 4:</u> Review the information displayed on the page, and select "Continue" if the information displayed is the teaching hospital you wish to register. If this is not the correct teaching hospital, select the "Back" button at the bottom of the page to return to the previous page and re-enter the information.

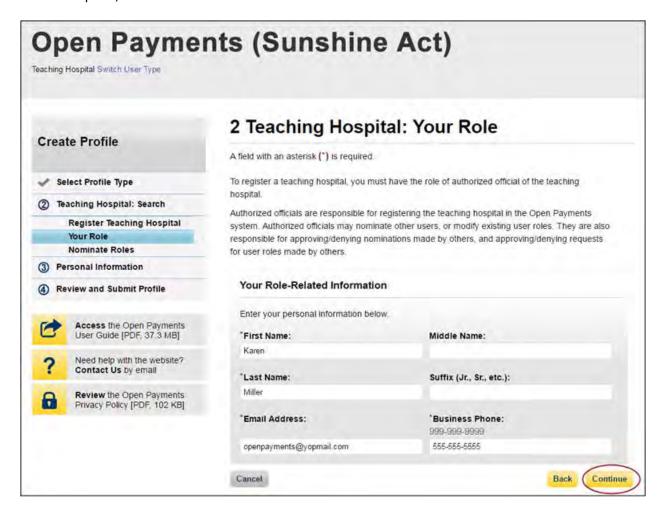


Step 5: Review the information displayed on the page and select "Continue."

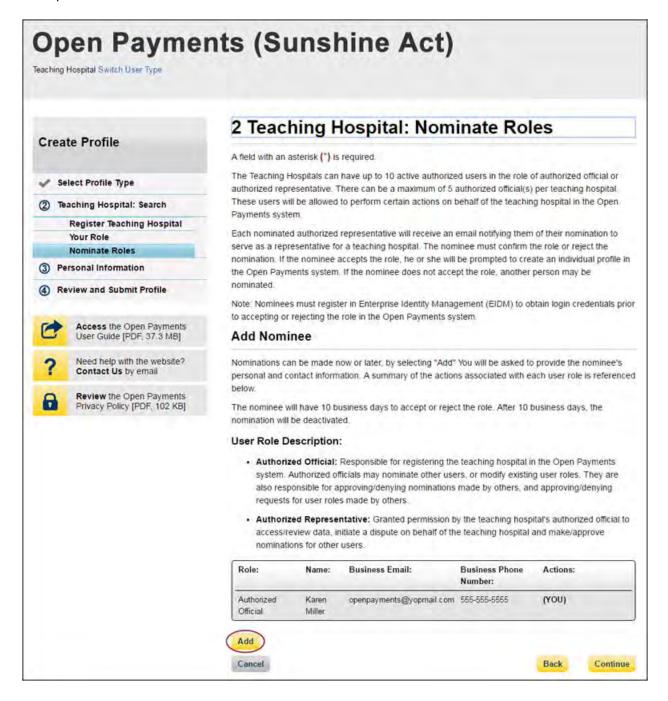


<u>Step 6:</u> Review the information generated by the system related to your role. You must select the role of "Authorized Official" for yourself to proceed with registration. Information on teaching hospital user roles is available in Section 6.4b.

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 (*). You will not be able to proceed with registration until all of the required fields have been entered. When complete, select "Continue."



<u>Step 7:</u> You may choose to nominate additional users to fill the authorized official or authorized representative roles. To do so, select "Add" to nominate any additional individual(s). If you choose not to add nominees at this time, select "Continue" without adding any nominee information and proceed to step 8.

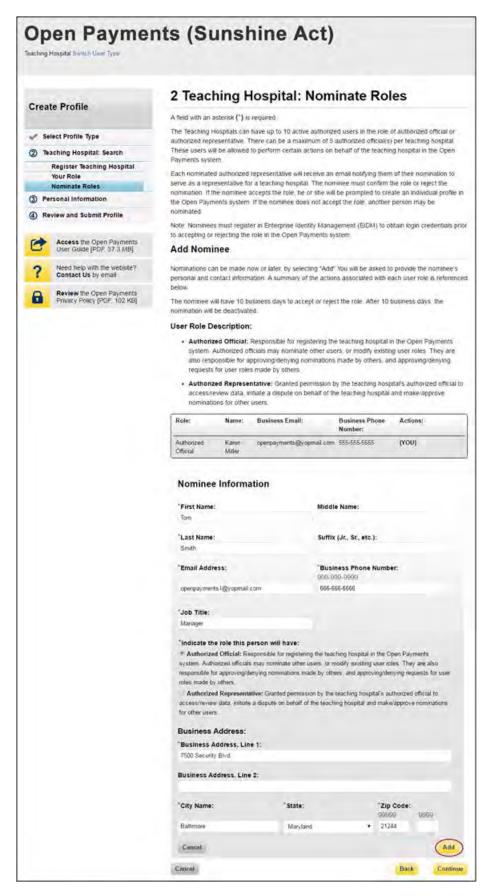


<u>Step 7a</u>: If you selected "Add," enter the required information for one individual and select either "Authorized Official" or "Authorized Representative" to nominate the individual for the selected role. Information on teaching hospital user roles is available in Section 6.4b. When you have entered the information, select "Add." This will add the nominee information to the teaching hospital's profile, as well as open another set of information fields to enter an additional nominee.

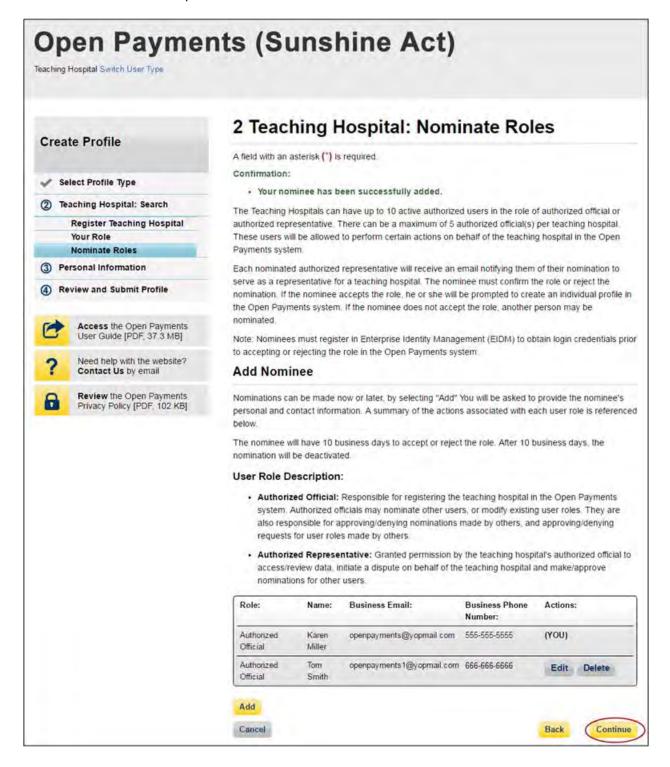
Repeat the process until you have entered all of the individuals you wish to nominate. A teaching hospital may have up to 10 active users, 5 of whom can hold the role of authorized official. When you have added all of the individuals you wish to nominate, select "Continue."

Each nominated individual will receive an email notifying them of their nomination. The nominee must confirm or reject the role within 10 calendar days.

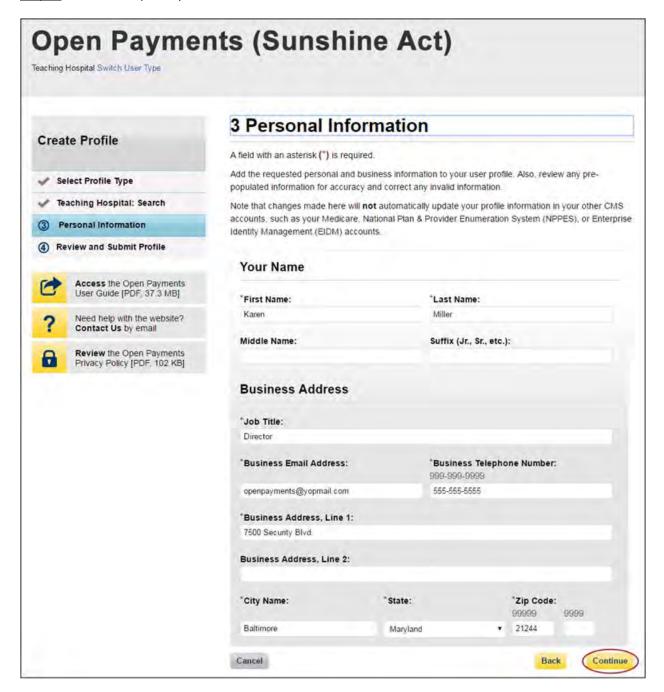
You do not have to nominate additional individuals during initial registration. You can nominate individuals later by updating your teaching hospital profile within the "Manage Teaching Hospitals" tab.



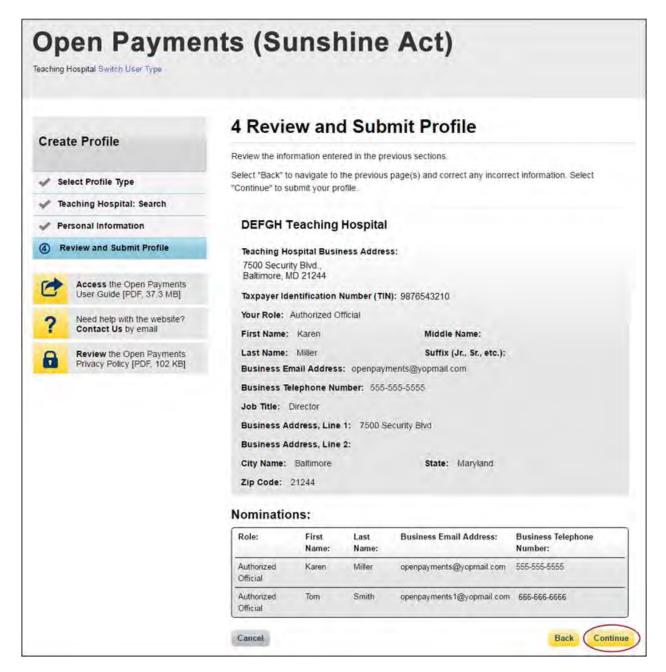
If you entered any nominees, you will see the nominee information displayed on the page. Confirm the information and when complete select "Continue."



Step 8: Enter the required personal information. When finished, select "Continue."



<u>Step 9:</u> Review your profile information on the "Review and Submit Profile" page. Select the "Back" button at the bottom of the page 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 have immediate access to the teaching hospital data. If you nominated additional individuals for user roles, an email notification will be sent to the nominees that will instruct them on their next steps.



6.3f Registering a Teaching Hospital (Prior Program Year)

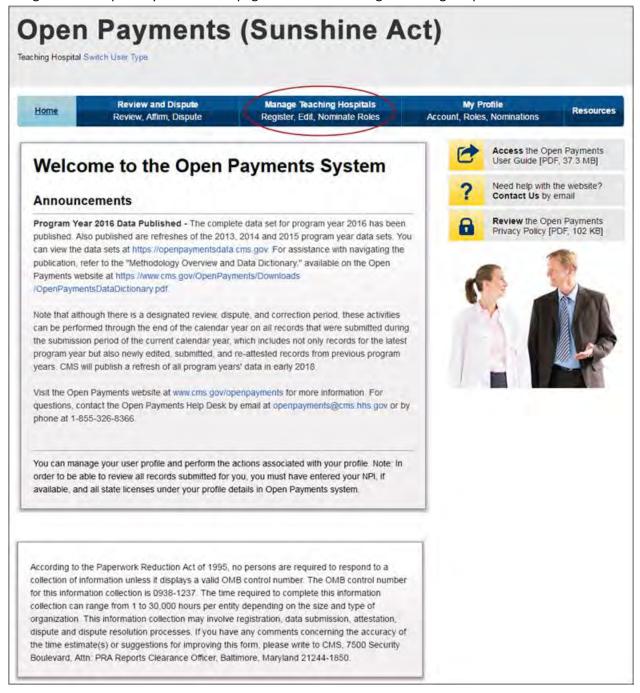
If you wish to register a teaching hospital in Open Payments that does **not** appear on the current program year's CMS Teaching Hospital List, but **does** appear in previous Teaching Hospital Lists, you can register the hospital for a prior program year. Doing so will allow you to view records associated with that teaching hospital from a prior program year.

If your teaching hospital is already registered in the Open Payments system, you do not need to reregister the teaching hospital for the prior program year.

If your teaching hospital does not appear in <u>any</u> CMS Teaching Hospital Lists, it will not have any records associated with it in the Open Payments system and cannot be registered.

To register your teaching hospital for a prior program year, follow these steps:

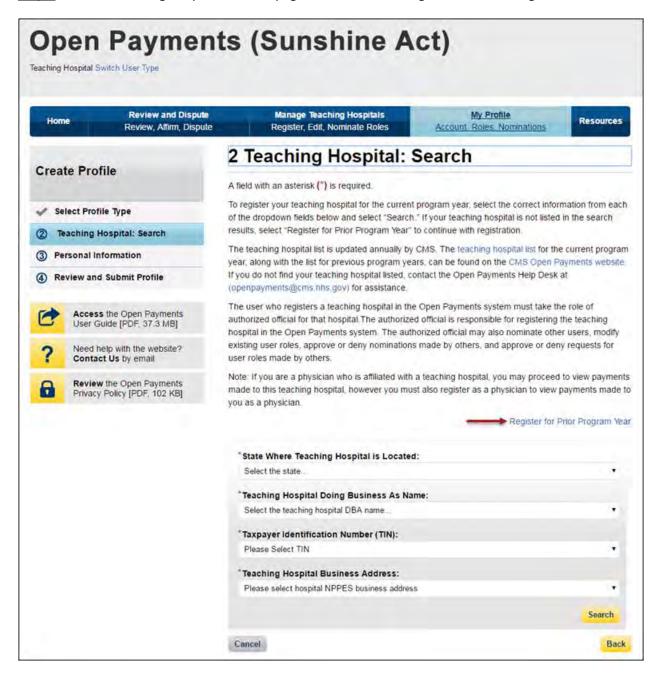
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "Manage Teaching Hospitals" tab.



Step 2: On the "Manage Teaching Hospitals" page, select "Register New Teaching Hospital."



Step 3: On the "Teaching Hospital: Search" page, select the link "Register for Prior Program Year."

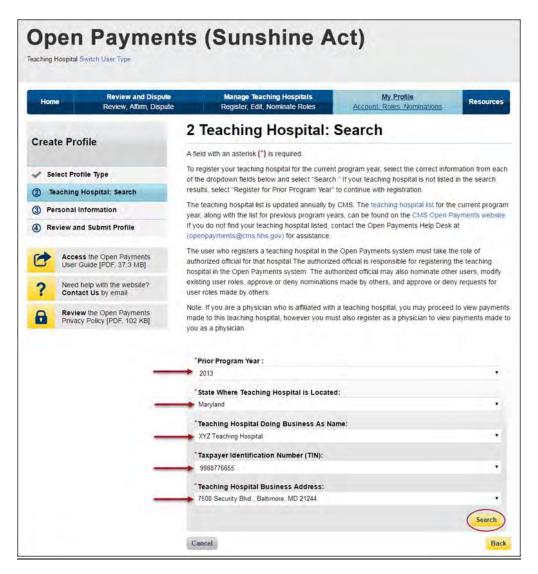


<u>Step 4</u>: Teaching hospitals are pre-populated in the Open Payments system based on the Teaching Hospital List for the program year you selected. Teaching hospitals not found in any program year will not have payments or other transfers of value reported about them for that program year.

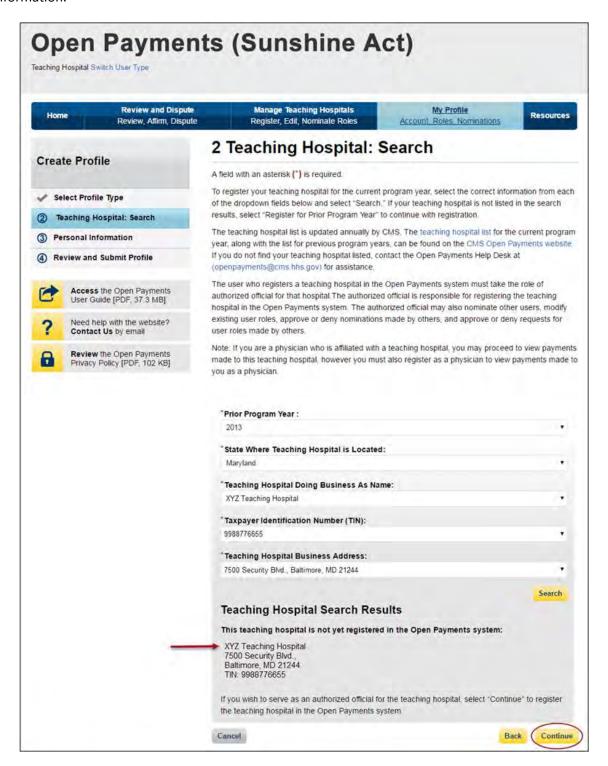
Search for the teaching hospital by selecting the program year you wish to register the hospital for, as well as the state, teaching hospital name, teaching hospital business address, and Taxpayer Identification Number (TIN) from the drop-downs and select "Search."

Teaching hospitals must be registered using the hospital's "Doing Business As" name as the hospital name. In the CMS Teaching Hospital List, the "Doing Business As" name is under the heading of "Hospital Name." (Note that this differs if you register the teaching hospital for program year 2013 only. Refer to Section 6.3f for detailed information on registering a teaching hospital for a prior program year.)

The address selected should be the address listed in the CMS Teaching Hospital List as the hospital's "NPPES Business Address."



<u>Step 5:</u> Review the information displayed on the page, and select "Continue" if the information displayed is the teaching hospital you wish to register. If this is not the correct teaching hospital, select the "Back" button at the bottom of the page to return to the previous page and re-enter the information.



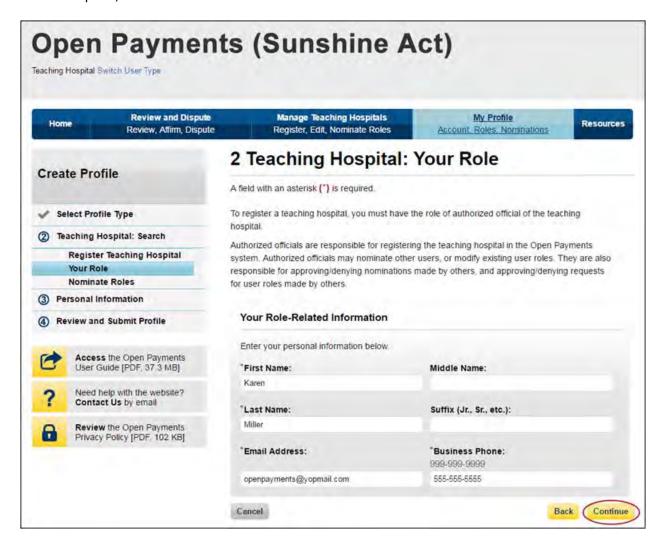
<u>Step 6:</u> Review the teaching hospital information displayed on the page. When complete, select "Continue."



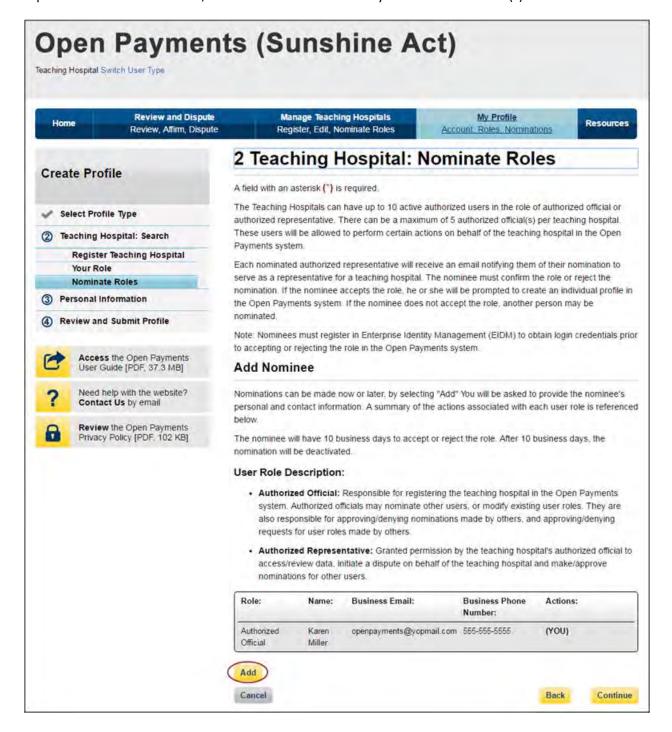
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<u>Step 7:</u> Review the information generated by the system related to your role. You must select the role of "Authorized Official" for yourself to proceed with registration. Information on teaching hospital user roles is available in Section 6.4b.

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 (*). You will not be able to proceed with registration until all of the required fields have been entered. When complete, select "Continue."



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



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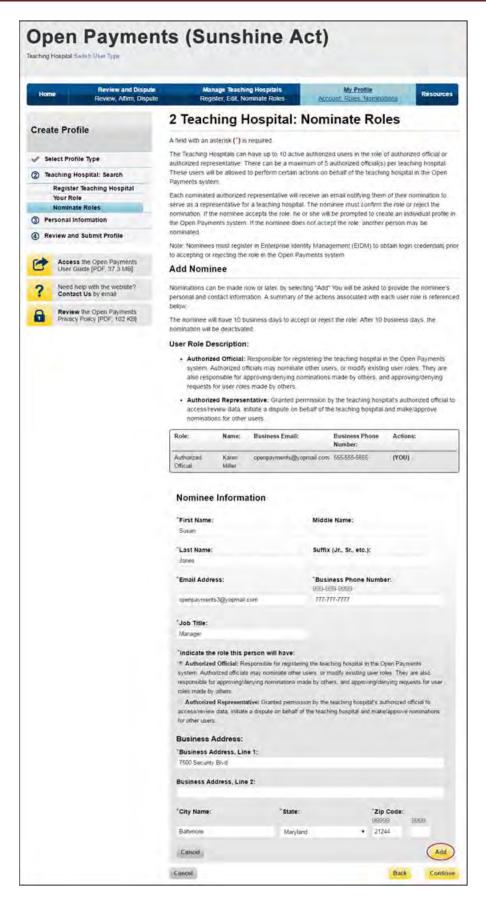
<u>Step 8a</u>: Enter the required information for one individual and select either "Authorized Official" or "Authorized Representative" to nominate the individual for the selected role. Information on teaching hospital user roles is available in Section 6.4b. When you have entered the information, select "Add."

Repeat the process until you have entered all of the individuals you wish to nominate. A teaching hospital may have up to 10 active users, 5 of whom can hold the role of authorized official. When you have added all of the individuals you wish to nominate, select "Continue."

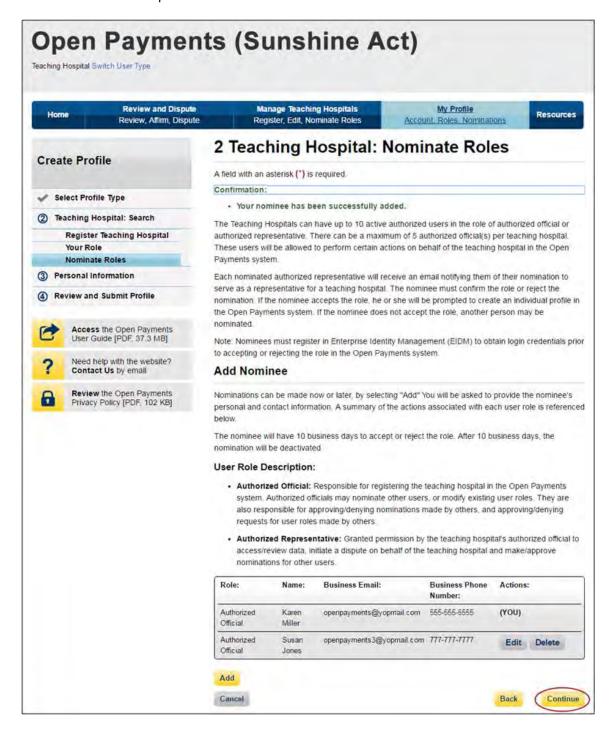
Each nominated individual will receive an email notifying them of their nomination. The nominee must confirm or reject the role within 10 calendar days.

You do not have to nominate additional individuals during initial registration. You can nominate individuals later by updating your teaching hospital profile within the "Manage Teaching Hospitals" tab.

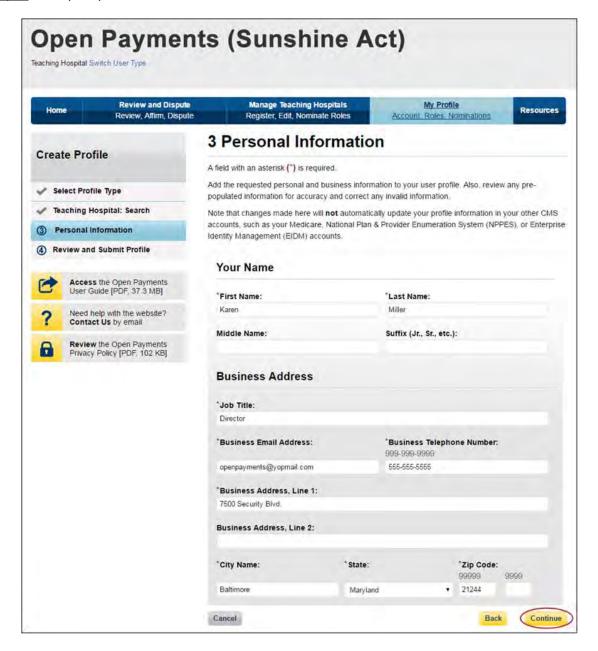
If you choose not to add nominees at this time, select "Continue" without adding any nominee information.



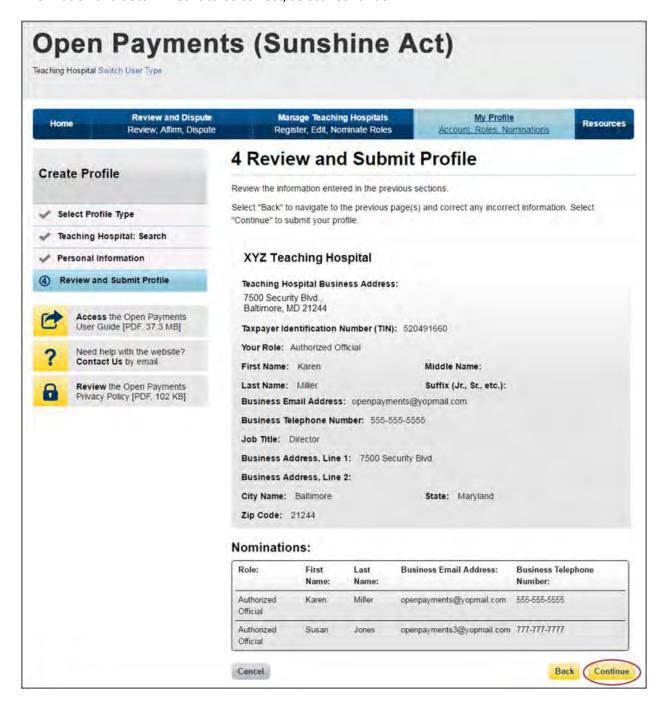
If you entered any nominees, you will see the nominee information displayed on the page. Confirm the information and when complete select "Continue."



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



<u>Step 10:</u> Review your profile information on the "Review and Submit Profile" page. Select the "Back" button at the bottom of the page 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 the hospital has been successfully registered. You will have immediate access to the teaching hospital data. If you nominated individuals for user roles, an email notification is sent to the nominees that will instruct them on their next steps.



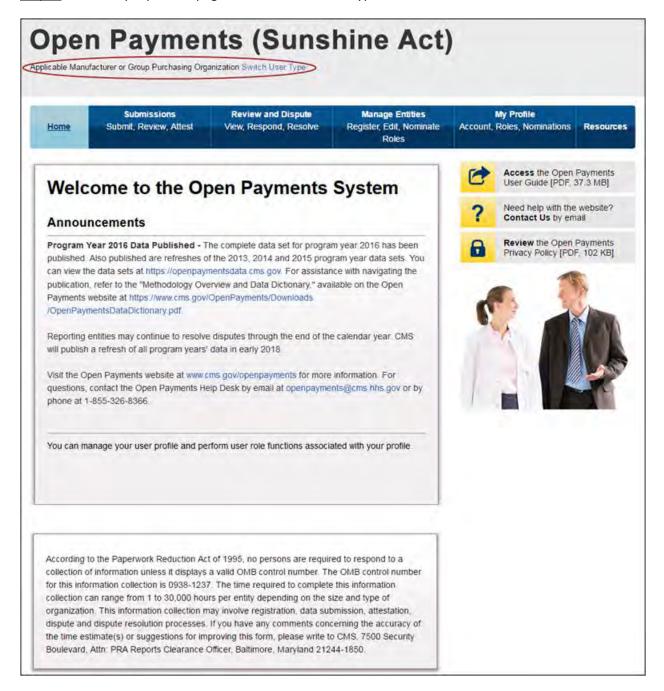
6.3g: Using the Switch User Functionality

The Open Payments system allows individuals to hold multiple user roles based on their affiliations with multiple entities. Users can switch among 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. The pages in the Open Payments system will look similar for each user type, though the actions available will change depending on the user type you are operating under at that time.

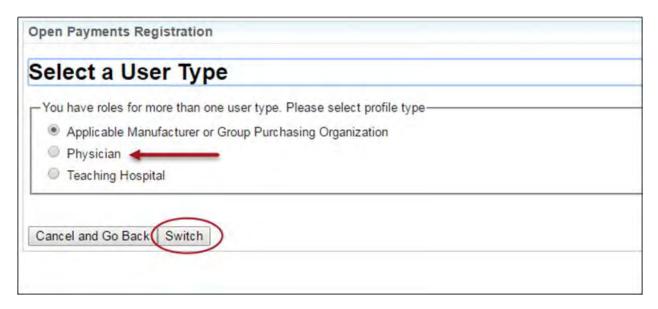
All users have access to the "Switch User Type" functionality. Users who have only a single user type can use the functionality to request roles for and/or register as another user type.

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 very top of the page, select "Switch User Type."



<u>Step 2:</u> Select the user type to which you would like to switch, or which user type you would like to request a role. 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."



<u>Step 3:</u> If you are not currently assigned a role for the selected user type, you will be prompted to create a profile. Select the "Create My Profile" button to begin that process.



<u>Step 3a</u>: 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 page.

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 6.4: 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.

6.4a: Physician User Roles

A physician may designate **one authorized representative** within the Open Payments system to take certain actions on behalf of the physician. 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. A physician cannot be his or her own authorized representative, and a physician can only have one physician authorized representative.

The physician will designate the level of access for their authorized representative; more than one access 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 6.7: Physician User Roles and User Role Functions

User Role	Function
Physician	 Registers him- or herself in the Open Payments system Nominates an authorized representative Has full access to review and dispute records
Authorized Representative	 Physician can grant one or more of the following access levels: Read-only: (default) Able to see physician 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

6.4b: Teaching Hospital User Roles

Teaching hospitals can have up to 10 unique users holding a role of either of authorized official or authorized representative. There can be a maximum of five authorized officials per teaching hospital. For teaching hospitals, authorized officials are responsible for approving all user role 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. The authorized representatives 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 6.8 below.

Figure 6.8: Teaching Hospital User Roles and User Role Functions

User Role	Function
Authorized Official	 Registers with the teaching hospital in the Open Payments system Nominates other users and modifies existing user roles Approves or modifies nominations made by others and requests for user roles made by others, including self-nominations Removes user roles from other users 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
- Email address

Section 6.5: Nominations

The nomination process allows users to assign specific roles to individuals to act on behalf of a physician or teaching hospital. Physicians can nominate an individual to serve as an authorized representative, and users affiliated with teaching hospitals can nominate individuals to serve as authorized representatives or authorized officials. Also, individuals can nominate themselves for a user role with a teaching hospital.

An authorized official from the teaching hospital must approve all nominations before users can begin performing actions in the system. Note: If you nominate yourself for a role with a teaching hospital that is already registered but lacks an active authorized official, contact the Open Payments Help Desk at openpayments@cms.hhs.gov to complete the registration.

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 made during registration or afterwards. 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 registration ID is specific to the teaching hospital; the nomination ID is specific to the individual nominee. 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 calendar 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. The Open Payments system will render the nomination expired if the nomination has not been accepted or rejected within 10 calendar 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 calendar 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 calendar day, an expired nomination notification will be sent to the nominee. **Figure 6.9** shows the five steps in the nomination acceptance process.

Figure 6.9: Accepting Nominations Process



Users can also be deactivated from a teaching hospital. Deactivation removes an individual's association with a teaching hospital in the Open Payments system, including removing the individual's access to that teaching hospital's information and records. It does not remove the individual from the Open Payments system.

In the "My Profile" page of the Open Payments system, user roles are listed with a status. An explanation of those statuses is in the table below.

Figure 6.10: User Role Statuses for Physicians and Teaching Hospitals

User Role Status	Meaning
Nominated	The individual has been nominated for a user role with the teaching hospital or physician
Declined	The individual declined the nomination for the user role
Accepted	The individual accepted the nomination for the user role
Requested (teaching hospital only)	An individual has self-nominated for a user role with a teaching hospital
Approved (teaching hospital only)	The individual's self-nomination for the user role has been approved by an authorized official with the teaching hospital
Vetted (physician only)	The physician has successfully completed the vetting process
Pending Vetting (physician only)	The physician has not yet undergone the vetting process
Vetting In Progress (physician only)	The physician is undergoing the vetting process
Failed Vetting (physician only)	The physician has not yet undergone the vetting process

6.5a: Nominating a Physician Authorized Representative (Returning System 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.

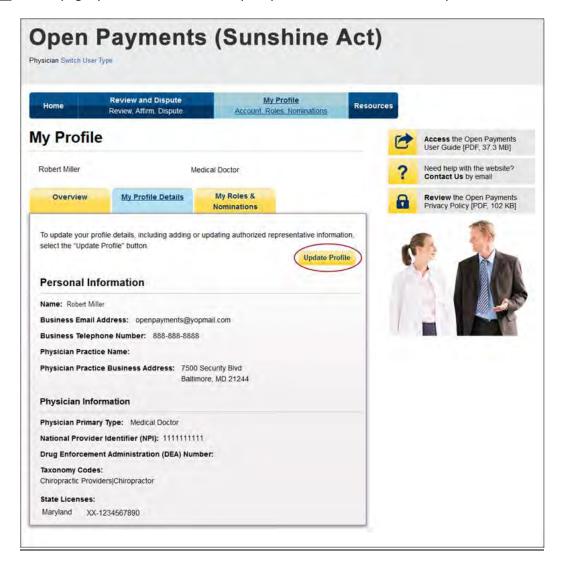
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page, and select the "My Profile" tab.



Step 2: From the "My Profile Overview" tab, select the "My Profile Details" tab.



Step 3: On this page, you will be able to view your profile information. Select "Update Profile."



<u>Step 4:</u> On the "My Profile" page, you can nominate an authorized representative if you did not do so during initial registration, or update the level of access for an existing authorized representative. You may also change your current authorized representative. To do this, replace the existing authorized representative's name, email address, telephone number, job title, business address and level of access information with new data. The system will generate an email notification with a Nomination ID to the nominee informing that person of their nomination for a role in the Open Payments system.

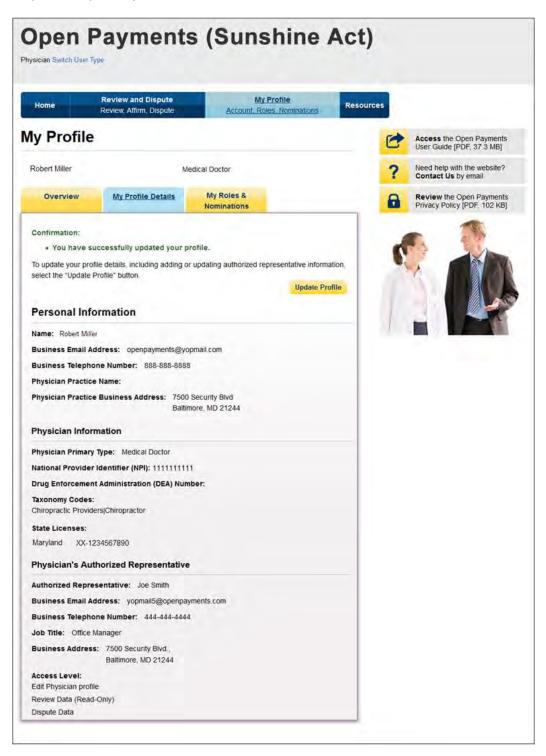
If you still do not wish to delegate an authorized representative, select "Not now" and select "Save Updates." On this page, you may also modify your profile information, such as adding or editing your state license information or physician taxonomy codes. See Section 6.6 for more information on profile updates.

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 page. 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 6.4. When complete, select "Save Updates."



<u>Step 5:</u> The nominee will receive an email notification that they have been nominated for a role in the Open Payments system. The email 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 receive access to the functions for that specific role. The nominee will have 10 calendar days to accept or reject the nomination.



6.5b: Nominating Additional Roles for a Teaching Hospital (Returning System Users)

If you are an authorized official for a teaching hospital that did not nominate individuals for 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.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page, and select the "Manage Teaching Hospitals" tab.



Step 2: Select the teaching hospital for which you wish to nominate a new role.



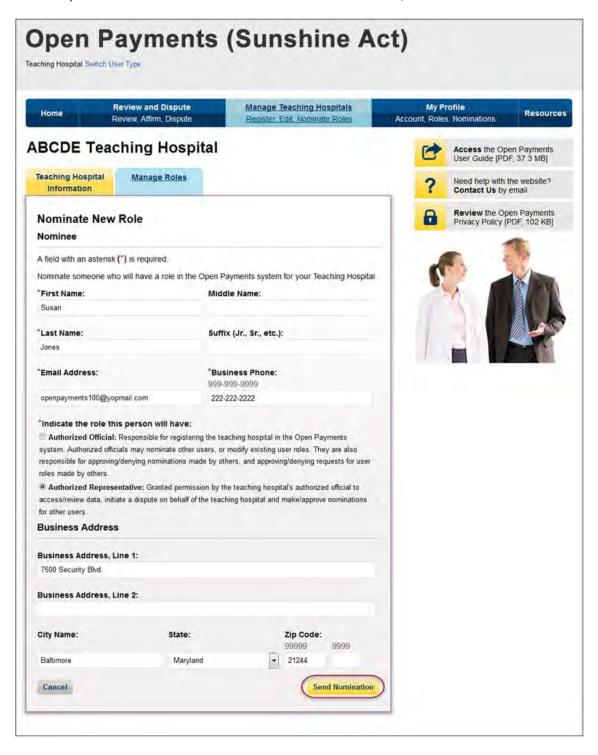
Step 3: Select the "Manage Roles" tab.



Step 4: Select "Nominate New Role."



<u>Step 5:</u> 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 nominee will receive an email notification that they have been nominated for a role in the Open Payments system. The email notifying the nominee 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 receive access to the functions for that specific role. The nominee will have 10 calendar days to accept or reject the nomination.

Instructions for confirming nominations can be found in the next section.

6.5c: Accepting or Rejecting a Nomination (Physician Authorized Representative – First-Time Users)

If you have been nominated for a physician authorized representative role, you will receive a notification email containing instructions and important information needed to accept your nomination. You will have 10 calendar days to accept or reject the nomination. If you have not taken action on your nomination within 10 days, the nomination will expire. Follow the steps below to accept the nomination.

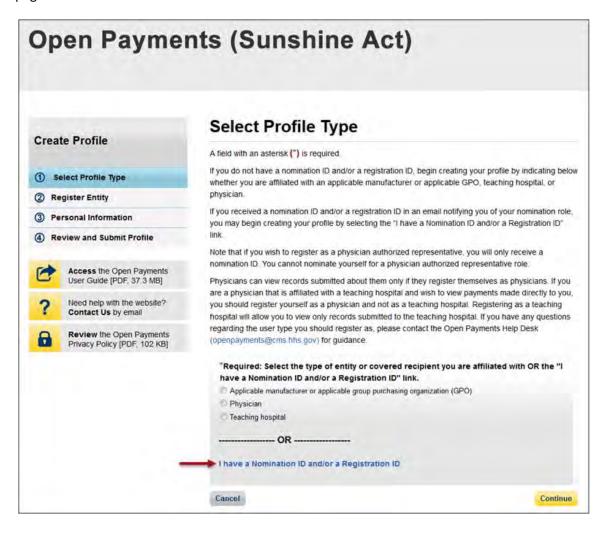
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.



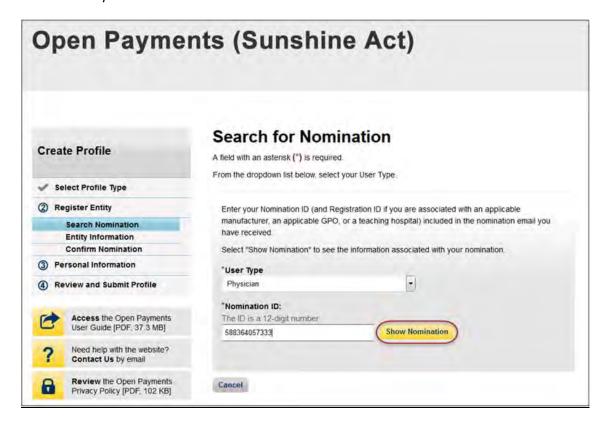
<u>Step 2:</u> The on-screen text contains important information regarding creating the physician and individual profiles. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile" at the bottom of the page when you are ready to continue.



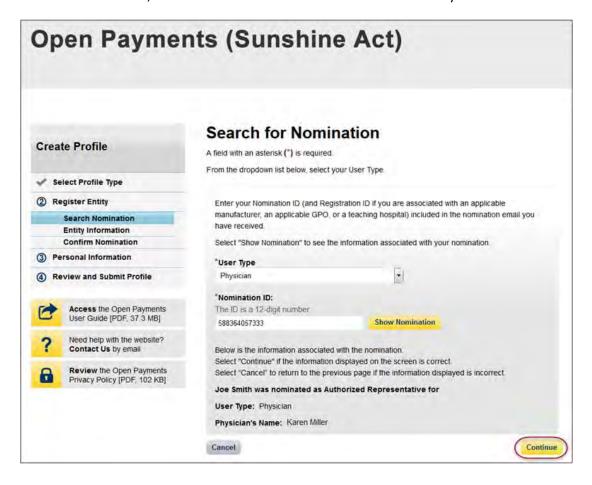
<u>Step 3:</u> Although you are affiliating with a physician, do not select "Physician" on the "Select Profile Type" page. Instead, select the "I have a Nomination ID and/or a Registration ID" link at the bottom of the page.



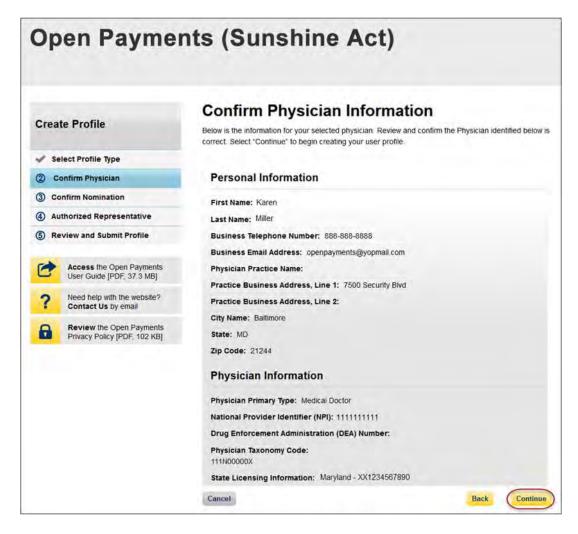
<u>Step 4:</u> Select the User Type "Physician." Enter the nomination ID included in the nomination notification email you received and then select "Show Nomination."



<u>Step 5:</u> Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select "Cancel" and contact the nominator directly.

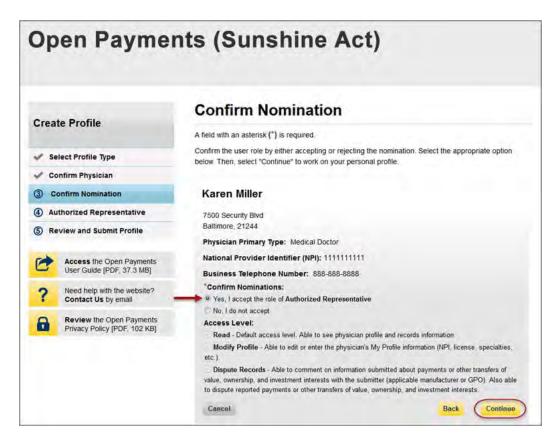


<u>Step 6:</u> Review the physician information displayed on the page. You will not be able to edit the information. Ensure that this is the physician for which you want to accept the user role nomination. If it is not the correct physician, either select the "Back" button at the bottom of the page to return to the previous page to correct the information you have entered, or select "Cancel" to end the acceptance process.

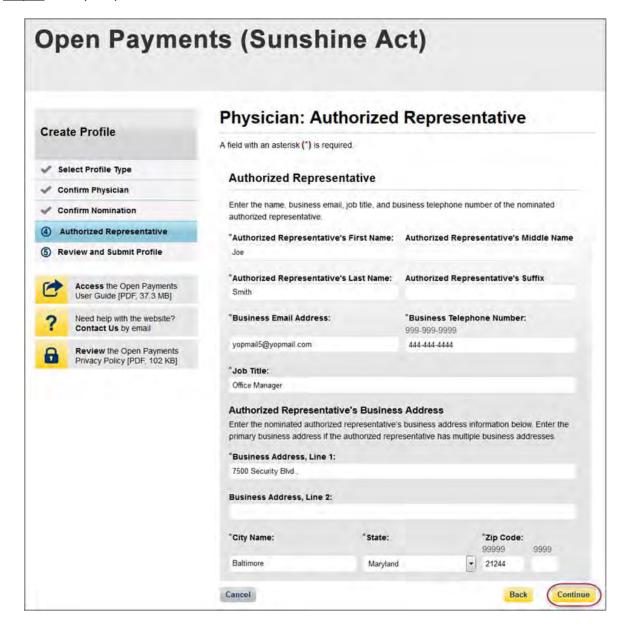


<u>Step 7:</u> Review the nomination information on the page. Select "Yes, I accept the role of Authorized Representative" if you wish to accept the role or "No, I do not accept" if you do not wish to accept the role. If you accept the role and select "Continue," you will continue the nomination confirmation process.

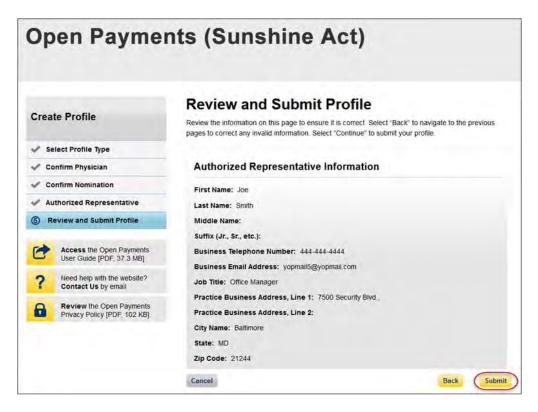
If you reject the role for which you have been nominated, select "Continue" after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will receive an email that you rejected the nomination. The nominator will then be allowed to nominate another individual for the role.



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



<u>Step 9:</u> Now you will be asked to review the information you have entered. To correct any errors, select the "Back" button at 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.



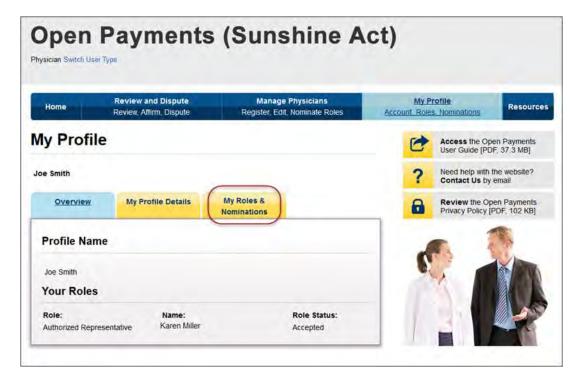
6.5d: Accepting or Rejecting a Nomination (Physician Authorized Representative – Returning System Users)

If you have been nominated for a physician authorized representative role, you will receive a notification email containing instructions and important information needed to accept your nomination. Once you have received this email, follow the steps below to accept the nomination.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "My Profile" tab from the menu bar on the Open Payments home page.



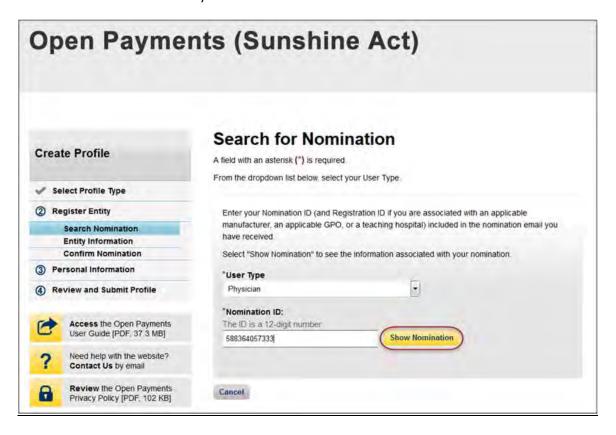
Step 2: From the "My Profile Overview" tab, select the "My Roles and Nominations" tab.



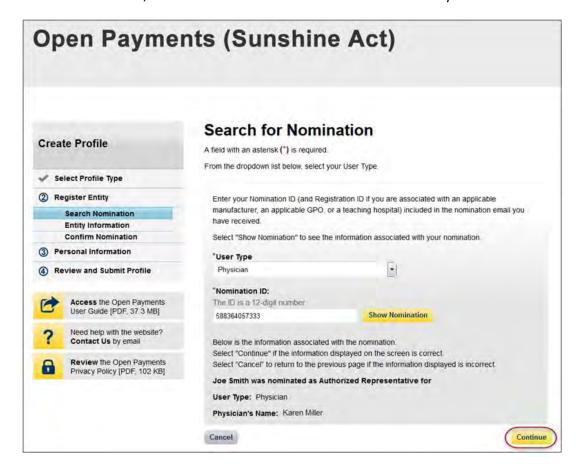
Step 3: From the "My Roles and Nominations" tab, select "Accept/Reject Nominations."



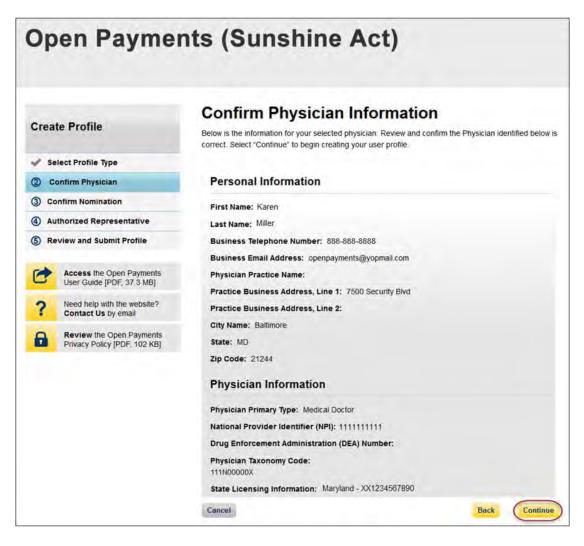
<u>Step 4:</u> The "User Type" should be pre-populated with "Physician." Enter the nomination ID provided in the nomination notification email you received and then select "Show Nomination."



<u>Step 5:</u> Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select "Cancel" and contact the nominator directly.

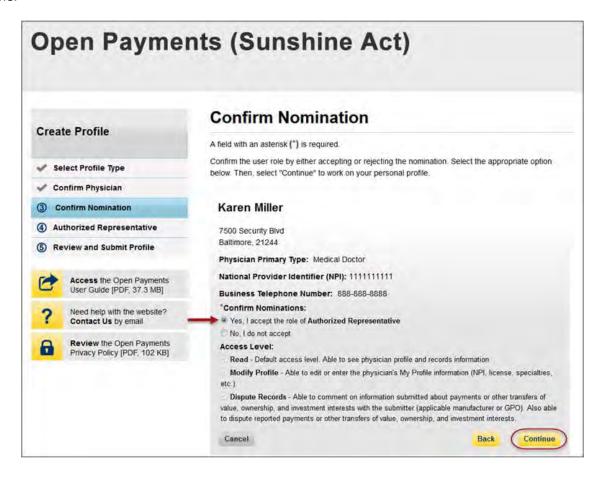


<u>Step 6:</u> Review the physician information displayed on the page. You will not be able to edit the information. Ensure that this is the physician for which you want to accept the user role nomination. If it is not the correct physician, either select the "Back" button at the bottom of the page to return to the previous page to correct the information you have entered, or select "Cancel" to end the acceptance process.

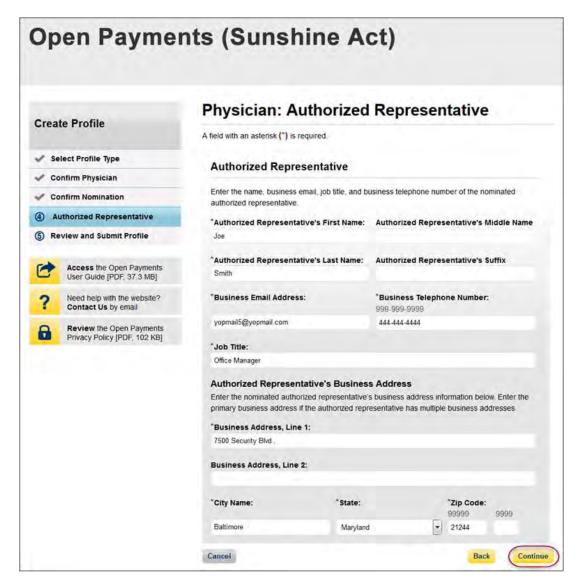


<u>Step 7:</u> Review the nomination information on the page. Select "Yes, I accept the role of" if you wish to accept the role or "No, I do not accept" if you do not wish to accept the role. If you accept the role and select "Continue," you will continue the nomination confirmation process.

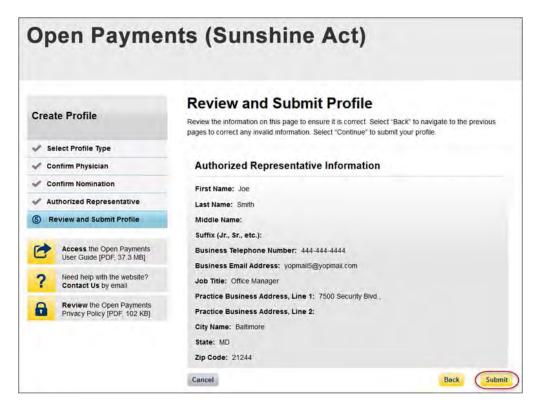
If you reject the role for which you have been nominated, select "Continue" after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will receive an email that you rejected the nomination. The nominator will then be allowed to nominate another individual for the role.



<u>Step 8:</u> Enter your personal information and select "Continue."



<u>Step 9:</u> Now you will be asked to review the information you have entered. To correct any errors, select the "Back" button at 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.



6.5e: Accepting or Rejecting a Nomination (Teaching Hospital – First Time System Users)

If you have been nominated for a teaching hospital user role, you will receive a notification email. Take note of the information in the email, including registration ID and nomination ID, then follow the steps below to accept the nomination.

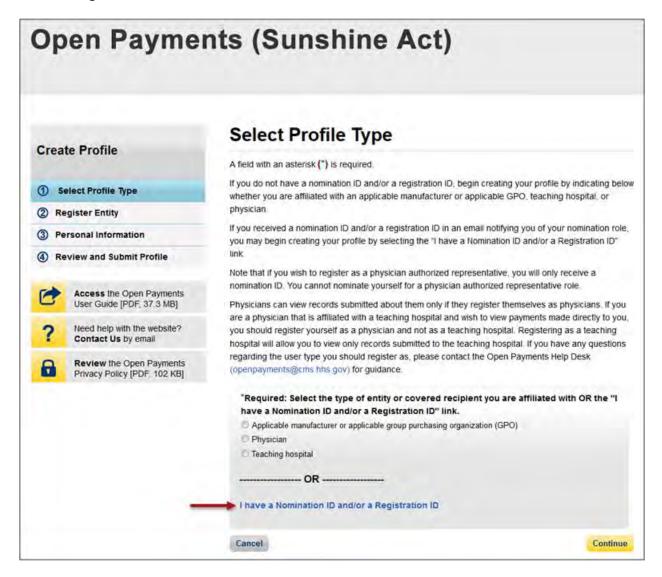
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.



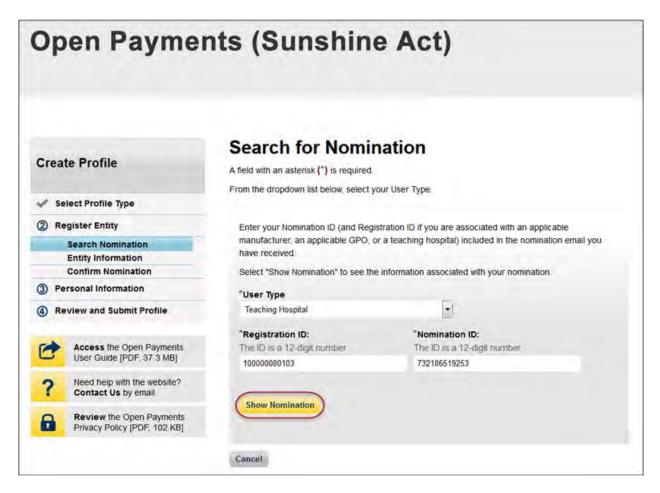
<u>Step 2:</u> The on-screen text contains important information regarding creating the physician and individual profiles. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile" at the bottom of the page when you are ready to continue.



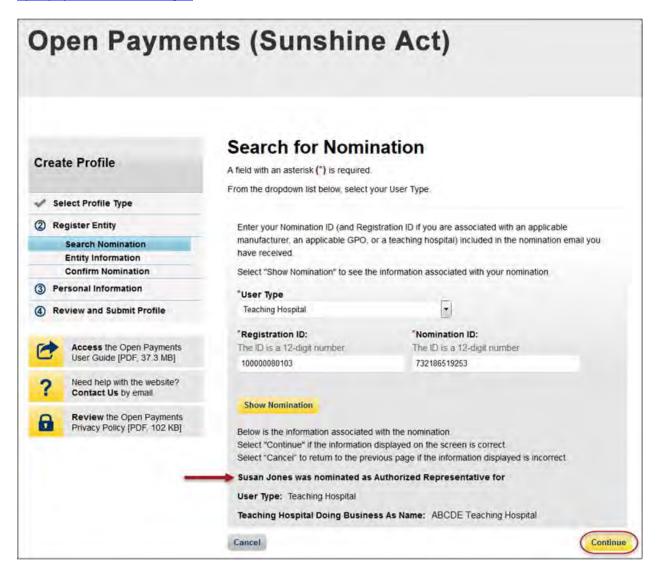
<u>Step 3:</u> On the "Select Profile Type" page, though you are affiliating with a teaching hospital, do not select "Teaching Hospital." Instead, select the link at the bottom of the page, "I have a Nomination ID and/or a Registration ID."



<u>Step 4:</u> 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."



<u>Step 5:</u> 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 at openpayments@cms.hhs.gov.

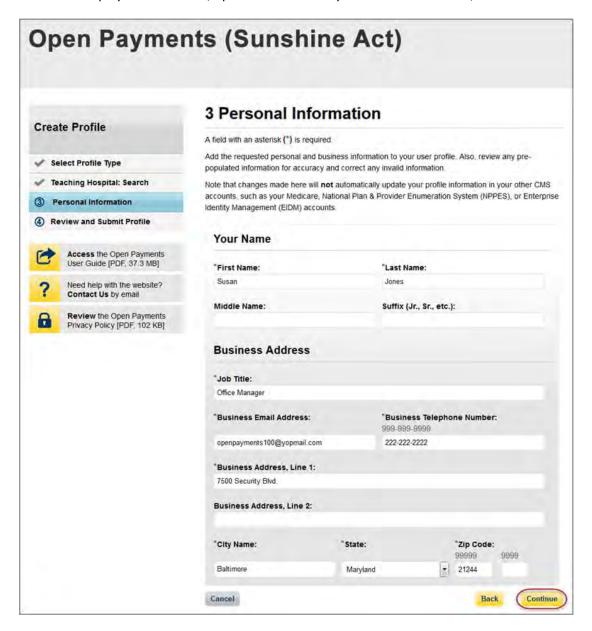


<u>Step 6:</u> Select "Yes, I accept the role of" if you wish to accept the role or "No, I do not accept" if you do not wish to accept the role. If you accept the role and select "Continue," you will continue the nomination confirmation process.

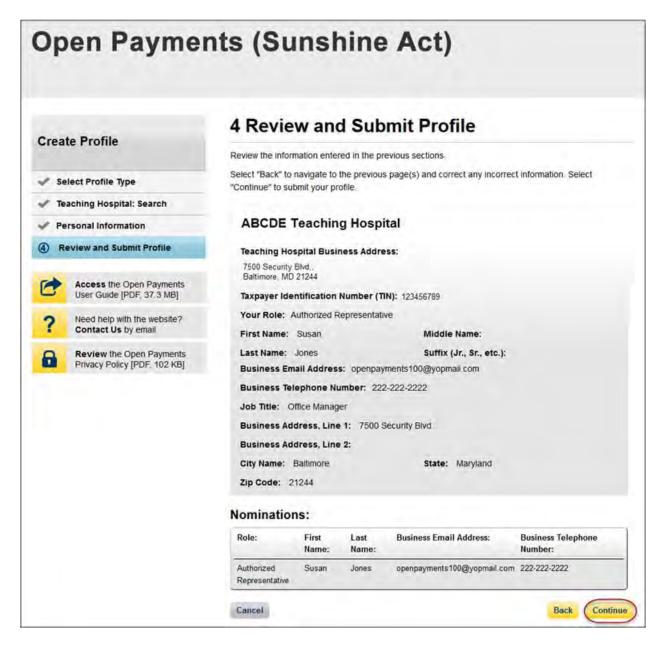
If you reject the role for which you have been nominated, select "Continue" after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will receive an email that you rejected the nomination. The nominator will then be allowed to nominate another individual for the role.



<u>Step 7:</u> 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."



<u>Step 8:</u> Review the information you have entered. To correct any errors, select the "Back" button at 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.



6.5f: Accepting or Rejecting a Nomination (Teaching Hospital – Returning System Users)

If you have been nominated for a teaching hospital user role you will receive a notification email. Take note of the information in the email, including registration ID and nomination ID, then follow the steps below to accept the nomination.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "My Profile" tab.



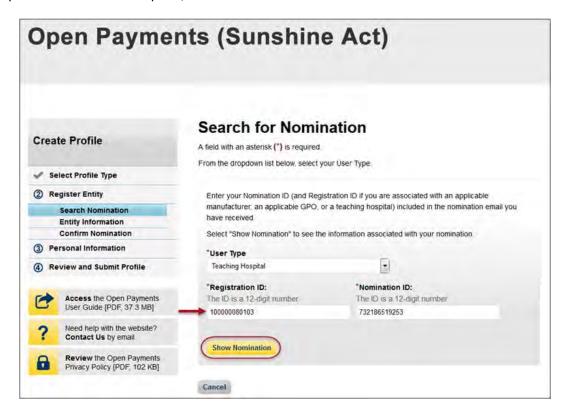
Step 2: Select "My Roles and Nominations."



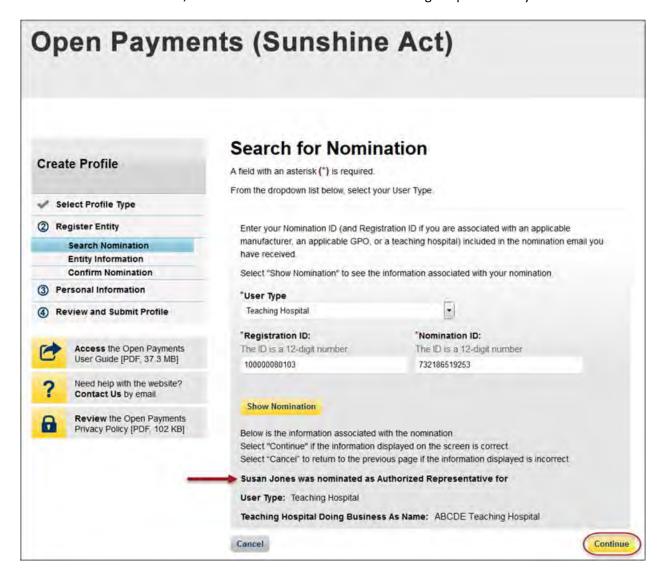
Step 3: Select "Accept/Reject Nominations."



<u>Step 4:</u> 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."



<u>Step 5:</u> 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.

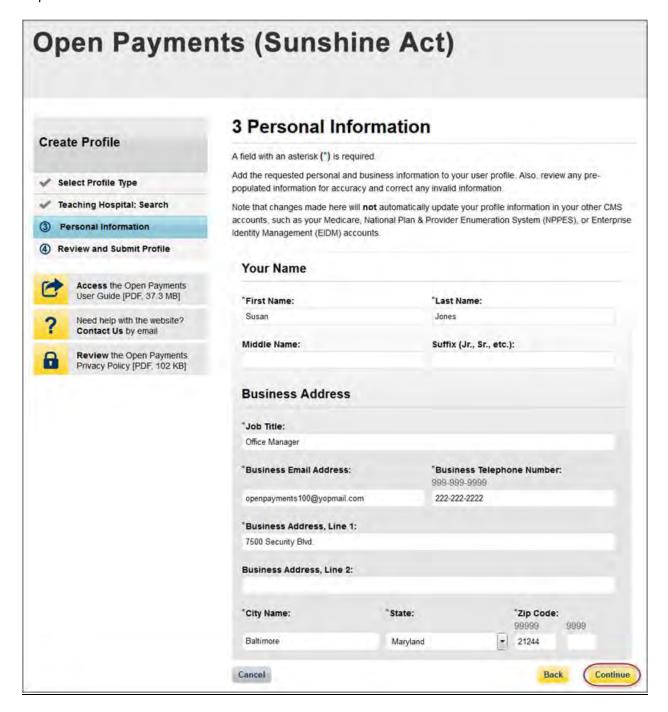


<u>Step 6:</u> Select "Yes, I accept the role of" if you wish to accept the role or "No, I do not accept" if you do not wish to accept the role. If you accept the role and select "Continue," you will continue the nomination confirmation process.

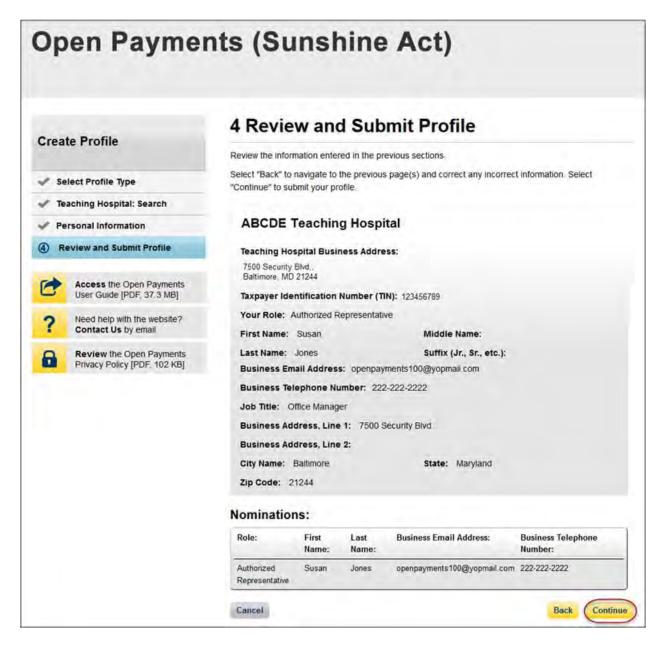
If you reject the role for which you have been nominated, select "Continue" after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will receive an email that you rejected the nomination. The nominator will then be allowed to nominate another individual for the role.



<u>Step 7:</u> Review your personal information and enter in any additional required fields. Select "Continue" to proceed.



<u>Step 8:</u> Review the information you have entered. To correct any errors, select the "Back" button at 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.



6.5g: Self-Nomination: Requesting a Role (Teaching Hospital - First Time System Users)

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.

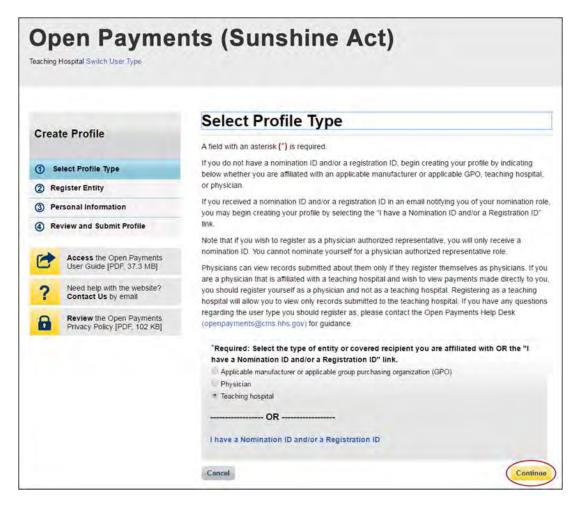
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.



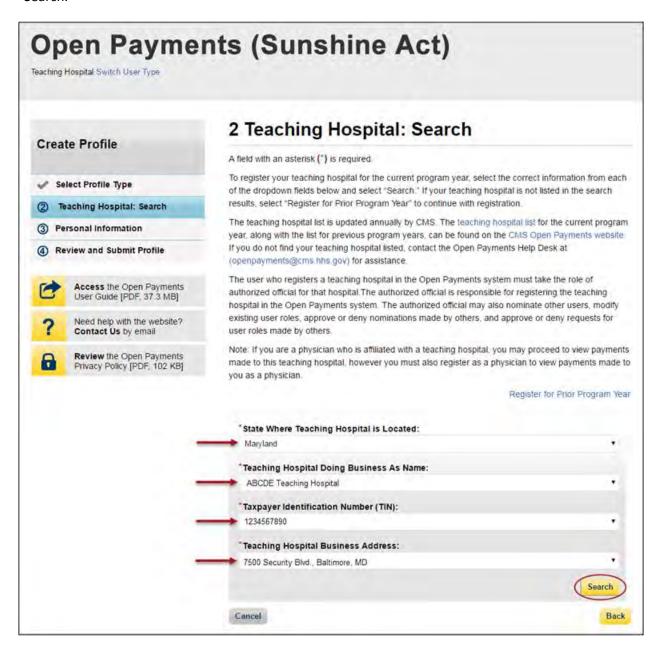
<u>Step 2:</u> The on-screen text contains important information regarding creating the physician and individual profiles. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile" at the bottom of the page when you are ready to continue.



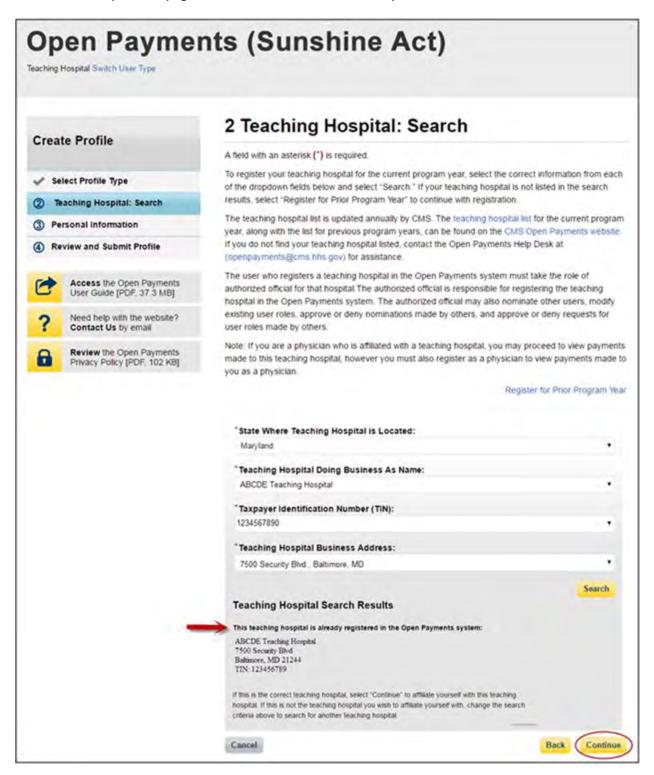
Step 3: Select the profile type "Teaching Hospital." When finished, select "Continue."



<u>Step 4:</u> Search the database for the correct teaching hospital. Select the teaching hospital's state, name, business address, and Taxpayer Identification Number (TIN) from the drop-downs. When finished, select "Search."



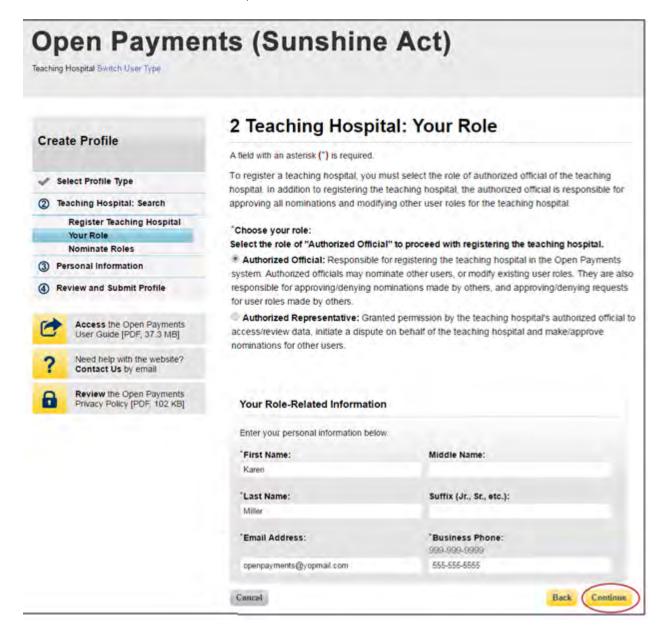
<u>Step 5:</u> Review the returned information displayed on the page. Select "Continue" if the information displayed is correct. If the information is not correct, select the "Back" button at the bottom of the page to return to the previous page and edit the search information you entered.



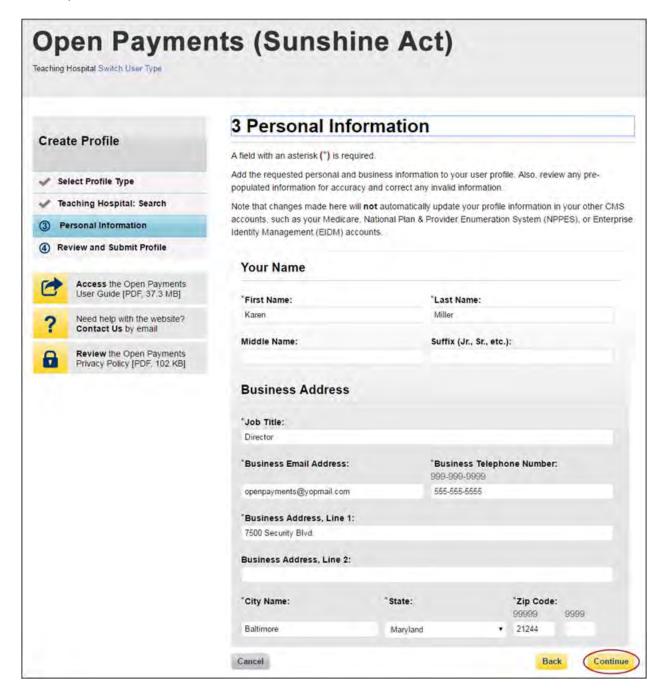
<u>Step 6:</u> Review the information displayed on the page. If the information is correct, select the "Continue" button. If the information is not correct, select the "Back" button at the bottom of the page to select a different teaching hospital.



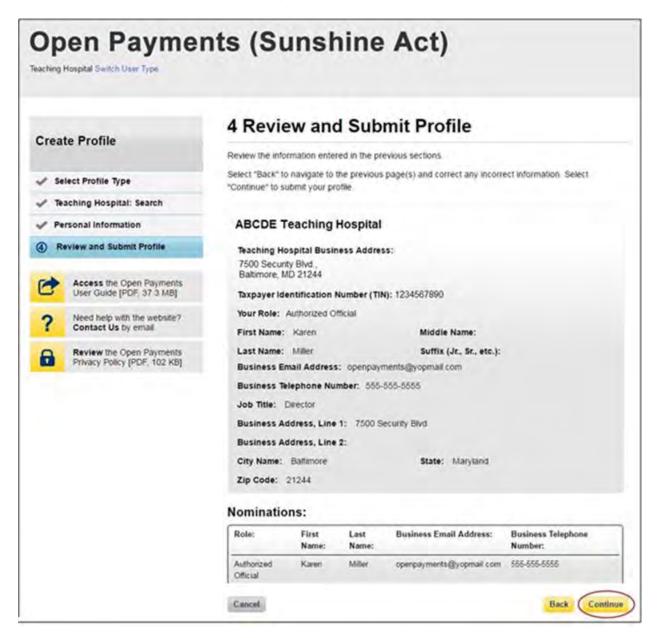
<u>Step 7:</u> Select the role you wish to nominate yourself for in the teaching hospital. Note that as you are not registering the teaching hospital, you may select either role. After you have chosen your role, enter in the role-related information in the data fields. Required fields are marked with an asterisk. Once you have entered in all of the information, select "Continue."



<u>Step 8:</u> Review your information displayed on the page. Enter your job title and business address. When finished, select "Continue."



<u>Step 9:</u> Review your profile information on the "Review and Submit Profile" page. Select the "Back" button at the bottom of the page to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Continue."



Open Payments User Guide

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. Also, the authorized officials for the teaching hospital will receive emails notifying them of your request for a user role.

If you are nominating yourself for a role with a teaching hospital that has already been registered but which lacks an active authorized official to approve your self-nomination, please contact the Open Payments Help Desk at openpayments@cms.hhs.gov.



6.5h: Self-Nomination: Requesting a Role (Teaching Hospital - Returning System Users)

If you would like to self-nominate for a teaching hospital role as an authorized official or authorized representative, and already have a profile in the Open Payments system, follow the steps below.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "My Profile" tab.



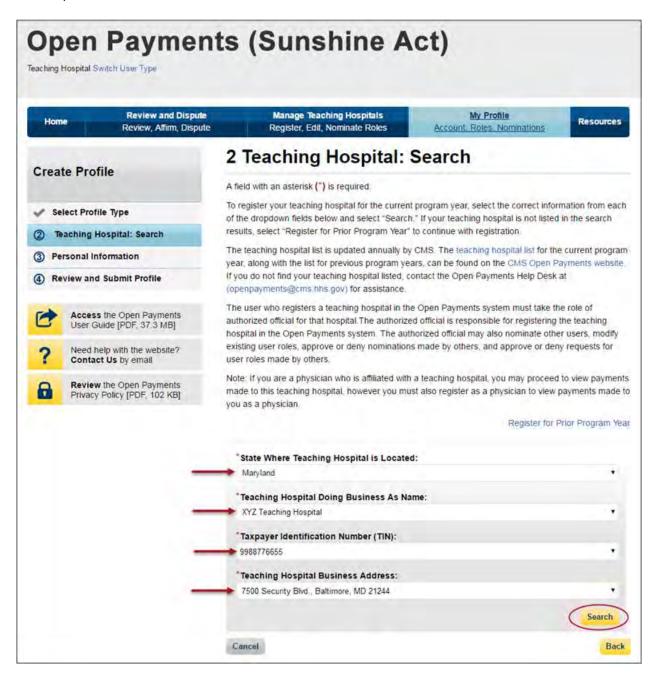
Step 2: Select the "My Roles and Nominations" tab.



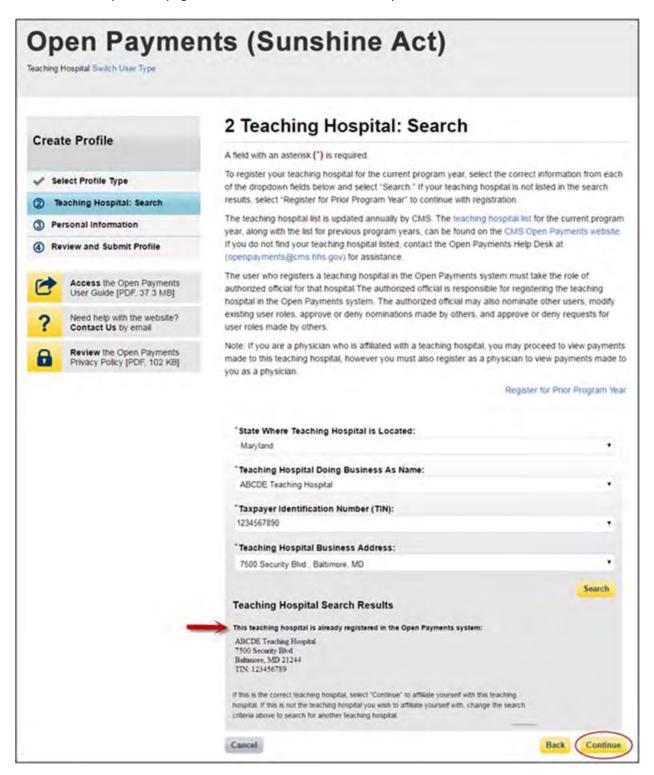
Step 3: From the "My Roles and Nominations" tab, select the "Request a Role" button.



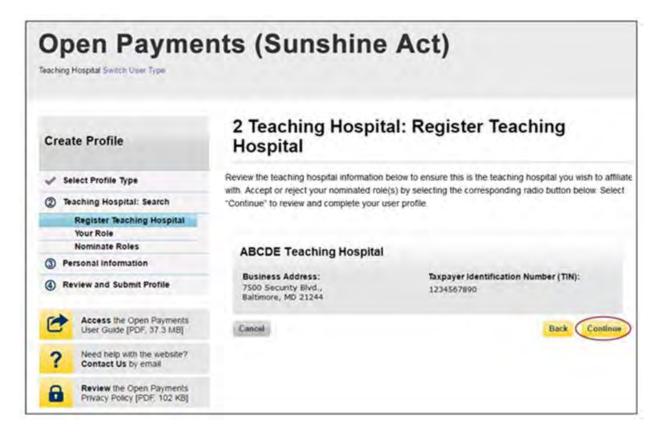
<u>Step 4:</u> Search the database for the correct teaching hospital. To do so, select the teaching hospital's state, name, business address, and Taxpayer Identification Number (TIN) from the drop-downs. When finished, select "Search."



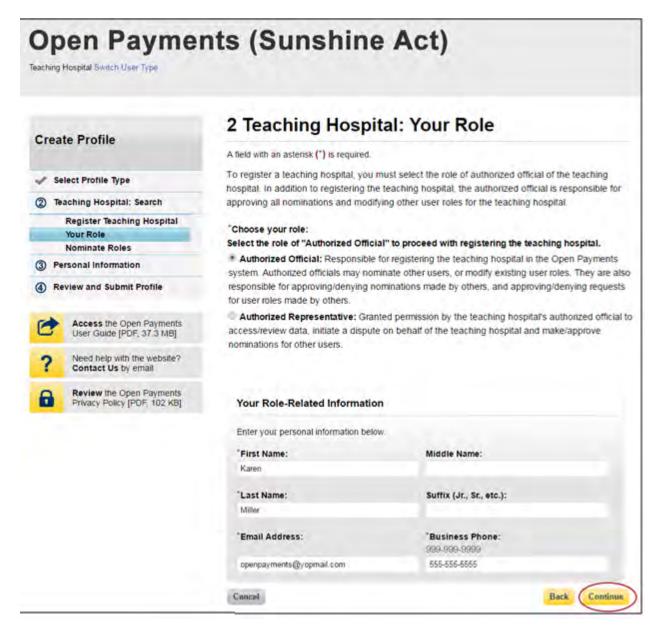
<u>Step 5:</u> Review the returned information displayed on the page. Select "Continue" if the information displayed is correct. If the information is not correct, select the "Back" button at the bottom of the page to return to the previous page and edit the search information you entered.



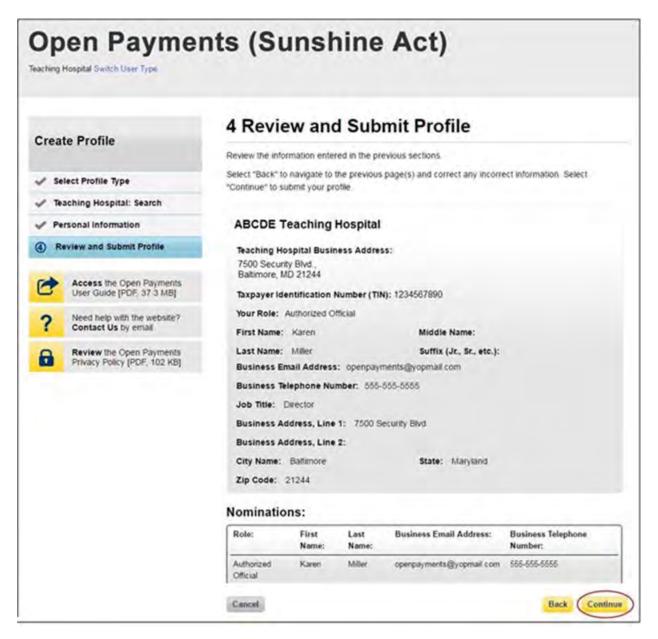
<u>Step 6:</u> Review the teaching hospital information. If the information is correct, select "Continue." If the information is not correct, select the "Back" button at the bottom of the page to select a different teaching hospital.



<u>Step 7:</u> Select the role you wish to nominate yourself for in the teaching hospital. Note that as you are not registering the teaching hospital, you may select either role. After you have chosen your role, enter in the role-related information in the data fields. Required fields are marked with an asterisk. Once you have entered in all of the information, select "Continue."



<u>Step 8:</u> Review your profile information on the "Review and Submit Profile" page. Select the "Back" button at the bottom of the page to go back and edit any information. Once you have reviewed the information and determined it to be correct, select "Continue."



Open Payments User Guide

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. Also, the authorized officials for the teaching hospital will receive emails notifying them of your request for a user role.

If you are nominating yourself for a role with a teaching hospital that has already been registered but which lacks an active authorized official to approve your self-nomination, please contact the Open Payments Help Desk at openpayments@cms.hhs.gov.



6.5i: Approving or Modifying a Nomination (Authorized Official Only)

If you are an authorized official for a teaching hospital and would like to approve or modify a nomination, follow the steps below.

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select "Manage Teaching Hospitals."



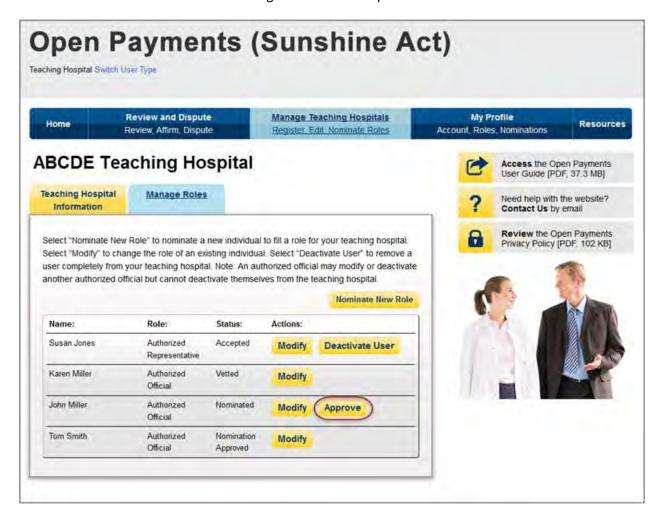
<u>Step 2:</u> On the "Manage Teaching Hospitals" page, select the teaching hospital for which you want to confirm a nomination.



Step 3: Select the "Manage Roles" tab.



<u>Step 4:</u> To approve a nomination, select the "Approve" button next to a nominee's name. The nominee will receive an email notification informing them of the acceptance of their nomination.



<u>Step 4a</u>: To modify a nomination, select the "Modify" button next to a nominee's name. This will allow you to change the individual's information and/or role. When modifications are complete, select "Save Role."

Note that you cannot remove all user roles from a nominee.



Open Payments (Sunshine Act) Teaching Hospital Switch User Type **Review and Dispute** Manage Teaching Hospitals My Profile Resources Review, Affirm, Dispute Account, Roles, Nominations ABCDE Teaching Hospital Access the Open Payments User Guide [PDF, 37.3 MB] Teaching Hospital Manage Roles Need help with the website? Contact Us by email Information Review the Open Payments Privacy Policy [PDF, 102 KB] Confirmation: . You have successfully modified a user role. Select "Nominate New Role" to nominate a new individual to fill a role for your teaching hospital. Select "Modify" to change the role of an existing individual. Select "Deactivate User" to remove a user completely from your teaching hospital. Note: An authorized official may modify or deactivate another authorized official but cannot deactivate themselves from the teaching hospital Status: Actions Susan Jones Authorized Accepted Modify Deactivate User Representative John Miller Authorized Modify Official Approved Tom Smith Authorized Nomination Modify Official Approved Karen Miller Authorized Approved Modify

Step 5: You will now see an updated list of nominations on the "Manage Roles" tab.

6.5j: Deactivating a User

A user holding the role of authorized official with a teaching hospital can deactivate other individuals' user roles with that teaching hospital, including other authorized officials. Deactivation removes an individual's association with a teaching hospital in the Open Payments system, including removing the individual's access to that teaching hospital's information and records. It does not remove the individual from the Open Payments system.

You cannot deactivate yourself. If you wish to be deactivated, contact the Open Payments Help Desk.

Only active users can be deactivated; individuals who have not yet accepted or rejected a user role nomination cannot be deactivated, nor can individuals who have self-nominated for a user role but their nomination has not yet been approved or denied.

To deactivate an individual's user role, follow these steps.

Open Payments User Guide

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Manage Teaching Hospitals" tab from the menu bar on the Open Payments home page.

<u>Step 2:</u> You will see a list of all of the teaching hospitals you are associated with. Select the hyperlink for the teaching hospital for which you will be deactivating a user.

Step 3: Select the "Manage Roles" tab.

Step 4: Select the "Deactivate User" button associated with name of the individual's name

<u>Step 5:</u> The Open Payments system will ask you to confirm the deactivation. Select "Continue" to confirm deactivation or "Cancel" to return to the Manage Roles page with no action taken. If you confirm deactivation, the Open Payments system will send emails to you and the individual being deactivated that confirms the individual's user role deactivation.

Section 6.6: Updating Profile Information in the Open Payments System

Physician and teaching hospital profiles can be kept current by updating them as information changes. The steps for profile updates are given below.

6.6a: 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.

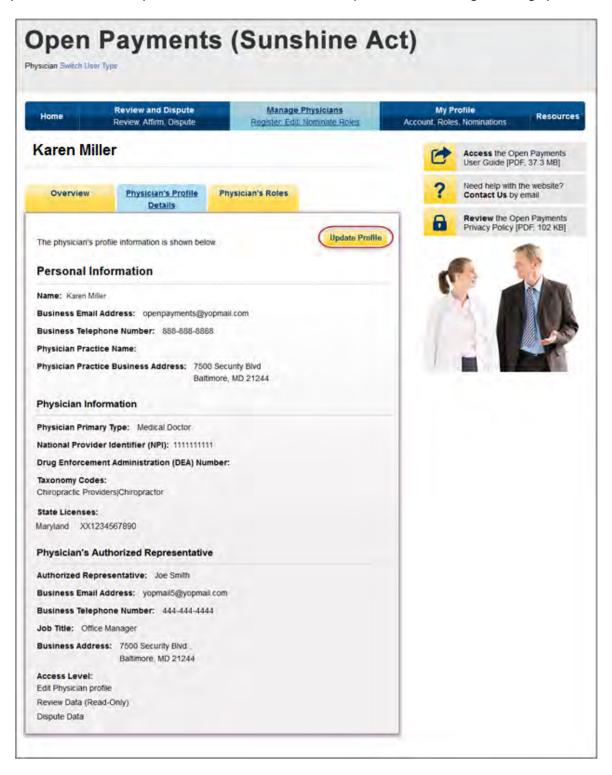
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Manage Physicians" tab.



Step 2: Select the physician for which you wish to make updates on the "Manage Physicians" page.



<u>Step 3:</u> 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."

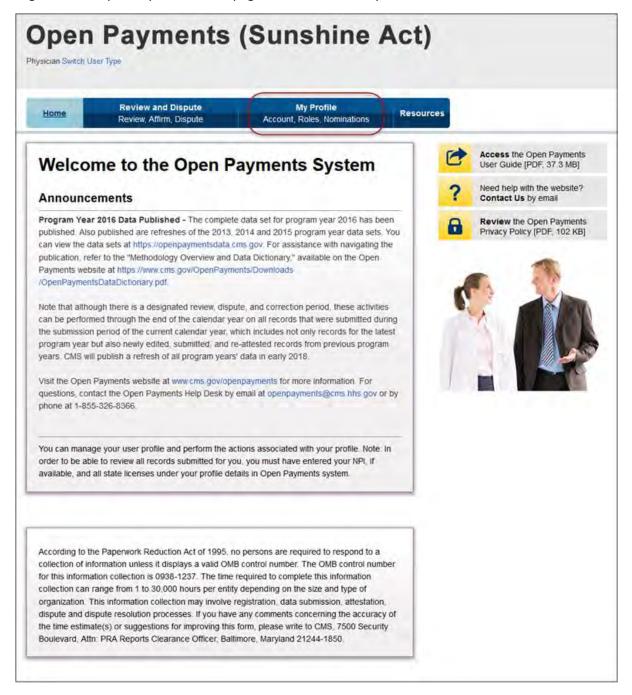


Note: Any updates made to the physicians profile will cause the physician to be re-vetted. Once the updated information has been re-vetted, both the physician and authorized official will be able to perform the necessary actions in the Open Payments system. See Section 6.3c for information on physician vetting.

6.6b: Updating Physician or Physician Authorized Representative 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.

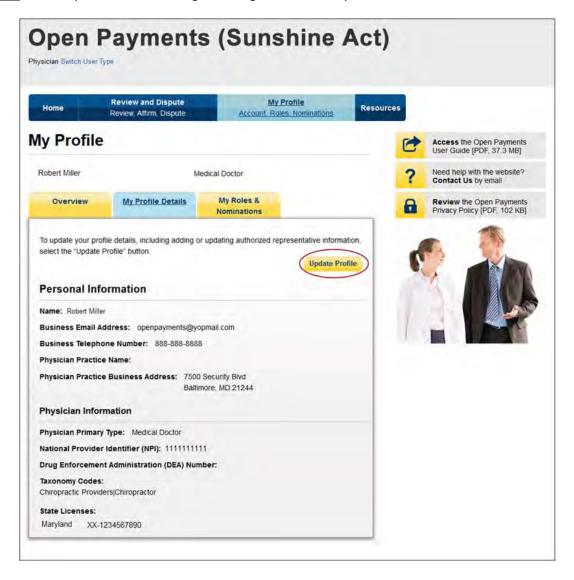
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "My Profile" tab.



Step 2: Select the "My Profile Details" tab. You will be able to view your existing profile information.



<u>Step 3:</u> Select "Update Profile" to begin making edits and/or updates.



Step 4: Update fields as necessary. When changes are complete, select "Save Updates."

The updated information will now appear on the "My Profile Details" page.



Review and Dispute For Physicians and Teaching Hospitals

Chapter 7: Review and Dispute for Physicians, Teaching Hospitals, and Principal Investigators

This chapter provides information on the review, dispute, and correction process for physicians, teaching hospitals, and physician principal investigators in the Open Payments system.

This chapter is divided into the following sections:

- **Review, Dispute, and Correction Overview** provides information on the review and dispute process within the Open Payments system.
- **Reviewing and Affirming Records** provides information on how physicians, teaching hospitals, and physician principal investigators can review and affirm data submitted about them by applicable manufacturers and applicable GPOs.
- Initiating and Withdrawing Disputes provides information on how physicians, teaching
 hospitals, and physician principal investigators can initiate or withdraw a dispute of submitted
 data.

This chapter covers the review and dispute functions for physicians, teaching hospitals, and physician principal investigators. Review, dispute, and correction functions for applicable manufacturers and applicable GPOs are covered in Chapter Five, "Review and Dispute for Applicable Manufacturers and Applicable GPOs."

Section 7.1: Review, Dispute, and Correction Overview

Physicians, teaching hospitals, and physician principal investigators may review data reported about them by applicable manufacturers and applicable GPOs in the Open Payments system. If errors are found in the reported data, a dispute may be initiated with the applicable manufacturer or applicable GPO. Physicians and teaching hospitals may dispute any part of a record in which they are identified as the covered recipient. Physicians identified in a record as a Principal Investigator (PI) may only dispute their own association with the record and their own personal identifying information given in that

record. They should not dispute any other information in the record, such as payment amount, nature of payment, etc.

Physicians, teaching hospitals, and physician principal investigators should work directly with reporting entities to resolve disputes outside of the Open Payments system. **CMS will not mediate disputes** between physicians, teaching hospitals, physician principal investigators, and reporting entities.

All physicians, teaching hospitals, and physician principal investigators who want to view data reported about them must register in both EIDM and Open Payments prior to accessing the Open Payments system. See Chapter 6 for registration information.

The review and dispute process is outlined in **Figure 7.1**, below.

Figure 7.1: Review, Dispute, and Correction Process

Review Activities	Dispute Activities	Correction Activities
Physicians, teaching hospitals, and physician principal investigators may review data submitted about them before it is published.	 Physicians, teaching hospitals, and physician principal investigators dispute information reported about them or their institutions if they find inaccuracies. 	 Applicable manufacturers and applicable GPOs work with the disputing physician, teaching hospital, or physician principal investigator to correct disputed data, or agree that no change to data is necessary to resolve the dispute. Applicable manufacturers and applicable GPOs re-
		submit and attest to corrected records, if necessary.

Email notifications are sent to alert applicable manufacturers, applicable GPOs, physicians, teaching hospitals, and physician principal investigators of review and dispute activities in the Open Payments system. These emails contain only the information necessary to locate the record in the Open Payments system and do not contain contact information for any of the parties involved in the dispute. You must view the record details in the system or obtain contact information if needed.

7.1a: Review, Dispute, and Correction Period

Each program year has a scheduled review, dispute, and correction period. This period begins with a 45-day period for physicians, teaching hospitals, and physician principal investigators to review, dispute, and work with the reporting entity to resolve the disputed record(s) submitted during the submission period. This includes records submitted for the previous program year and any records submitted late

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from prior program years. Immediately following the initial 45-day period is an additional 15-day correction period for reporting entities to make final corrections to records and resolve any active disputes. Records that are flagged for delay in publication by the reporting entity are eligible for review and dispute by physicians, teaching hospitals, and physician principal investigators.

Note that although there is a distinct review, dispute, and correction period, these activities can be performed throughout the year. The designated review and dispute period only affects when and how the dispute is displayed in the data publication and subsequent data refresh. Therefore, if a dispute is not resolved within the review, dispute, and correction period for a program year, all parties should continue to seek a resolution until the dispute is resolved. Once the dispute is resolved and any necessary corrections made to the record(s), the data will be updated in a subsequent publication based on when they were corrected in the Open Payments system.

Disputes initiated within the initial 45-day review, dispute, and correction 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. If the dispute is not resolved by the end of the correction period, the record will be published and identified as being under dispute.

Disputes initiated or resolved after the full 60-day review, dispute, and correction period will not be reflected 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. See Chapter 8, "Data Publication," for details on how dispute and resolution timing affect data publication. In the publication, the data will be associated with the program year of the data, not the date of its publication.

7.1b: Effects of Changing a Record to Resolve a Dispute

When a dispute resolution results in changes to a record, applicable manufacturers and applicable GPOs must re-submit the record with the revisions to the Open Payments system and attest to the revisions. The physician, teaching hospital, or physician principal investigator will be able to view the updated record once it has been re-submitted and re-attested also.

If the physician, teaching hospital, or physician principal investigator identified in a record is changed as part of a dispute resolution, the original physician, teaching hospital, or physician principal investigator will no longer see the record in his or her profile. Only the newly identified physician, teaching hospital, or physician principal investigator identified in the record will see it. The newly identified physician, teaching hospital, or physician principal investigator will see the record during the next calendar year's review and dispute period. To review the record, the newly identified physician, teaching hospital, or physician principal investigator would need to search through records submitted for the program year referenced in the new record.

For example, if a program year 2013 record was edited during the calendar year 2015 review and dispute period to identify a new covered recipient, the record would be available for review and dispute for the newly identified physician, teaching hospital, or physician principal investigator during calendar

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year 2016 review and dispute period, and the record would be found along with all records from the 2013 program year.

Records may be identified as under dispute in data publications, and dispute resolutions may affect what versions of data are published. For details on data publication, see Chapter 8.

7.1c: Review and Dispute Statuses

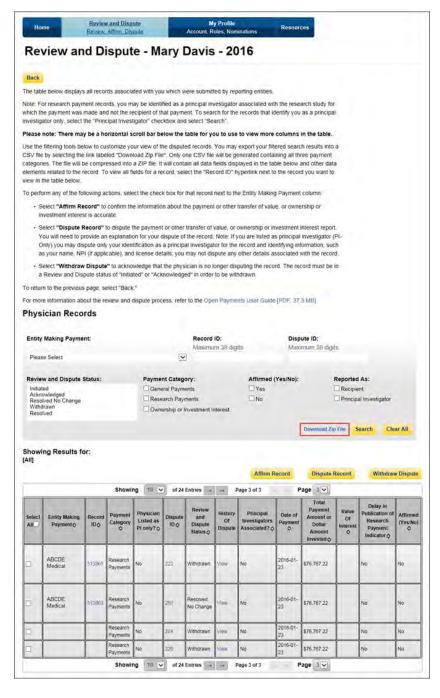
Records in the review and dispute process will have one of the following review and dispute statuses:

- Initiated: indicates that a physician, teaching hospital, or physician principal investigator 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 by a physician, teaching hospital, or physician principal investigator.
- Resolved, No Change: Indicates that the applicable manufacturer or applicable GPO and the
 physician, teaching hospital, or physician principal investigator have resolved the dispute in
 accordance with the guidance in the Final Rule, and no changes were made to the disputed
 record.
- Withdrawn: Indicates that a physician, teaching hospital, or physician principal investigator 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 re-submitted and re-attested to by the applicable manufacturer or applicable GPO.

7.1d: Exporting Disputed Data

The Open Payments system allows users to download disputed data into a separate CSV file. Records are exported into a pipe ("|") delimited CSV file by selecting the link labeled "Download Disputes" on your "Review and Dispute" page.

The file will be compressed into a ZIP file. It will contain all data fields displayed in the table and other data elements related to the dispute. Downloaded data files cannot exceed the acceptable limit of 20,000 records. If your record volume exceeds the record limit, apply filtering criteria to create smaller subsets of records and download them in multiple files.



Section 7.2: Reviewing and Affirming Records

Log in to Open

Payments, Select

'Review and

Dispute"

Physicians, teaching hospitals, and physician principal investigators that have registered with the Open Payments system may review all payments, other transfers of value, and physician ownership or investment interests submitted about them by an applicable manufacturer or applicable GPO. Records that have been reviewed and determined to be accurate can be affirmed by the physician, teaching hospital, or physician principal investigator in the Open Payments system. Affirmation is not a required action. Records that have not been affirmed will still be included in the next data publication. You may initiate disputes on records that have been previously affirmed if you determine that the record contains an error.

The process for reviewing and affirming records is illustrated in Figure 7.2 below. Step-by-step walkthroughs of various scenarios follow.

View Listed Select Covered Review Selected Records for the Select Record(s) Records and Recipient and Covered

to Affirm

Affirm Records

Figure 7.2: Review and Affirmation Process

Recipient

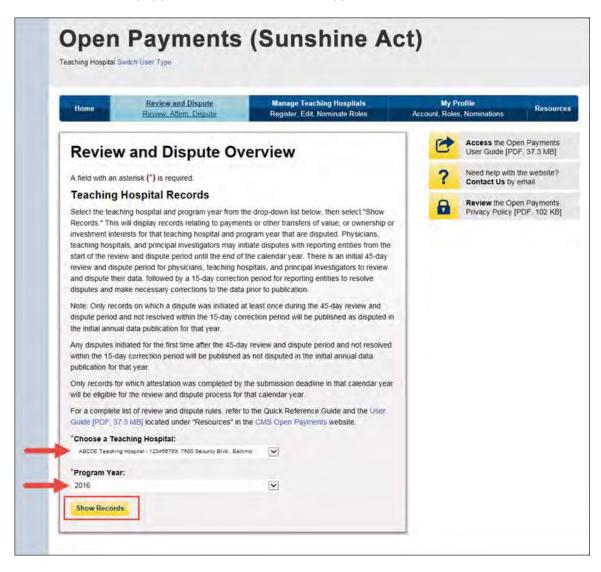
7.2a: Teaching Hospital - Reviewing and Affirming Submitted Data

Program Year

Step 1: Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.



<u>Step 2:</u> From the drop-down menus, select the teaching hospital and program year for which you wish to review data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."



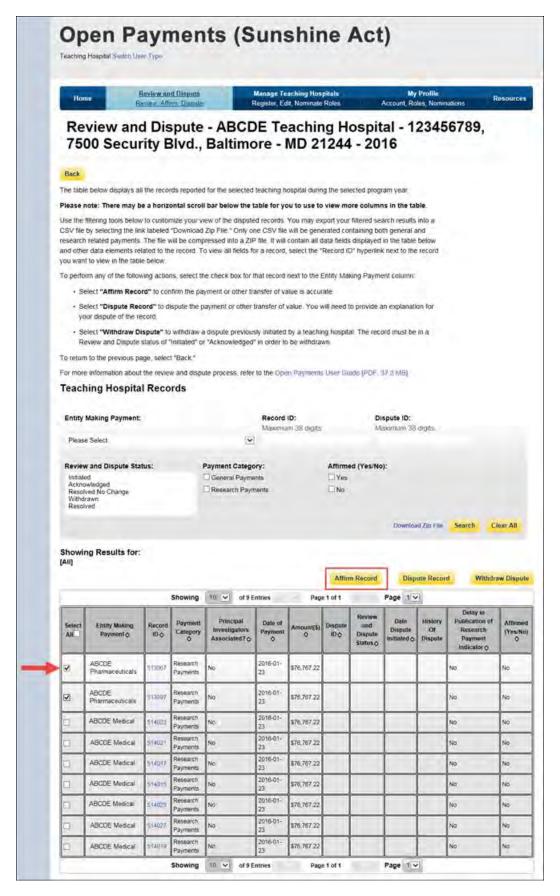
If the chosen teaching hospital has no records associated with it, you will receive a message at the top of the page saying "There are no payments or other transfers of value reported for this teaching hospital." If there are records associated with your chosen teaching hospital, proceed to Step 3.

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<u>Step 3:</u> On the Review and Dispute page, you will see a list of all the records reported for the selected teaching hospital during the selected program year. 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, and/or dispute ID. You do not need to filter the results in order to proceed. For instructions on how to export this data, see Section 7.1d.

If you wish to view details associated with the record, select the "Record ID" hyperlink of the record you wish to view. The Record ID page also contains contact information for the entity that submitted the record.

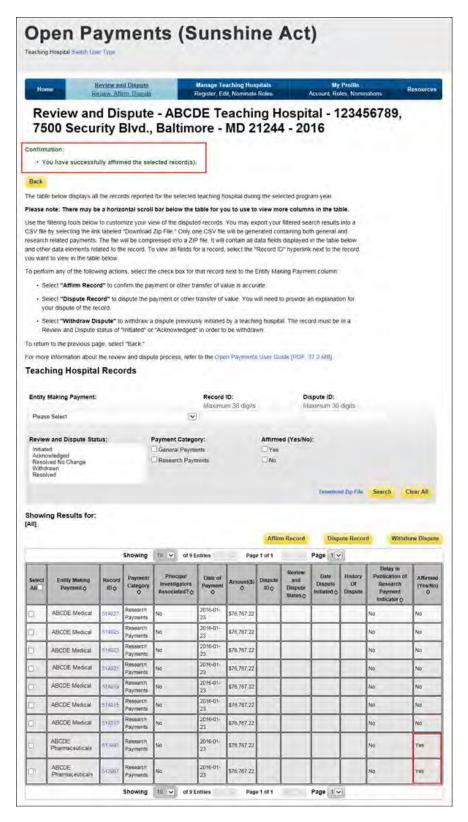
Select the checkboxes next to the record(s) you wish to affirm. You may affirm records with no dispute status, or records that have a review and dispute status of "Resolved, No Change," "Withdrawn," or "Resolved." After you have selected the record(s), select "Affirm Record."



<u>Step 4:</u> Review the information on the Affirm Records page. If the information is correct, select "Affirm Records." If the information is not correct, select "Back" and either change which record you are affirming or initiate a dispute on a record.



The following message will be displayed on the page 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 "Yes."

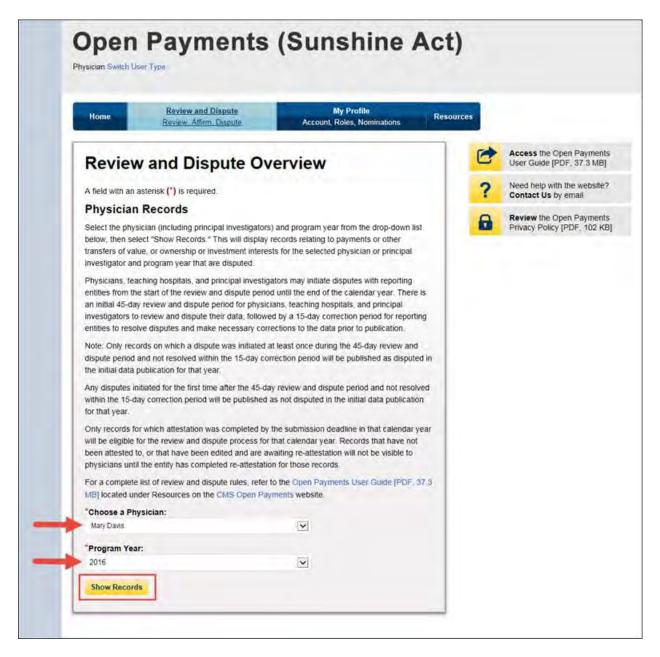


7.2b: Physician and Principal Investigator – Reviewing and Affirming Submitted Data

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



<u>Step 2:</u> From the drop-down menus, select the physician (or physician principal investigator) and program year for which you wish to review data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."



If the chosen physician has no records associated with him or her, you will receive a message at the top of the page saying "There are no payments or other transfers of value or ownership or investment interests reported for you or your family members." If there are records associated with your chosen physician, proceed to Step 3.

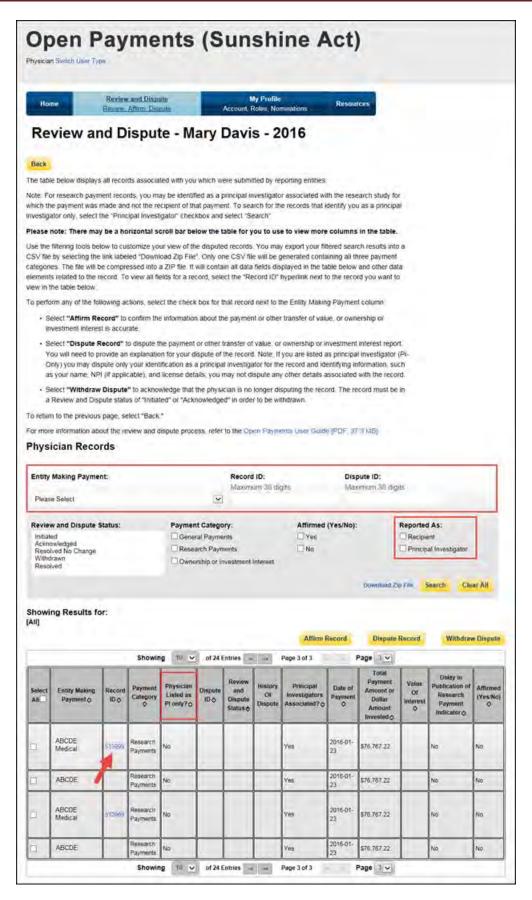
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<u>Step 3:</u> On the Review and Dispute page, you will see a list of all submitted records for the selected physician. You may filter the records by selecting "Entity Making Payment" from the appropriate dropdown menu. You may further filter information by including the Record ID, and/or Dispute ID.

You may also filter records by "Recipient" or "Principal Investigator." When a user selects the "Recipient" checkbox, the system will only display records on which the physician is reported as a covered recipient. When a user selects the "Principal Investigator" checkbox, the system will only display records on which the physician is reported as a principal investigator. Additionally, you can determine if the physician is a principal investigator on a record by looking at the column labeled "Physician Listed as PI Only" field. For instructions on how to export this data, see Section 7.1d.

Note: Physicians who are identified in a record as a Principal Investigator (PI) may only dispute their own association with the record and their own personal identifying information given in the record. They cannot dispute any other information in the record, such as payment amount, nature of payment, etc.

If you wish to view details associated with the record, select the "Record ID" hyperlink of the record you wish to view. On the Record ID page is contact information for the entity that submitted the record.

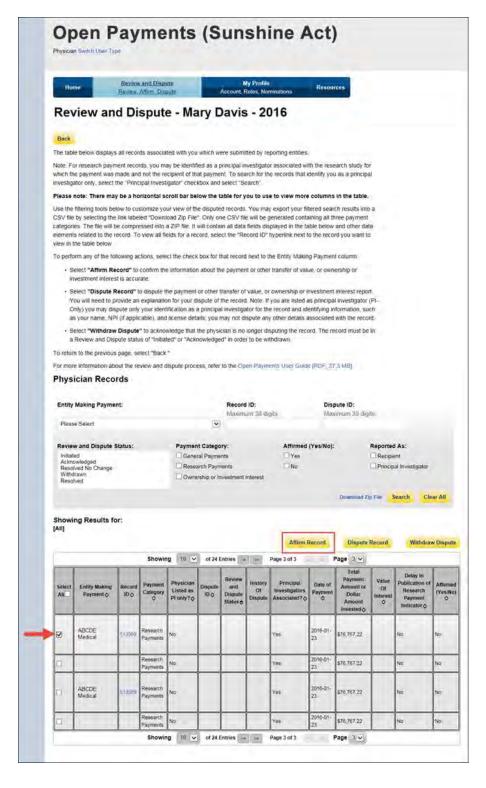


<u>Step 4</u>: Review the information in the submitted record, including principal investigator information. Contact information for the reporting entity will also be visible on this screen. When finished, select "Back" to return to the Review and Dispute page.

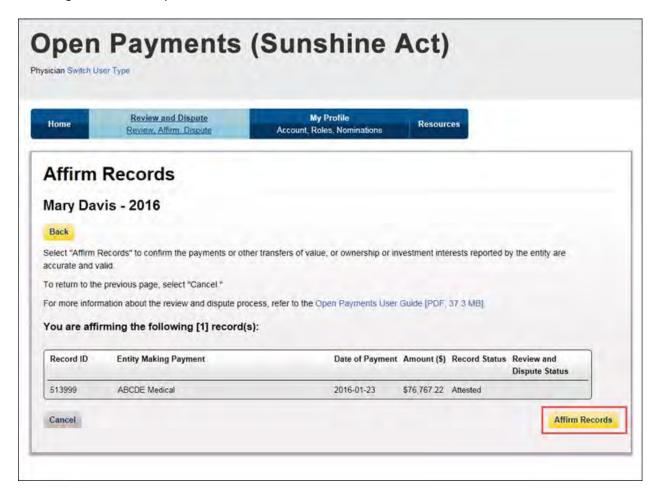


<u>Step 5:</u> Select the checkboxes next to the record(s) you wish to affirm. You may affirm records with no dispute status, or records that have a review and dispute status of "Resolved, No Change," "Withdrawn," or "Resolved".

After you have selected the record(s), select "Affirm Record."

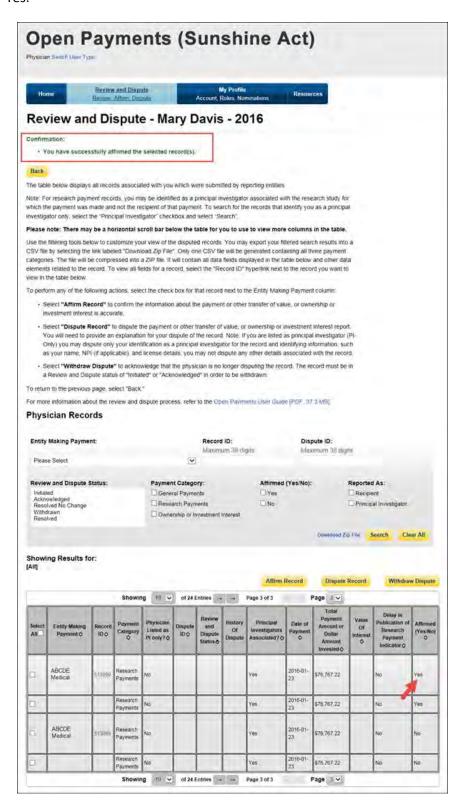


<u>Step 6:</u> Review the information on the Affirm Records page. If the information is correct, select "Affirm Records." If the information is not correct, select "Back" and either change which record you are affirming or initiate a dispute on a record.



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The following message will be displayed on the page below, confirming the successful affirmation of the submitted record. Also, the record's "Affirmed Yes/No" indicator, visible in the "View Records" table, will be set to "Yes."



Section 7.3: Initiating and Withdrawing Disputes

Physicians, teaching hospitals, and physician principal investigators can dispute data submitted by applicable manufacturers and applicable GPOs regarding payments or other transfers of value if the data contains inaccuracies.

When a physician, teaching hospital, or physician principal investigator initiates or withdraws a dispute, the applicable manufacturer or applicable GPO will receive an email notification regarding the dispute status with relevant information about the action taken. The process for initiating and withdrawing disputes is illustrated in **Figure 7.3** below. Step-by-step walkthroughs of various dispute scenarios are provided in this section.

Figure 7.3: Initiating and Withdrawing Disputes Process



When an applicable manufacturer or applicable GPO revises a record to address a dispute, the record will no longer be visible to the physician, teaching hospital, or physician principal investigators identified in that record until the revision is complete and the record is re-attested by the applicable manufacturer or applicable GPO.

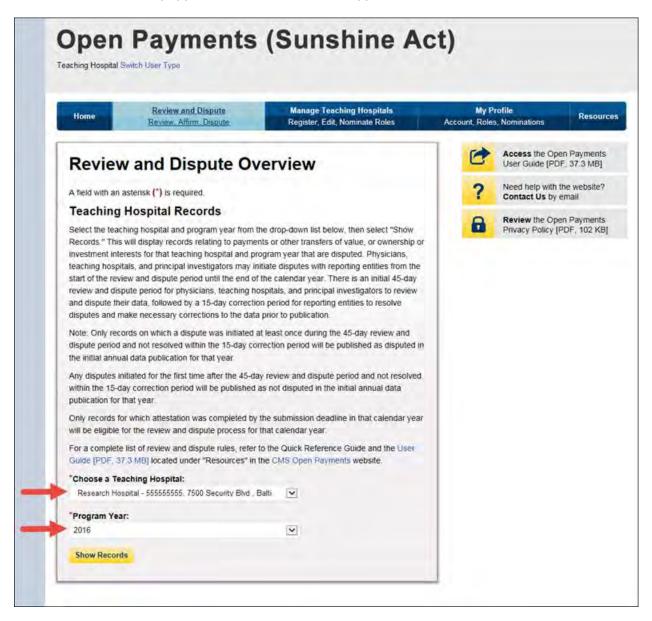
Therefore, if you can no longer find a record that you have disputed, first check to see if the applicable manufacturer or applicable GPO has acknowledged the dispute. If the dispute has been acknowledged, you will have received an acknowledgement email from the Open Payments system for that dispute. This email confirms that the record exists and the dispute received. If you cannot find a record that you have disputed and you do not have an acknowledgement email for that record, contact the Open Payments Help Desk at openpayments@cms.hhs.gov.

7.3a: Teaching Hospital – Initiating a Dispute

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.



<u>Step 2:</u> From the drop-down menus, select the teaching hospital and program year for which you wish to review data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."

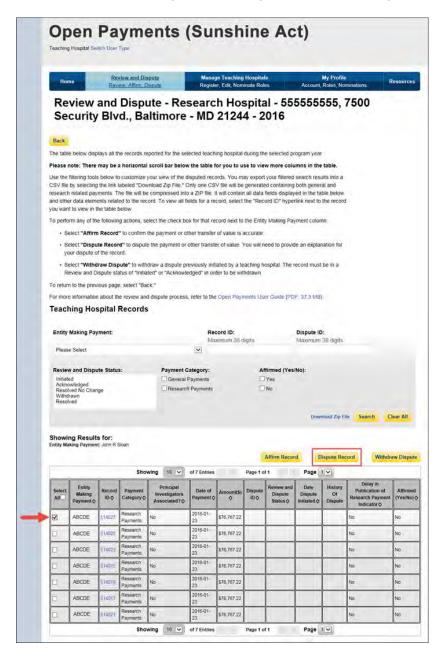


If the chosen teaching hospital has no records associated with it, you will receive a message at the top of the page saying "There are no payments or other transfers of value reported for this teaching hospital." If there are records associated with your chosen teaching hospital, proceed to Step 3.

<u>Step 3:</u> On the Review and Dispute 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," and/or "Dispute ID." You do not need to filter the results in order to proceed. For instructions on how to export this data, see Section 7.1d.

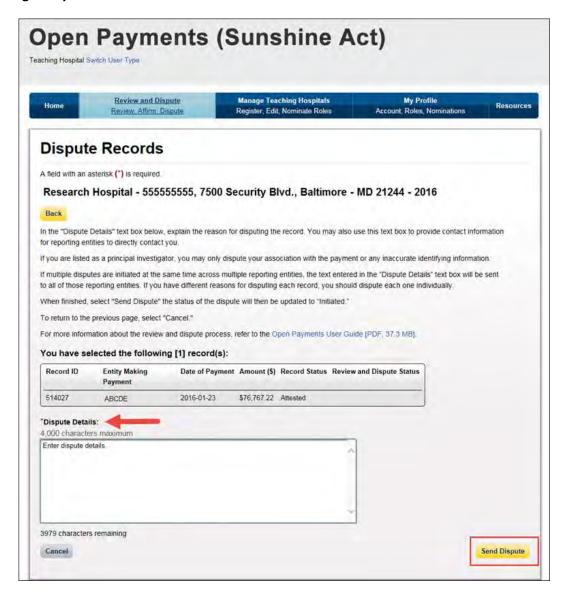
Select "View" under the column title "View Record" if you wish to view the record details. On the individual record's detail page, you will see the specifics of the record and the reporting entity's designated review and dispute point of contact.

Select the checkboxes next to the record(s) you wish to dispute, then select "Dispute Record."



<u>Step 4:</u> Review the information on the Dispute Records page. You must enter a reason the dispute has been initiated in the "Dispute Details" text box before continuing. The text box can contain up to 4,000 characters, including spaces, and allows all special characters on a standard U.S. keyboard (not including ALT+NUMPAD ASCII Key characters). It is recommended that you add review and dispute contact information, such as an email address and/or phone number, within the text box, as this will assist the reporting entity in resolving the dispute in a timely manner.

When you select "Send Dispute," the system will send an email to the reporting entity or entities notifying them that a dispute has been initiated. This email will include the contents of the "Dispute Details" text box. If a dispute is initiated for multiple records across multiple reporting entities simultaneously, all reporting entities referenced in the dispute will receive the same email notification including the "Dispute Details" text. If the reasons for dispute vary for each disputed record, perform the actions above separately for each dispute to ensure the correct reasons are provided to each reporting entity.

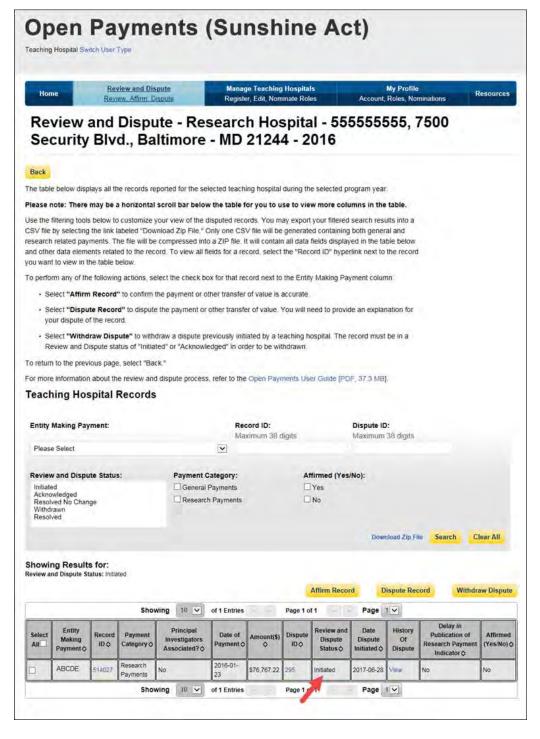


The following "Dispute Confirmed" message will be displayed on the page. An email notification will be sent to the reporting entity. Select "Continue" to return back to the "Review and Dispute" page.



You will receive an email notification from the Open Payments system when the status of your disputed record changes. The Review and Dispute Status of the record will be changed to "Initiated."

If, as part of the resolution to the dispute, the teaching hospital identified in the record is changed and your hospital is no longer associated with that record, you will no longer see the record in your profile. In such an event, you will receive an email notification that your dispute has been resolved, though you will no longer be able to see the record. If the record is deleted, you will no longer see it in your profile.

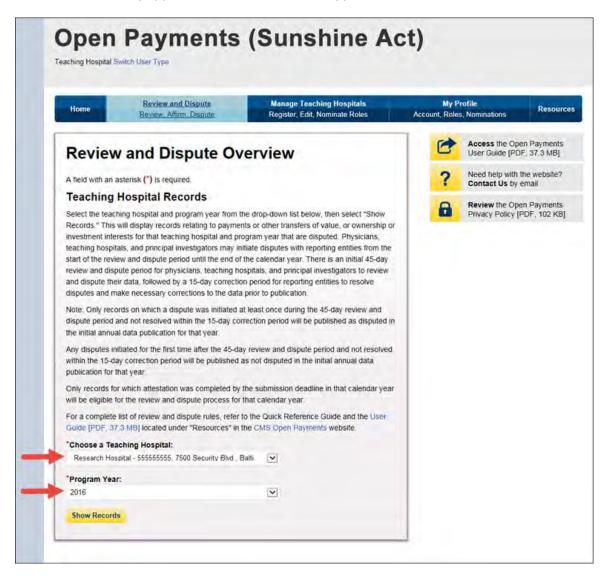


7.3b: Teaching Hospital – Withdrawing a Dispute

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.



<u>Step 2:</u> From the drop-down menus, select the teaching hospital and program year for which you wish to review data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."

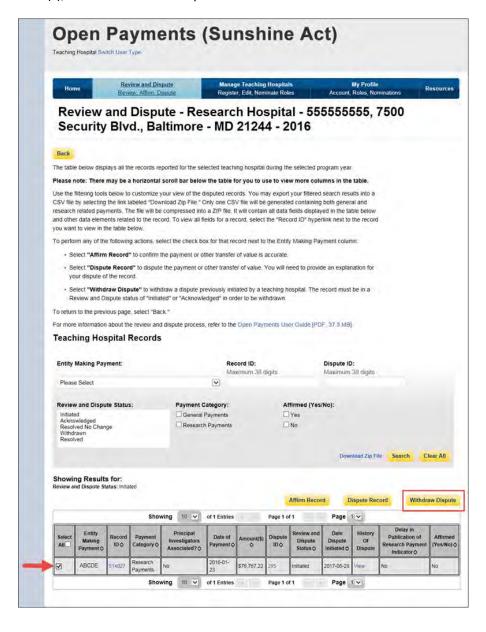


If the chosen teaching hospital has no records associated with it, you will receive a message at the top of the page saying "There are no payments or other transfers of value reported for this teaching hospital." If there are records associated with your chosen teaching hospital, proceed to Step 3.

<u>Step 3:</u> On the Review and Dispute 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, and/or Dispute ID. You do not need to filter the results in order to proceed. For instructions on how to export this data, see Section 7.1d.

Select "View" under the column title "View Record" if you wish to view the record details. On the individual record's detail page, you will see the specifics of the record and the reporting entity's designated review and dispute point of contact.

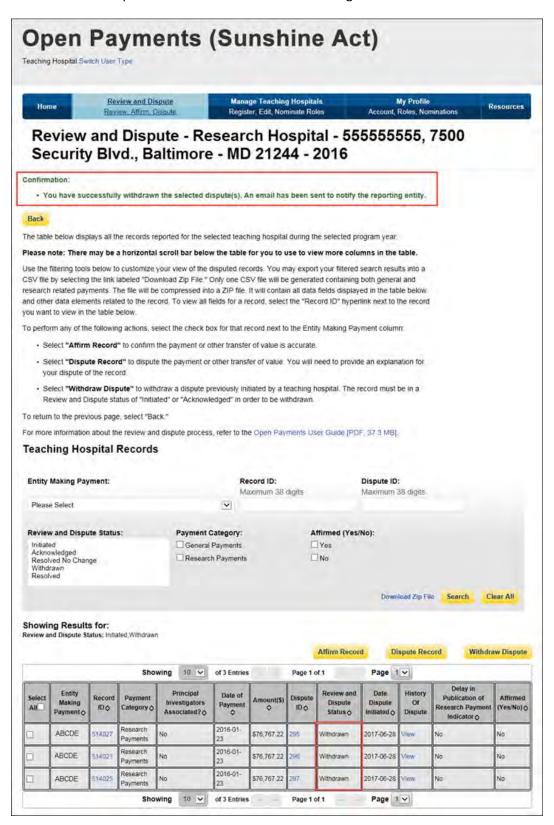
Select the checkboxes next to the disputed record(s) you wish to withdraw. You may only withdraw disputes on records with a review and dispute status of "Initiated" or "Acknowledged." After you have selected the record(s), select "Withdraw Dispute."



<u>Step 4:</u> Review the information on the Withdraw Disputes page. If the information is correct, select "Withdraw Disputes." If the information is not correct, select "Back" and either change which record you are withdrawing or perform another action.



The following message will be displayed on the page. An email notification will be sent to the reporting entity. The Review and Dispute Status of the record will be changed to "Withdrawn."



7.3c: Physician and Principal Investigator - Initiating a Dispute

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.



<u>Step 2:</u> From the drop-down menus, select the physician and program year for which you wish to review data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."



If the chosen physician has no records associated with him or her, you will receive a message at the top of the page saying "There are no payments or other transfers of value or ownership or investment interests reported for you or your family members." If there are records associated with your chosen physician, proceed to Step 3.

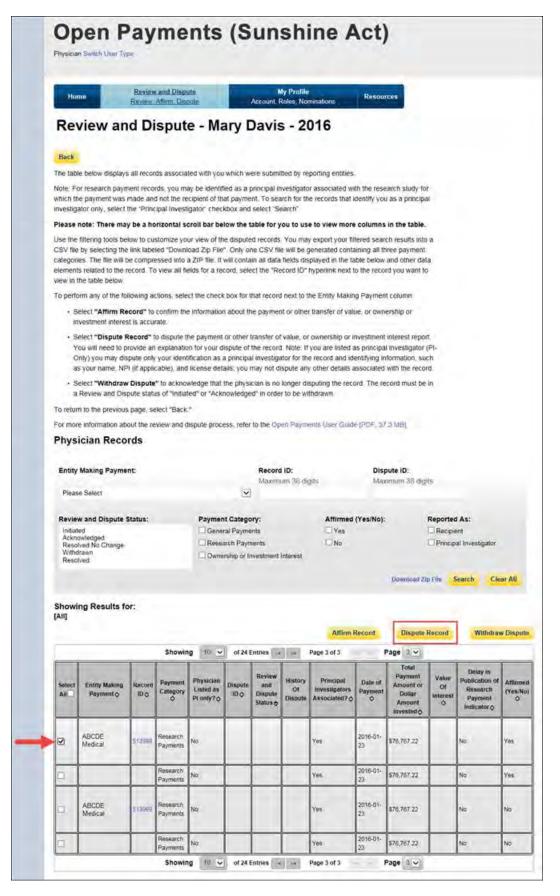
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<u>Step 3:</u> On the Review and Dispute page, you will see a list of all submitted records for the chosen physician. If you wish, you may filter the records by selecting the "Entity Making Payment" from the specified drop-down. You may also filter further by including the Record ID, and/or Dispute ID. For instructions on how to export this data, see Section 7.1d.

You may also search records by "Recipient" or "Principal Investigator." When a user selects the "Recipient" checkbox, the system will only display records on which the physician is reported as a covered recipient. When a user selects the "Principal Investigator" checkbox, the system will only display records on which the physician is reported as a principal investigator. Note: Physicians identified as a Principal Investigator (PI) in a record may only dispute their own association with the record and their own personal identifying information given in the record. They cannot dispute any other information in the record, such as payment amount, nature of payment, etc.

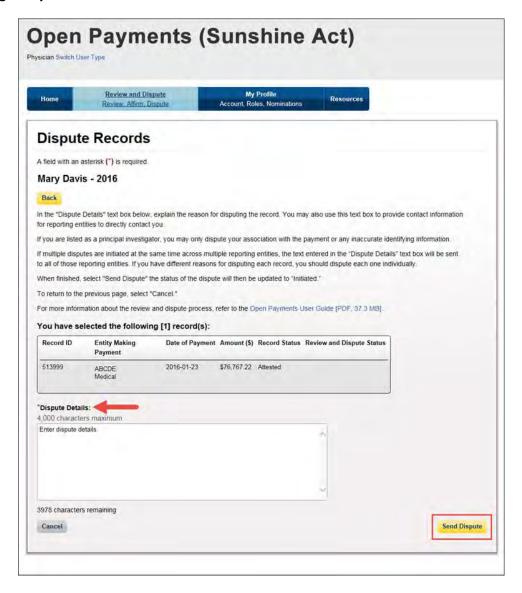
Select "View" under the column title "View Record" if you wish to view the record details. On the individual record's detail page, you will see the specifics of the record and the reporting entity's designated review and dispute point of contact.

Select the checkboxes next to the record(s) you wish to dispute, then select "Dispute Record."

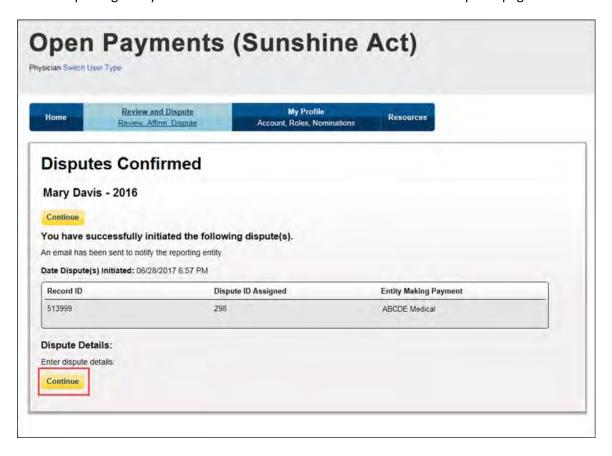


<u>Step 4:</u> Review the information on the Dispute Records page. You must enter a reason the dispute has been initiated in the "Dispute Details" text box before continuing. The text box can contain up to 4,000 characters, including spaces, and allows all special characters on a standard U.S. keyboard (not including ALT+NUMPAD ASCII Key characters). It is recommended that you add review and dispute contact information, such as an email address and/or phone number, within the text box, as this will assist the reporting entity in resolving the dispute in a timely manner.

When you select "Send Dispute," the system will send an email to the reporting entity or entities notifying them that a dispute has been initiated. This email will include the contents of the "Dispute Details" text box. If a dispute is initiated for multiple records across multiple reporting entities simultaneously, all reporting entities referenced in the dispute will receive the same email notification including the "Dispute Details" text. If the reasons for dispute vary for each disputed record, perform the actions above separately for each dispute to ensure the correct reasons are provided to each reporting entity.

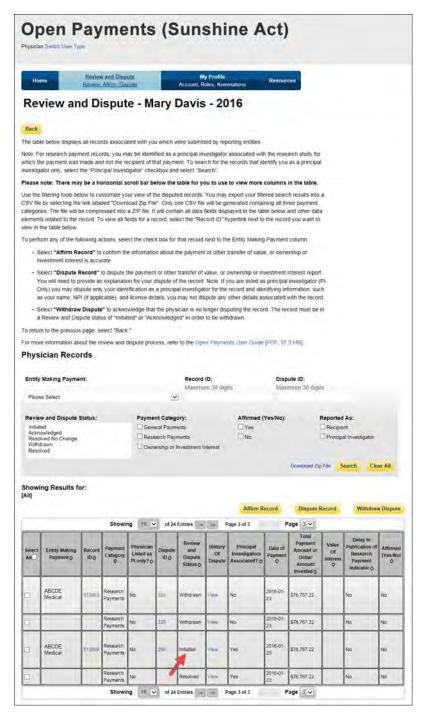


The following "Dispute Confirmed" message will be displayed on the page. An email notification will be sent to the reporting entity. Select "Continue" to return to the "Review and Dispute" page.



You will receive an email notification from the Open Payments system when the status of your disputed record changes. The Review and Dispute Status of the record will be changed to "Initiated."

If, as part of the resolution to the dispute, the physician or physician principal investigator identified in the record is changed so that you are no longer identified in it, you will no longer see that record in your profile. In such an event, you will receive an email notification that your dispute has been resolved, though you will no longer be able to see the record. If the record is deleted, you will no longer see it in your profile.

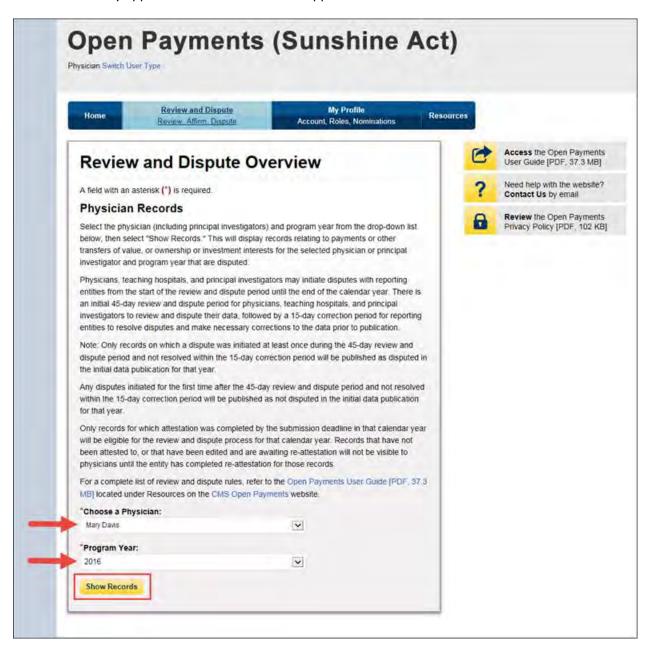


7.3d: Physician and Principal Investigator - Withdrawing a Dispute

<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.



<u>Step 2:</u> From the drop-down menus, select the physician and program year for which you wish to review data submitted by applicable manufacturers and applicable GPOs. Select "Show Records."



If the chosen physician has no records associated with him or her, you will receive a message at the top of the page saying "There are no payments or other transfers of value or ownership or investment interests reported for you or your family members." If there are records associated with your chosen physician, proceed to Step 3.

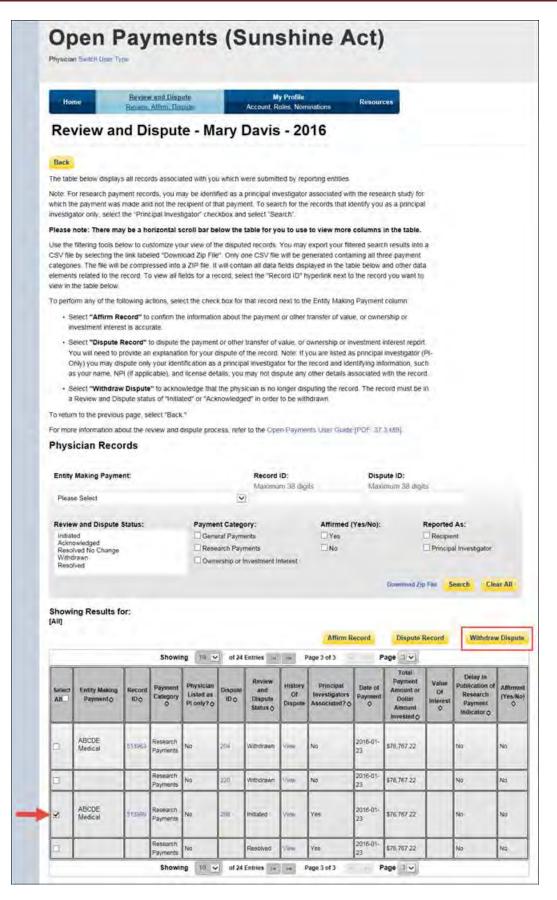
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<u>Step 3:</u> On the Review and Dispute page, you will see a list of all submitted records for the chosen physician. If you wish, you may filter the records by selecting the "Entity Making Payment" from the specified drop-down. For instructions on how to export this data, see Section 7.1d.

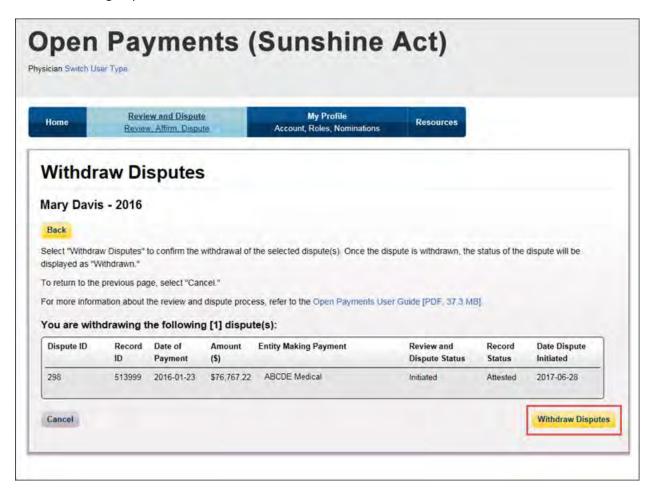
You may also filter further by including the Record ID, and/or Dispute ID. You may also search records by "Recipient" or "Principal Investigator." When a user selects the "Recipient" checkbox, the system will only display records on which the physician is reported as a covered recipient. When a user selects the "Principal Investigator" checkbox, the system will only display records on which the physician is reported as a principal investigator.

Select "View" under the column title "View Record" if you wish to view the record details. On the individual record's detail page, you will see the specifics of the record and the reporting entity's designated review and dispute point of contact.

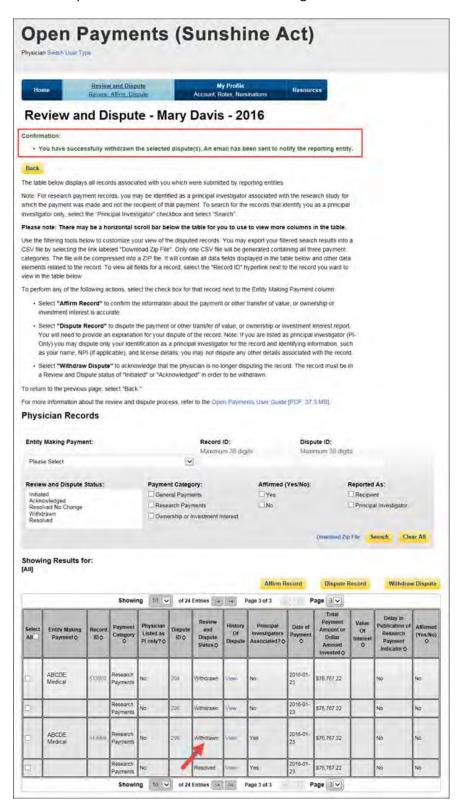
Select the checkboxes next to the disputed record(s) you wish to withdraw. You may only withdraw disputes on records with a review and dispute status of "Initiated" or "Acknowledged." After you have selected the record(s), select "Withdraw Dispute."



<u>Step 4:</u> Review the information on the Withdraw Disputes page. If the information is correct, select "Withdraw Disputes." If the information is not correct, select "Back" and either change which record you are withdrawing or perform another action.



The following message will be displayed on the page. An email notification will be sent to the reporting entity. The Review and Dispute Status of the record will be changed to "Withdrawn."



PART V: PUBLIC DATA PUBLISHING

Chapter 8: Data Publication

The Open Payments program provides information to the general public on payments and other transfers of value made by industry to physicians and teaching hospitals, as well as physician ownership or investment interests in industry. This information is made public on https://openpaymentsdata.cms.gov/ for online browsing and downloading.

This chapter provides general information about the Open Payments published data, publication criteria, exclusions to the publication, and links to additional resources. For details on reporting requirements, data submissions, and the review and dispute process, please see the corresponding chapters in this User Guide.

For a more detailed guide to Open Payments data publication, refer to the "Open Payments Methodology Overview and Data Dictionary," which provides the publication rules, limitations, and exclusions, the data files available from CMS, the fields in each data file, and how to download them. This document is available at https://www.cms.gov/OpenPayments/Explore-the-Data/Data-Overview.html.

Section 8.1: Methodology

Applicable manufacturers and applicable group purchasing organizations (GPOs) are required to submit data about payments and other transfers of value made to physicians and teaching hospitals between January 1 and December 31 of each program year. They are also required to submit information regarding ownership or investment interests held by physicians or their immediate family members during the program year.

This data may then be reviewed and, if necessary, disputed by the physicians and teaching hospitals associated with those records. This data is then made available to the public at https://openpaymentsdata.cms.gov/ for online browsing and downloading. Data submitted to Open Payments that is eligible for publication is published twice annually; first, in an initial publication, and then in a refresh publication. Figure 8.1, below, provides a high-level representation of the various periods during a given program year.

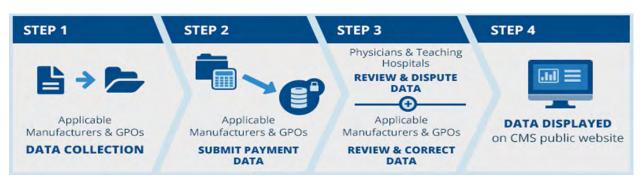


Figure 8.1: Steps of the Open Payments Program

Only data submitted and attested to by the submission closing date are eligible for publication in the subsequent initial and refresh publications. Data submitted and attested after the submission closing date are considered late and will not be eligible for publication until the initial publication in the following calendar year.

Data submitted to Open Payments that is eligible for publication is published twice annually, as explained below. Explanations of record limitations, exclusions, and ineligibility are given in Section 8.3 and the publication rules are in Section 8.4.

• June 30 Publication - Initial Publication

- The first publication of the eligible records submitted and attested on or before the submission closing date of the latest program year.
- The republication of eligible records from prior program years, including updates to previously published records made since the previous publication.
- The data published is the latest attested version of the payment records at the end of the correction period of the latest program year.

• Early Year Publication - Refresh Publication

- o Publication of updates to the data made since the Initial Publication.
- The second publication of eligible records submitted and attested on or before the submission closing date of the latest program year.
- It contains updates made to records after the correction period of the latest program year and before the end of the calendar year (or before the modified-without-dispute cutoff date in November for records not under dispute).
- o The data published is the latest attested version of the data at the end of the calendar year.

For example, the June 30, 2017 data publication included the initial publication of the program year 2016 data as well as the republication of prior program year data, including any changes made to the prior years' data. The early 2018 data publication will include the refresh publication of program year 2016 data and republication of prior program year data, including any changes made to the prior years' data.

8.1a: Effect of Disputes on Data Publication

If a dispute is resolved by making corrections to the record(s), whether the updated data will be published depends upon when the records were corrected. See Section 8.1, above, for an explanation of which version of the data will be published.

Records still under dispute at the time of publication may be published with an indicator that identifies those records as being under dispute. Whether a record is identified as disputed in data publications

depends upon when the dispute was initiated and when/if the dispute was resolved. The table below lists scenarios for dispute initiation and resolution and explains how records are identified in data publications based upon those scenarios.

Figure 8.2: Records Identified as Disputed

Dispute Initiated/Resolved	Published As Disputed in Initial Publication?	Published As Disputed in Refresh Publication?
Initiated: During the 45-day Review and Dispute Period Resolved: By the end of the 15-day Correction Period	No	No
Initiated: During the 45-day Review and Dispute Period Resolved: After the end of the 15-day Correction Period	Yes	Yes, unless the dispute is resolved before the end of the calendar year
Initiated: During the 15-day Correction Period Resolved: By the end of the 15-day Correction Period	No	No
Initiated: During the 15-day Correction Period Resolved: After the end of the 15-day Correction Period	No	Yes, unless the dispute is resolved before the end of the calendar year
Initiated: After the Correction Period Resolved: By the end of the calendar year	No	No
Initiated: After the Correction Period Resolved: After the end of the calendar year	No	Yes

Note: If a record was initially disputed during the 45-day review and dispute period and more disputes are initiated on that same record during the 15-day correction period, then the data attested to as of the end of the 15-day correction period is published in the initial publication, including any changes made due to dispute resolution.

Section 8.2: Data Sources and Types

Applicable manufacturers and applicable GPOs must enter detailed information about payments, other transfers of value, or investment interests into CMS's Open Payments system.

These payments, other transfers of value, and ownership or investment interests are categorized into three (3) payment types:

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

3. <u>Physician Ownership or Investment Interest Information</u>: Information about physicians who hold an ownership or investment interest in an applicable manufacturer or applicable GPO or who have an immediate family member holding such interest.

Section 8.3: Reporting Limitations and Exclusions

The Open Payments data published by CMS is subject to limitations and exclusions.

Certain payments or other transfers of value are excluded from reporting, such as product samples and educational materials intended for patient use. Records of such payments and other transfers of value should not be submitted to the Open Payments system. These exclusions are outlined in the Open Payments final rule, at 42 C.F.R. § 403.904(i), available at https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Final-Rule.pdf.

Payment records will only be accepted by the Open Payments system if they are both successfully validated and successfully matched to a valid physician or teaching hospital.

Section 8.4: Publication Rules

The publication rules for Open Payments are as follows:

- Eligible records submitted and attested before the end of the data submission period will be published in that year's initial and data refresh publications.
- The data published in the <u>June 30 (initial) publication</u> is the latest attested version of the data at the end of the correction period.
- The data published in the <u>January (refresh) publication</u> is the latest attested version of the data at the end of the calendar year.

Records may not be eligible for publication based upon publishing limitations. See Section 8.4a for details.

8.4a: Publishing Limitations

The following limitations apply to what records are published by CMS through the Open Payments program:

- 1. **Data submitted and attested after the submission closing date** is considered late and will not be included in the initial publication or the next data refresh publication. Late submissions may be eligible for publication in the following calendar year's data publication.
- Records in which physician or physician principal investigator identifying information is changed after the submission closing date will not be included in the initial publication or the next data refresh publication. These records may be eligible for publication in the following calendar year's data publication.
- 3. **Records deleted** prior to the end of the correction period for that year will not be published in the initial data publication or in any subsequent publications.

- Records deleted after the correction period but prior to December 31 of that calendar year will be published in the initial publication but will be removed in the data refresh publication and any subsequent publications.
- 4. Records without disputes against them that are updated after the end of the submission period will not have those updates included in the initial data publication.
 - The updated version of the record may be eligible for the next data refresh publication if it
 was resubmitted and attested by the modified-without-dispute cutoff date in November of
 that year.
 - Updates to undisputed records that are resubmitted and attested after the modifiedwithout-dispute cutoff date in November will not be published in the subsequent refresh publication but may be eligible for publication in the following calendar year's publication.
- 5. **Records that had been published previously and were then edited after their publication** and not re-attested to by the end of the next correction period are not published.
- 6. Reporting entities may request a delay in the publication of research payment records if the records relate to research or development of a new drug, biological, device, or medical supply; a new application of an existing drug, biological, device, or medical supply; or clinical investigations regarding a new drug, biological, device, or medical supply. These payments will be published in later Open Payments publications as appropriate. See the Open Payments Final Rule, at 42 C.F.R. § 403.910, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Final-Rule.pdf.
 - Records for which submitters requested a delay in publication or a renewal of a delay in publication prior to the end of the submission period will not be published for one year.
 These records will be eligible for publication in the next year's publication, unless the delay in publication is renewed for another year. Records cannot be delayed after four years have elapsed from the date of payment.
 - Records with a delay in publication request removed after the end of the submission period that do not have a dispute against them will not be published in the initial publication, but will be published in the refresh publication.
- Program year 2013 includes only data collected from August 1– December 31, 2013. All
 subsequent program year publications contain data collected from the entire calendar year
 (January 1 December 31).

Section 8.5: Data in Context

The context of the data is shown in two different ways. General contextual information about the program can be found on the "Data in Context" page on the Open Payments website. In addition, context at the individual payment level is also available when reported by the applicable manufacturer or

applicable GPO. This data is posted exactly as it was submitted and was not altered by CMS. This may be viewed when exploring the data.

Section 8.6: Accessing the Data

Open Payments data can be accessed at https://openpaymentsdata.cms.gov. From this site, all Open Payments data can be viewed online and downloaded.

8.6a: Online Data Access

CMS has made available two tools for online viewing. One is the Search Tool, which allows users to search Open Payments data for physicians, teaching hospitals, and companies making payments. The other online viewing tool is the Data Explorer tool, which allows users to browse datasets; search records by physician, teaching hospital, principal investigator, and reporting entity; and filter the data.

8.6b: Downloading the Data

CMS has made available the capability to download complete Open Payments data sets. Data sets for all program years are available. The data sets are contained in downloadable ZIP files. Each program year zip file contains several comma-delimited character-separated value (CSV) files and a README text file. The program year is included in each ZIP file's name.

Also available for download is a supplement file that contains more detailed information about physicians who were indicated as recipients of payments, other transfers of value, or as holding ownership or investment interests in applicable manufacturers on records that were published by CMS through the Open Payments program. The supplement file also contains information about physician principal investigators who were associated with research payments or other transfers of value in records published by CMS through the Open Payments program. The supplement file contains only physicians who have at least one payment record associated with them that has been published by CMS through the Open Payments program. This list is available in a downloadable ZIP file, which contains a comma-delimited character-separated value (CSV) file and a README text file.

CMS recommends against using Windows File Compression to decompress downloaded files. Programs recommended for file decompression are WinZip, WinRAR, and 7-Zip.

The **Program Year zip files** contain CSV files of the following types:

General Payments Details

- General payment records provide the total value of general payments or other transfers of value to a particular recipient for a particular date.
- Each record includes identifying information for the applicable manufacturer or applicable
 GPO who made the payment, and identifying information for the recipient.
- For program year 2016 and upcoming years, each record may list up to five products if the payment was made in relation to any such products. Note that records for program years 2013-2015 may include up to five covered drugs or biologicals and also up to five covered

devices or medical supplies.

• Research Payments Details

- Research payment records provide the total value of a payment or other transfer of value made for research purposes to a particular recipient for a particular date.
- Each record includes identifying information for the applicable manufacturer or applicable
 GPO who made the payment, and identifying information for the recipient. Information is also provided for up to five physician principal investigators associated with the payment.
- For program year 2016 and upcoming years, each record may list up to five products if the
 payment was made in relation to any such products. Note that records for program years
 2013-2015 may include up to five covered drugs or biologicals and also up to five covered
 devices or medical supplies.
- Physician Ownership Details The complete published data set for physician ownership or investment interest data. Physician ownership records provide information on physician ownership or investment interests in an applicable manufacturer or applicable GPO.

Records for all three payment categories (general, research, physician ownership) include a Change Type indicator that explains the record's status relating to previous publications.

Change Type value	Meaning
NEW	The payment record is submitted during the most recent submission window and is being published for the first time.
ADD	The payment record had been submitted prior to the most recent submission window but had been ineligible for publication until the current publication. The record is being published for the first time.
CHANGED	The payment record has been published in a previous publication and has been modified since its last publication, which may include an update to its dispute status.
UNCHANGED	The payment record was published in the previous publication and is being republished without change in the current publication.

Figure 8.3: Change Type Values and Meanings for Payment Records

- Deleted and Removed Records The Deleted Records File contains the Record ID, Payment
 Type, and Program Year of records that were previously published and have been deleted or
 removed from the Open Payments system for that program year. Each record also has a Change
 Type indicator, which shows if the record was deleted or removed.
 - O Note: The initial publication of the latest program year's data will not include a Deleted and

Removed Record file, as the initial publication contains records that have not been previously published.

The text file in the program year zip files is:

 README – A text file that provides information about the files available for download, their formats, special handling considerations, and other alternatives for viewing the Open Payments data.

A complete list of data elements displayed in the General Payments Details, Research Payments Details, Physician Ownership Details, and Deleted Records files, including descriptions and sample data for each data element, can be found in the Open Payments Methodology Overview and Data Dictionary.

Also available for download is the <u>Physician Profile Supplement Detail zip file</u>, which contains one (1) CSV file and one (1) README file. The CSV file contains all of the identifying information for physicians who were indicated as recipients of payments, other transfers of value, or ownership and investment interest in Open Payments records, as well as physician principal investigators who were associated with payments or other transfers of value. The README file provides information about the contents of the CSV file. A complete list of data elements displayed in the Physician Profile Supplement File, including descriptions and sample data for each data element, can be found in the Open Payments Methodology Overview and Data Dictionary.

Note: The CSV data files may be too large for Microsoft Excel and other common spreadsheet programs. Excel cannot display worksheets with more than 1,048,576 rows. To display the data in its entirety requires the use of programs capable of handling very large numbers of records.

Appendices

Appendix A: Glossary of Terms for Open Payments

Note: The text of the Open Payments Final Rule (42 C.F.R. § 403.902) is available at https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf.

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 provides 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 C.F.R. § 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 C.F.R. § 403.902)

Assistance or Support:

Assistance or 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 403.908(d))

Covered Recipients:

Covered recipients are any physicians (see <u>Physicians</u> 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 C.F.R. § 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.

Non-Covered Recipient Entity:

Non-covered recipient entities are entities that do not meet the Open Payments definition of a covered recipient (see 42 C.F.R. § 403.902). Non-covered recipient entities may include non-teaching hospitals or clinics. A payment or other transfer of value to a non-covered recipient entity is reportable if it is a research payment with at least one associated covered recipient principal investigator.

Non-Covered Recipient Individual:

Non-covered recipient individuals are individuals who do not meet the Open Payments definition of a covered recipient (see 42 C.F.R. § 403.902). Non-covered recipient individuals may include non-physician employees of a teaching hospital or physician-owned practice. A payment or other transfer of value to a non-covered recipient individual is reportable if it is a research payment with at least one associated covered recipient principal investigator.

Open Payments:

Open Payments is a national transparency program which requires:

- Applicable manufacturers of covered drugs, devices, biologicals, or medical supplies to report 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 report information about ownership and investment interests held by physicians or their immediate family members to CMS every year.
- Applicable GPOs to report 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 interests 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 non-alphanumeric symbols.

Special characters are required in registration fields where appropriate. For example, the "@" symbol and the period are required in email address fields, while dashes are required in telephone number fields.

Data elements of submitted records may contain only the special characters allowed per the "Submission Data Mapping Document," which is found on the Resources page of the Open

Payments website at https://www.cms.gov/OpenPayments/About/Resources.html. Note that there are multiple versions of the Submission Data Mapping Document based on program year. Consult the Submission Data Mapping Document for the program year of your records.

Free text fields allow all special characters on a standard U.S. keyboard, excepting ALT+NUMPAD ASCII Key characters. Below are the special characters allowed in free text fields.

Figure A.1: Special Characters Allowed in Free-Text Fields

Special Character	Description	
+	Plus sign	
&	Ampersand	
1	Apostrophe	
*	Asterisk	
@	At sign	
\	Backslash	
۸	Caret	
:	Colon	
,	Comma	
\$	Dollar sign	
Space	Space character	
=	Equal	
!	Exclamation mark	
/	Forward slash	
`	Grave accent	
>	Greater than	
_	Minus sign/hyphen	
(Left parenthesis	
{	Left curly brackets	
[Left square brackets	
<	Less than	
%	Percent	
	Period	
#	Pound	
?	Question mark	
11	Quotation marks	
)	Right parenthesis	
}	Right curly brackets	
]	Right square brackets	
;	Semi-colon	
	Pipe	
~	Tilde	
+	Plus sign	

Characters used in foreign languages that are not used in English must be converted to English characters to be acceptable to the Open Payments system. Refer to the conversion table below.

Figure A.2: Conversions for Foreign Language Characters

Foreign Character	Convert to English Character
À	A
Á	Α
Â	A
Ã	A
Ä	A
Å	A
È	Е
É	Е
Ê	Е
Ë	E
ì	I
ĺ	I
Î	I
Ϊ	I
Ò	0
Ó	0
Ô	0
Õ	0
Ö	0
Ø	0
Ù	U
Ú	U
Û	U
Ü	U

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 C.F.R. § 403.902). The full list of affected teaching hospitals can be found on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.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 Key, which is located on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html.

Appendix C: Medicare Provider/Supplier to Healthcare Provider Taxonomy

Provider taxonomy codes can be found at: https://www.cms.gov/OpenPayments/Downloads/Physician-Taxonomy-Crosswalk.pdf.