

User Guide for Covered Recipients

OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY
INTO INDUSTRY-PHYSICIAN
FINANCIAL RELATIONSHIPS

September 2019

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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INTRODUCTION

Purpose of the Open Payments User Guide

This Open Payments User Guide includes definitions, descriptions, screenshots, tools, and tips designed to help physicians and teaching hospitals better understand how to comply with Open Payments (the Sunshine Act).

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
- Physician and Teaching Hospital Registration
- Review and Dispute
- 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12.0	June 2017	Update	Updated publication chapter, removed outdated information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
14.0	January 2018	Update	Updated to reflect system updates
15.0	March 2018	Update	Updated to reflect system updates for Review and Dispute
16.0	January 2019	Update	Updated to reflect system updates
17.0	September 2019	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 <u>physicians</u> and <u>teaching hospitals</u>, 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 publicly 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. For details refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at https://www.cms.gov/openpayments/About/Resources.html.

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

• June 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 Program Year 2016 data and republication of prior program years. The early 2018 data publication included 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 reported data and dispute any data they believe is inaccurate; industry makes corrections to the data (reflected in the initial publication)	Review, Dispute, and Correction period: April-May
Initial program year initial data publication Prior program year data refresh publication	On or about June 30
Physicians and teaching hospitals continue to review and dispute data; industry continues to make corrections to the data (reflected in the data refresh publication)	June – December 31
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.**

<u>Step 6:</u> Determine if the entity engages in <u>activities</u> of an applicable GPO. See the reference guide in **Figure 1.3.**

<u>Step 7:</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 1.3.**

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 legally authorized to practice by their state as follows:

- 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
- Chiropractors

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

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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 <u>openpaymentsnnotifications@cms.hhs.gov</u>.

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.

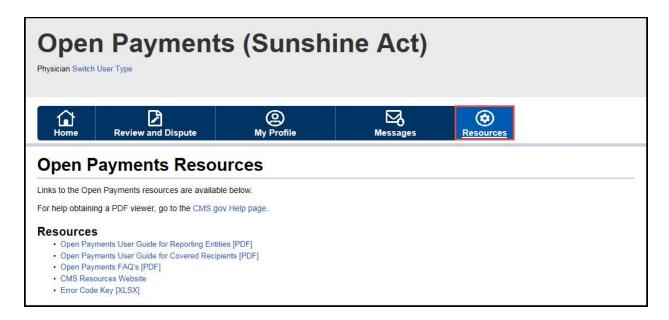
1.5a: Open Payments Website

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.

Covered recipients can also access the Open Payments User Guide for Covered Recipients, the Open Payments FAQ's and other useful resources within the Open Payments system on the "Resources" tab.



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. For the TTY line, call 1-844-649-2766. The Help Desk's hours of operation are posted on the Open Payments website.

1.5d: Open Payments Mailing List

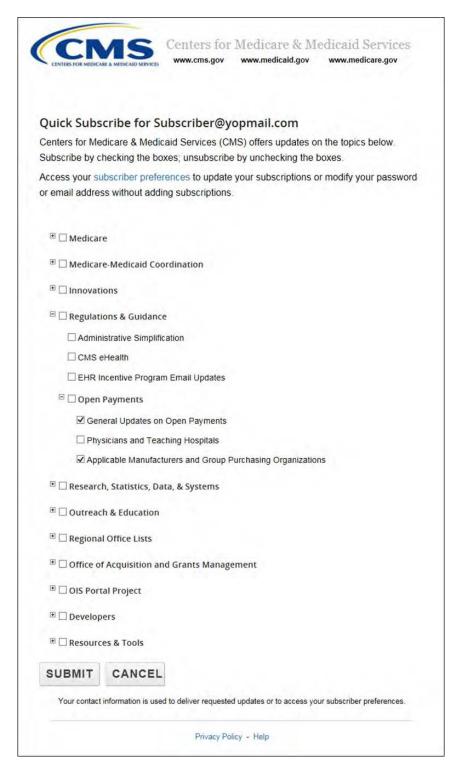
By registering for the Open Payments mailing list, you will be signed up to receive periodic email notifications regarding program, system, and resource updates. This is a good way to keep informed on any updates, changes, or important messages from CMS. To sign up for the Open Payments mailing list, 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.



Reporting and Data Collection

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 <u>general payments</u> made by applicable manufacturers and applicable GPOs to recipient physicians and teaching hospitals are 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), users can find and download the CSV sample files that show how the data elements listed below will be reported to the Open Payments system.

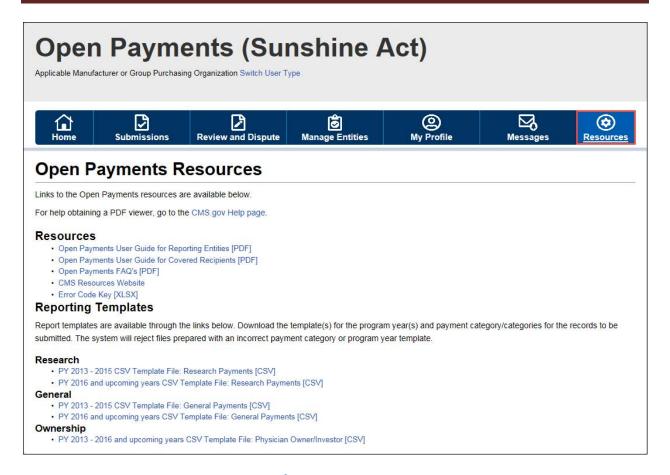
Section 2.2: Research Payments Reporting and Data Collection

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 are 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), users can find the CSV sample files that show how the data elements listed below will be reported to the Open Payments system.

Users who hold a submitter role can access submission templates within the Open Payments system on the "Resources" tab.



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 are 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), users can find the CSV sample files that show how the data elements listed below will be reported to the Open Payments system.

Registration

Chapter 3: 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 3.1: 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 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 you with access to various CMS applications. Registering in EIDM provides you with log in credentials **required** for access to the Open Payments system. You will be able to set up your own log in credentials in the form of a user ID and password during the EIDM registration process. EIDM credentials allows you 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 website at https://www.cms.gov, 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. If you already have EIDM credentials, you can move ahead to section 3.3, Registering in the Open Payments System.

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 the account, enter the user ID and correctly answer all challenge questions. Then enter a new password in the input fields of "New Password" and "Confirm New Password". If the account does not reactivate, contact the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366. For the TTY line, call 1-844-649-2766.

EIDM will automatically deactivate your account if you have not logged in for 180 days or more. If your account has been deactivated, you will not be able to access CMS applications, including the Open Payments system. If your account is deactivated due to inactivity, you can contact the Open Payments Help Desk at 1-855-326-8366 to reinstate the account. For the TTY line, call 1-844-649-2766.

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.

3.2a: System Requirements

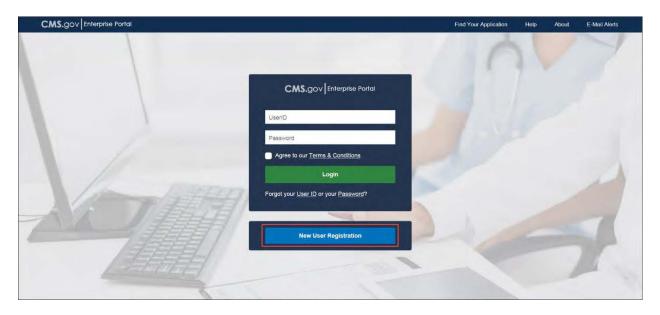
CMS screens are designed to be viewed at a minimum screen resolution of 1024×768 . For optimal performance, screen resolution should be set to 1920×1080 . The following additional considerations optimize access to the CMS Enterprise Portal:

- Disable pop-up blockers prior to accessing CMS Enterprise Portal.
- Use one of the following browsers with JavaScript enabled:
 - o Internet Explorer (IE), version 11.0 or higher
 - o Chrome (recommended for optimal performance)

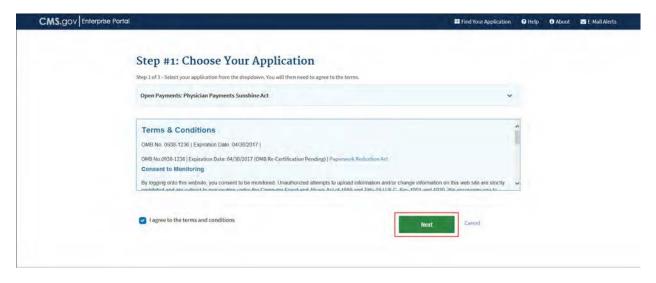
- o Firefox
- o Safari

3.2b: EIDM New User Registration

Go to the CMS Enterprise Portal page at https://portal.cms.gov. The system displays the CMS Enterprise Portal public landing page.



<u>Step 1:</u> On the "Choose Your Application" page, select "Open Payments: Physician Payments Sunshine Act" from the drop down list and agree to the Terms and Conditions of the CMS Enterprise Portal page, then select the "Next" button to continue.

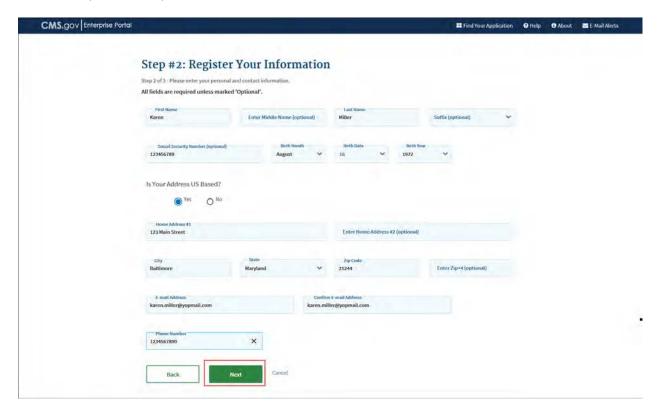


<u>Step 2:</u> On the "Register Your Information" page enter your personal user information. Be sure to enter all information in all required fields. **Note: Selecting the "Cancel" button will cause you to lose all data entered.** Select the "Next" button when all information has been entered.

Data fields to be completed are the following:

- Name (First, Middle, Last, Suffix)
- Social Security Number (Optional)
- Birthday (Month, Date Year)
- Is Your Address US Based (Yes/No)
- Home Address, City, State, Zip Code
- Primary Phone Number
- Email Address
- Confirm Email Address

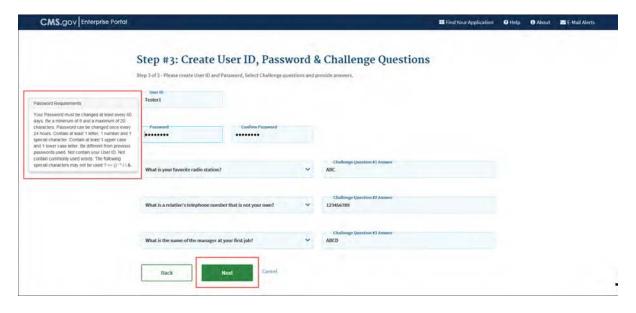
Enter your legal name, current home address, primary phone number, and email address correctly. EIDM collects personal information only to verify your identity with Experian, an external identity verification provider (explained in the next section).



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.

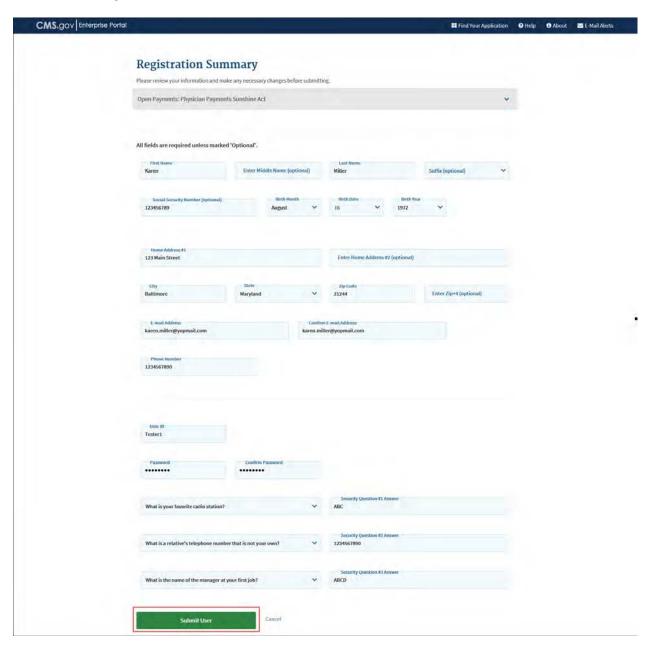
<u>Step 3:</u> On the "Create User ID, Password & Challenge Questions" page, create an EIDM user name and password in accordance with the guidance provided below. You will also be asked to select three challenge questions and provide answers in the open text fields next to the question fields. Select the "Next" button when finished.

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

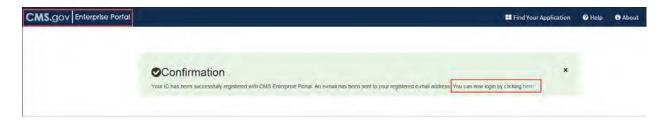


- The CMS Portal User ID must:
 - Be a minimum of 6 and a maximum of 74 alphanumeric characters;
 - Contain at least 1 letter;
 - Cannot contain your SSN or any 9 consecutive numbers;
 - Allowed special characters are dashes (-), underscores (_), apostrophes ('), at signs (@), and periods (.)
 - User ID cannot end with special characters
- Password Requirements:
- Password must be changed at least every 60 days;
- Be a minimum of 8 and a maximum of 20 characters;
- Passwords can be changed once every 24 hours;
- Contain at least 1 upper case and 1 lower case letter, 1 number and 1 special character;
- Be different from previous passwords used;
- Not contain your User ID;
 - Not contain commonly used words;
 - The following special characters may not be used? <> () " / \ &

<u>Step 4:</u> On the "Registration Summary" page, review the information and make any necessary changes before submitting. Select the "Submit User" button to submit the information.



<u>Step 5</u>: A "Confirmation" page is displayed acknowledging successful registration. Select the "CMS.gov Enterprise Portal" link (top left) or the "You can now login by clicking here" link (bottom right) to take users to the CMS Enterprise Portal home page. Note that profile configuration can take up to 24 hours. If users are unable to login after that timeframe, contact the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366. For the TTY line, call 1-844-649-2766.

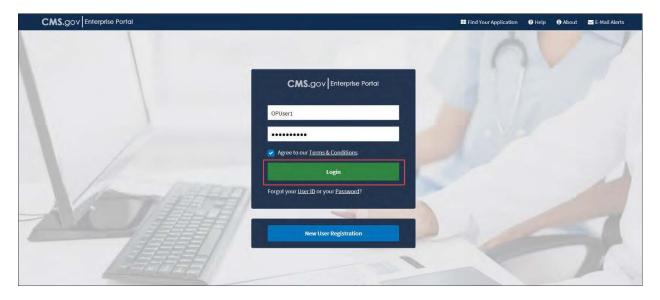


<u>Step 6:</u> Request access to the Open Payments system. Proceed to Section 3.2c for instructions on how to do so.

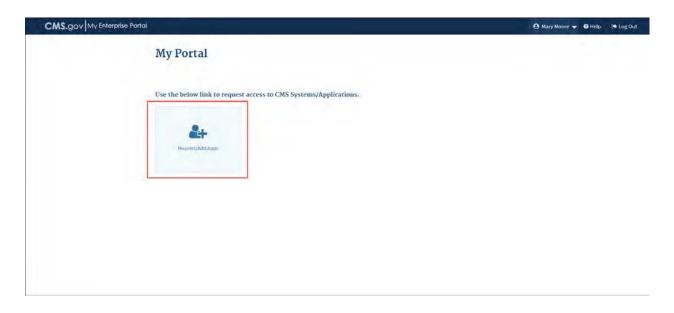
3.2c: Requesting Access to Open Payments with EIDM Credentials

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

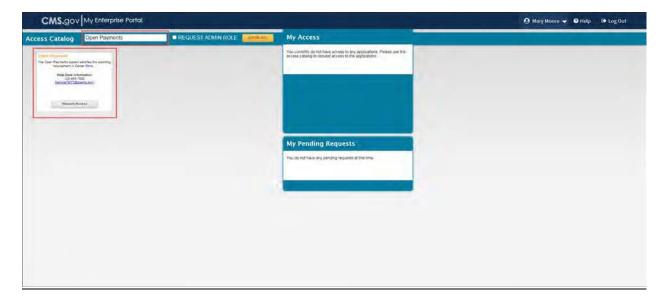
<u>Step 1:</u> On the CMS Enterprise Portal home page, enter the CMS User ID and Password and agree to "Terms & Conditions" by selecting the checkbox next to "Agree to our Terms & Conditions" link. Select the "Login" button to login.



<u>Step 2:</u> Upon initial login, the CMS Enterprise Portal "My Portal" page is displayed. Select the "Request/Add Apps" tile.

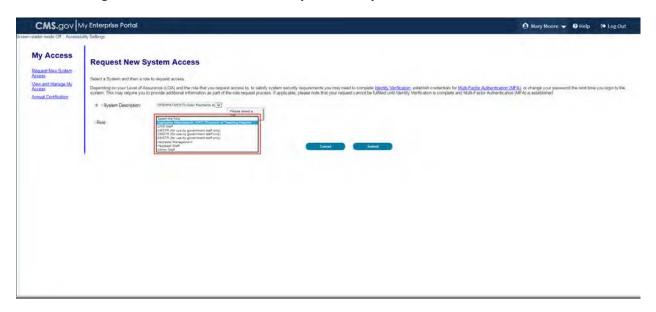


<u>Step 3:</u> On "My Access" page, type in "Open Payments" in the "Access Catalog" text box to search for "Open Payments" application. "Open Payments" application "Request Access" tile is displayed. Select the "Request Access" button.

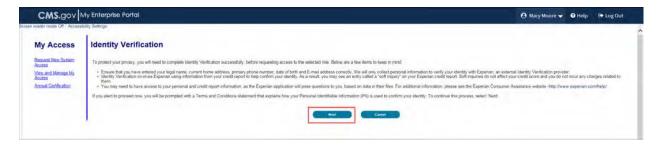


<u>Step 4:</u> On the "Request New System Access" page, "OPENPAYMENTS-Open Payments Application" will be pre-populated for "System Description" drop-down menu. Select a role to request access. Select "Applicable Manufacturer, GPO, Physician or Teaching Hospital" from the "Role" drop-down menu. Select the "Submit" button when complete.

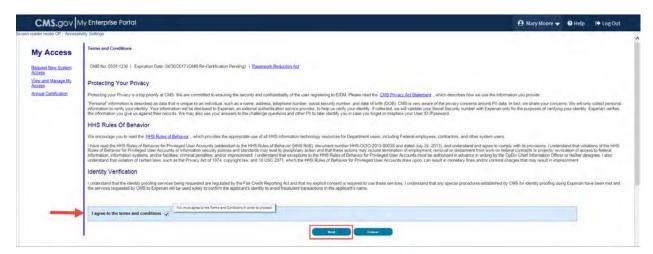
Note: Selecting the "Cancel" button will cause you to lose your selected choices.



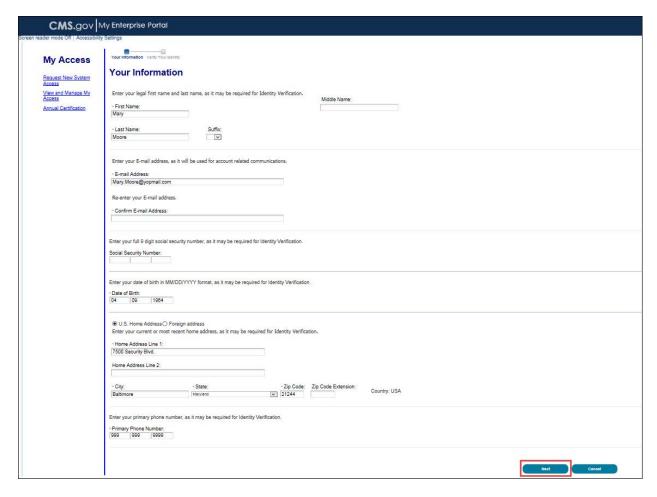
<u>Step 5:</u> Once you have requested access to the Open Payments application, you will then be asked to review the identity verification information. Select the "Next" button once you have reviewed the information.



Step 6: Accept the Terms and Conditions by selecting the checkbox. Select the "Next" button.



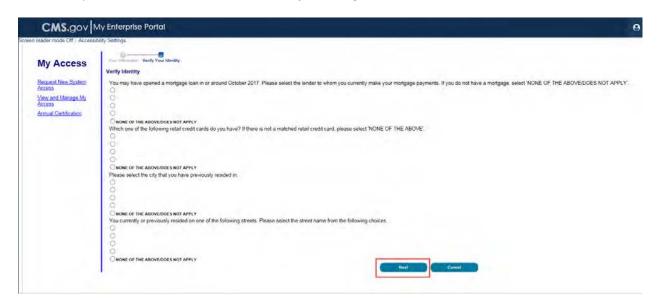
<u>Step 7:</u> Verify your information and make any updates as necessary. **Note: Selecting the "Cancel" button will cause you to lose all data entered.** Select "Next" when finished.



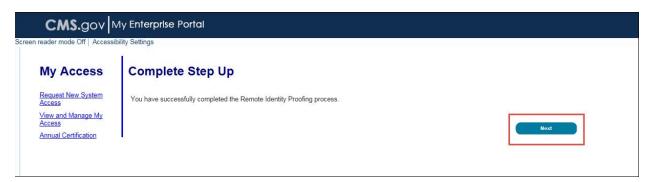
Step 8: Verify your identity by answering the identity proofing questions. The identity proofing questions are created by Experian based upon the information you entered during EIDM registration as well as information in Experian's databases. Experian also performs a soft credit inquiry to verify your identity. Identity proofing does not affect your credit score. 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. 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. **Pressing the "Cancel" button will cause** you to lose all data entered.

Note: This process is called the Remote Identity Proofing Process (RIDP).



<u>Step 9:</u> You will receive an on-screen confirmation message that you have successfully completed the Remote Identity Proofing process. Select "Next" to proceed.



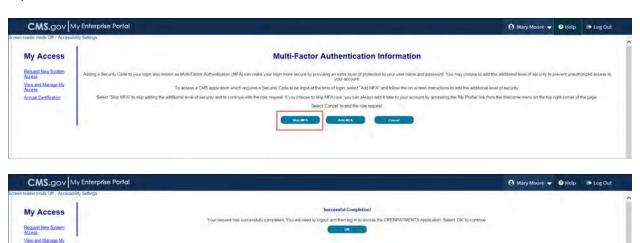
Note: If identity verification fails, you must call the Experian Verification Support Services number provided with the on-screen notification; or, contact Experian Proofing Support Services at 1(866)578-5409. You will need to have the incident ID given to you by EIDM. If you do not have this ID you will need to repeat the previous steps and retain the incident ID to provide to Experian Proofing Support Services.

If Experian is unable to verify identity over phone, contact the Open Payments Help Desk at openpayments@cms.hhs.gov or call 1-855-326-8366. For the TTY line, call 1-844-649-2766.

Step 10: You will now be taken to the "Multi-Factor Authentication (MFA) Information" registration page. During the MFA registration process, you will have the option of registering a Phone/Tablet/PC/Laptop, Text Message Short Message Service (SMS), Interactive Voice Response (IVR), 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 "Enterprise Portal User Manual," available at https://portal.cms.gov for more information on the MFA process.



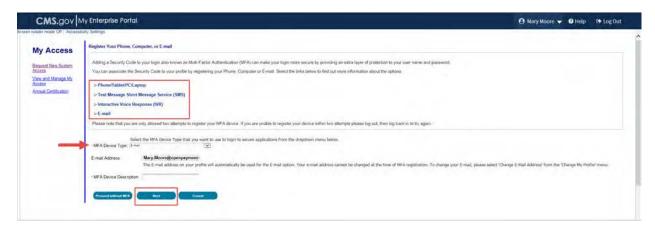
<u>Step 11:</u> **To proceed without MFA**, select "Skip MFA." A confirmation screen will be displayed that you have successfully requested access to the Open Payments system. Access to the Open Payments system will be instantaneous. Nevertheless, after you register, you will need to log out of the Enterprise Portal and then log back in before the link to the Open Payments system will appear in the menu bar at the top.



Step 11a: 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 a time. Additional devices may be added later through the EIDM profile settings. Enter the required information for the device you are registering and select "Next" button to continue.



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



A confirmation screen will be displayed with "Successful Completion!" message "Your request has successfully completed. You will need to logout and then log in to access the OPENPAYMENTS Application. Select 'OK' to continue."



"My Access" page displays the System(s) and Roles(s) the user has access to.



Section 3.3: 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 3.3c for more on physician vetting. Physician registration has five steps, as shown in **Figure 3.1** below. Details on these steps are included later in this chapter.

Figure 3.1: Physician Registration Process



Figures 3.2 and **3.3** 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.

Required or Optional? **Fields 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

Figure 3.2: Required and Optional Fields for Physician Profiles

Records submitted to Open Payments are associated with physician license numbers and NPI. Therefore, when registering in the Open Payments system, physicians must enter at least one of the state license numbers they hold, as well as their NPI number (if they have one).

Figure 3.3: Required and Optional Fields for Individual User Profiles

^{**}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.

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 3.3f.) 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 3.4** below. Details on these steps are included later in this chapter.

Confirm Your Review Search for Log in to Role and Teaching and Open Nominate an Submit **Hospital Using** Authorized Rep Payments Profile Required Fields (Optional)

Figure 3.4: Teaching Hospital Registration Process

Figures 3.5 and **3.6** 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 3.5: 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 3.6: 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. You cannot save entries or complete the profile at a later time. You 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:

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- 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.

3.3a: 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 3.3d 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. You may be registered for both options and can alternate between physician and teaching hospital profiles using the "Switch User" functionality described in Section 3.3g.

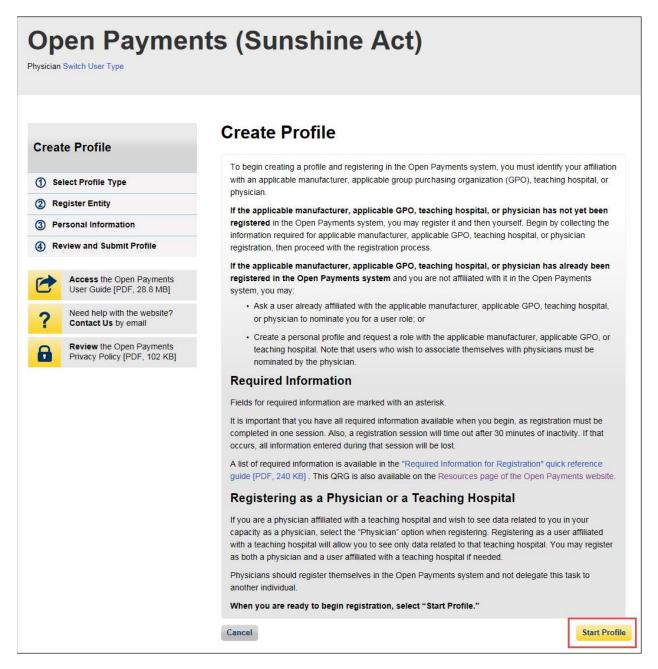
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the Application link.



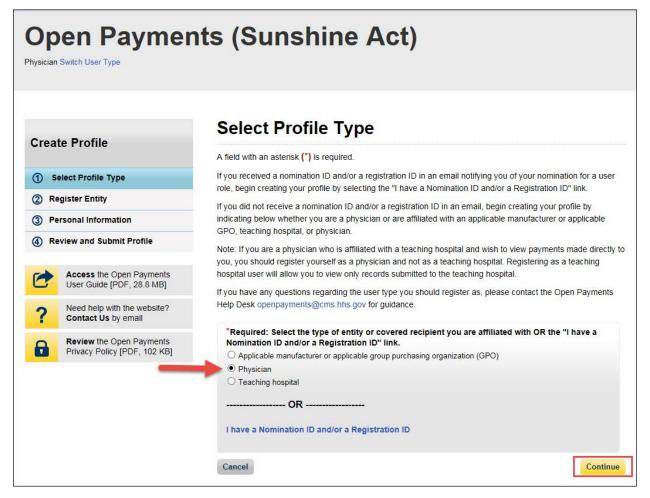
The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.



<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.



<u>Step 3:</u> Select the profile type "Physician" and select the "Continue" button.

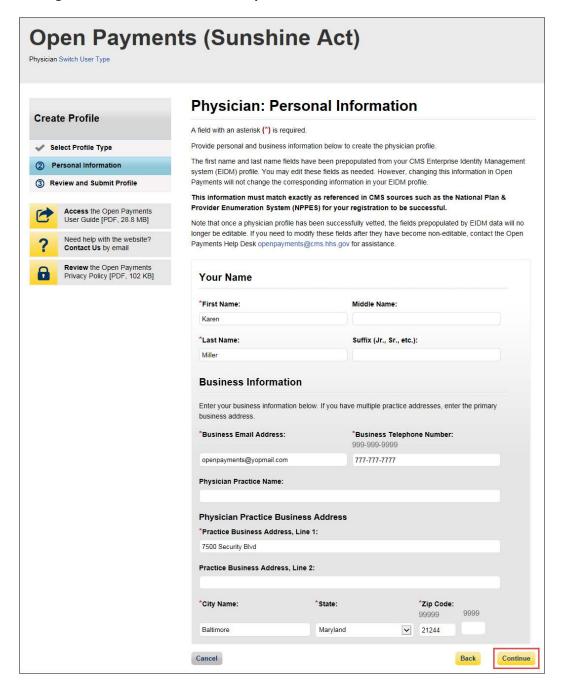


<u>Step 4:</u> Enter your personal information. All required fields will be marked with an asterisk (*). You will not be able to proceed with registration until all of the required fields have been entered.

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 done, select the "Continue" button.

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



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

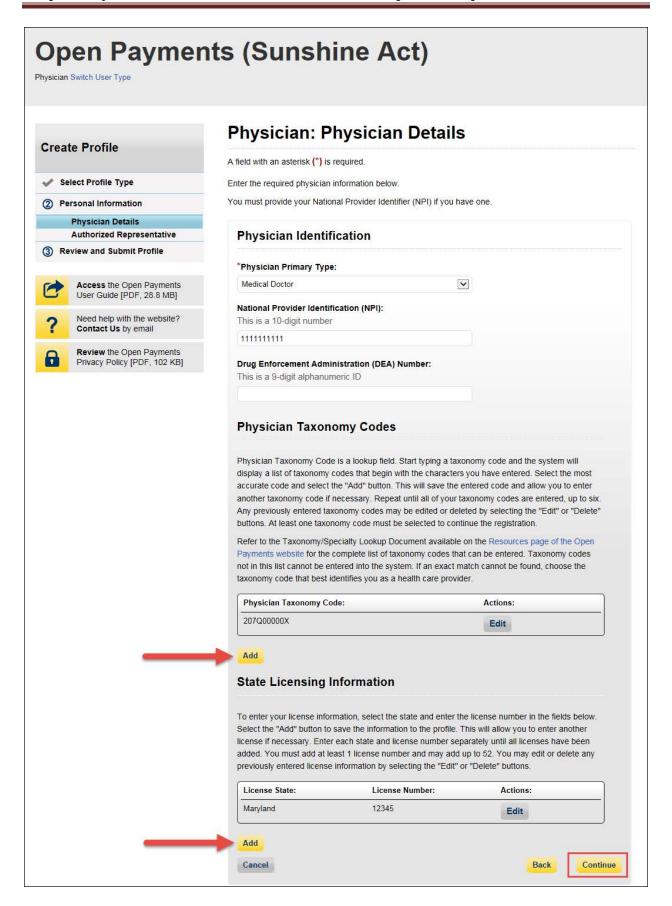
The National Provider Identifier (NPI) and Drug Enforcement Administration (DEA) Number fields are not marked as required, however, they must be entered if you have them. If you do not have these identifiers, you can still proceed with registration.

Note the following:

- If the physician has a National Provider Identifier (NPI), enter it exactly as listed in NPPES for the current calendar year.
- Enter at least one active state license.
- For each license or taxonomy code entered, select the "Add" button to save the information to the profile. Without selecting the "Add" button, the information will not be saved. Physicians can register using up to 6 Taxonomy Codes. To update or replace an existing Taxonomy select the "Edit" or the "Delete" button.

Refer to the taxonomy code list on the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html). 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.

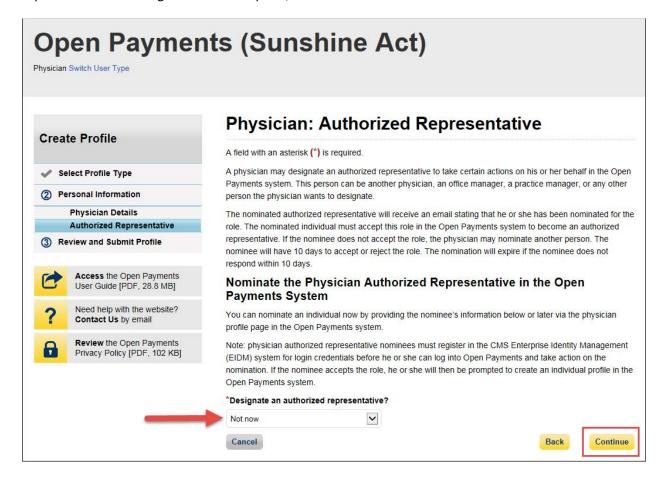
To enter license information, select the state in which the license is held and enter the license number. Select the "Add" button to add the license. The license number field may contain up to 25 characters, including special characters such as hyphens (-). You are required to enter at least one license.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



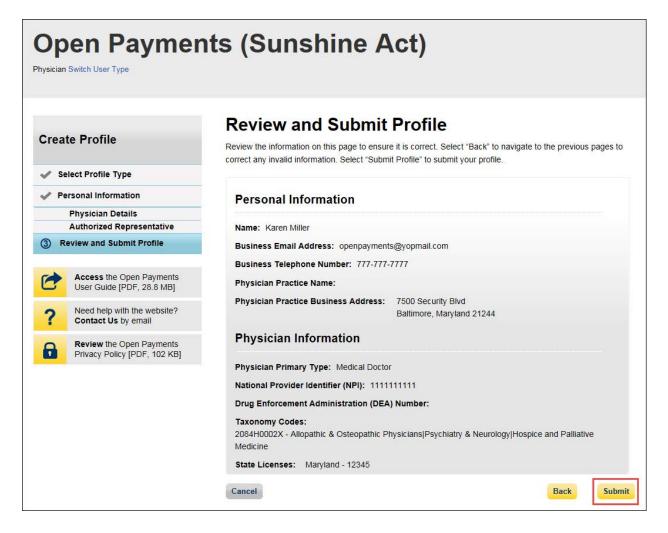
<u>Step 6:</u> At this point in registration, you may nominate an individual to serve as your authorized representative within the Open Payments system. By default, "Designate an Authorized Representative" will be selected. **A physician cannot be his or her own authorized representative.**

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 3.4a. The access levels are also summarized on the page. When you are finished, select the "Continue" button.

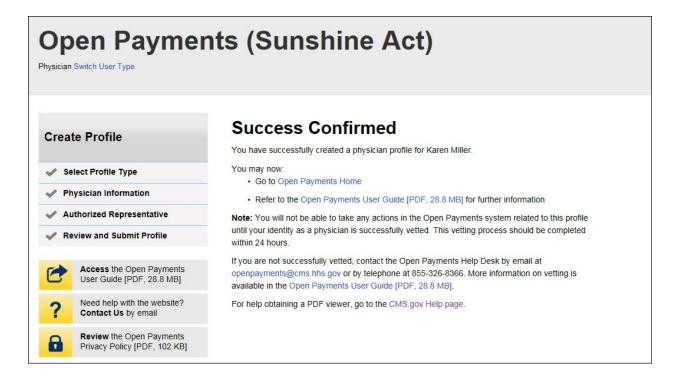
You do not need to designate an authorized representative during initial registration and may do so at a later time. If you choose not to designate an authorized representative at this time, select "Not Now" and then select the "Continue" button. For instructions on how to nominate an authorized representative after registration is complete, see Section 3.5a.



<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."



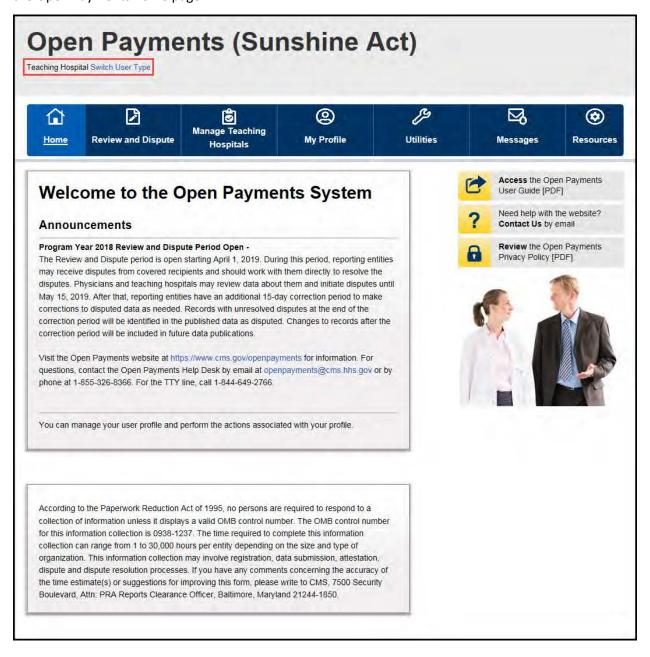
The following message will appear on-screen to confirm your profile has been successfully created. If you have chosen to delegate someone to be an authorized representative, an email notification with a nomination ID will be sent to that individual.



3.3b: 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 "Switch User Type" link above the menu bar on the Open Payments home page.

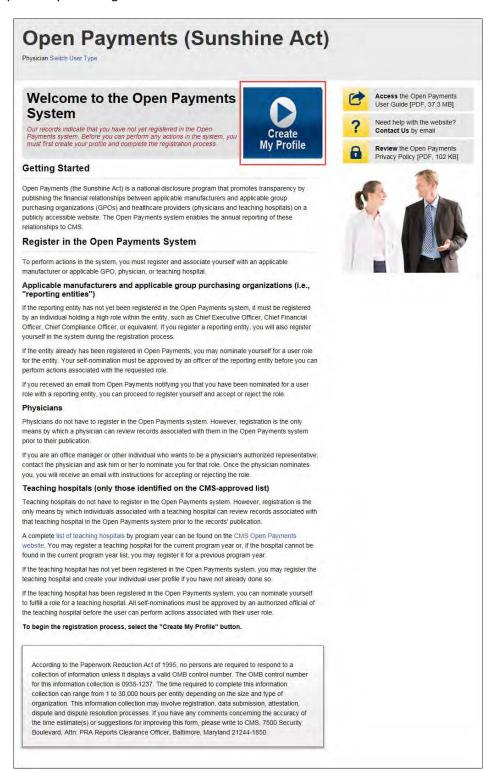


<u>Step 2:</u> On the "Open Payments Registration" page, under the heading "Select a User Type" select the "Physician" radio button. Select the "Switch" button.

Note: Changes made here will not automatically update user's profile information in his/her other CMS accounts.



<u>Step 3</u>: Select the "Create My Profile" button to create the Physician profile. Follow the steps in Section 3.3a to complete Physician registration.



3.3c: 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 (if physician has an NPI), state license information, and primary type. The Open Payments system will match physician information against multiple data sources. Note: If the physician has an NPI but neglects to provide it they will not be able to successfully complete vetting.

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.

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 (openpayments@cms.hhs.gov) or call 1-855-326-8366. For the TTY line, call 1-844-649-2766.

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.

3.3d: 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 3.4b 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

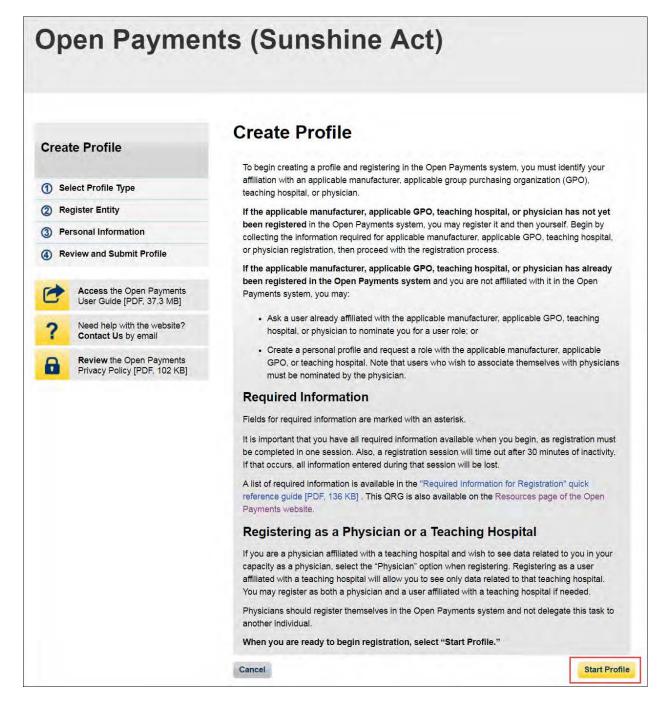
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Hospital" option when registering will only be able to view payments made to the teaching hospital they are affiliated with. If you wish to see data related to you as a physician, register a second time and select the "Physician" option. Users may be registered for both options.

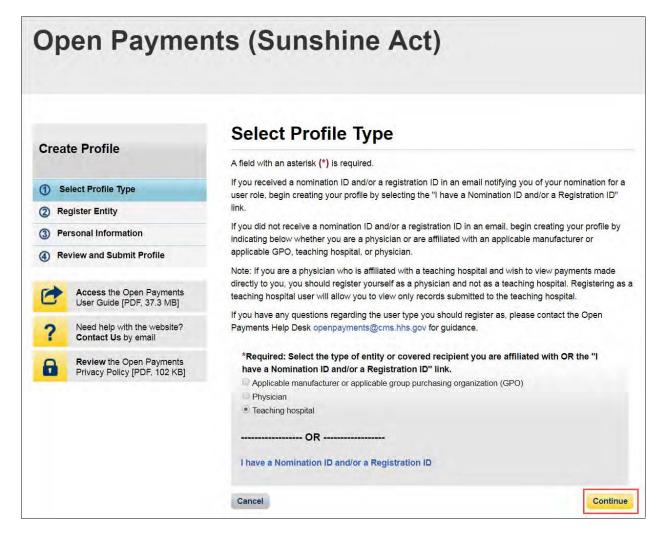
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are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



<u>Step 3:</u> Select the profile type, when finished select the "Continue" button.



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<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."

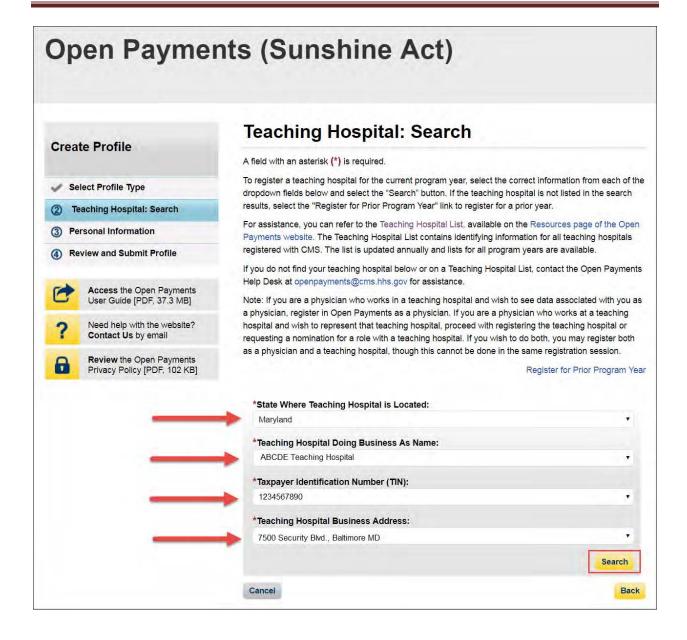
If your teaching hospital is not found, select "Register for Prior Program Year" to search for your teaching hospital in a previous program year. If you can find your teaching hospital only in a prior program year, you may select the teaching hospital and proceed with registration. For instructions on registering a teaching hospital for a prior program year, see Section 3.3f.

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

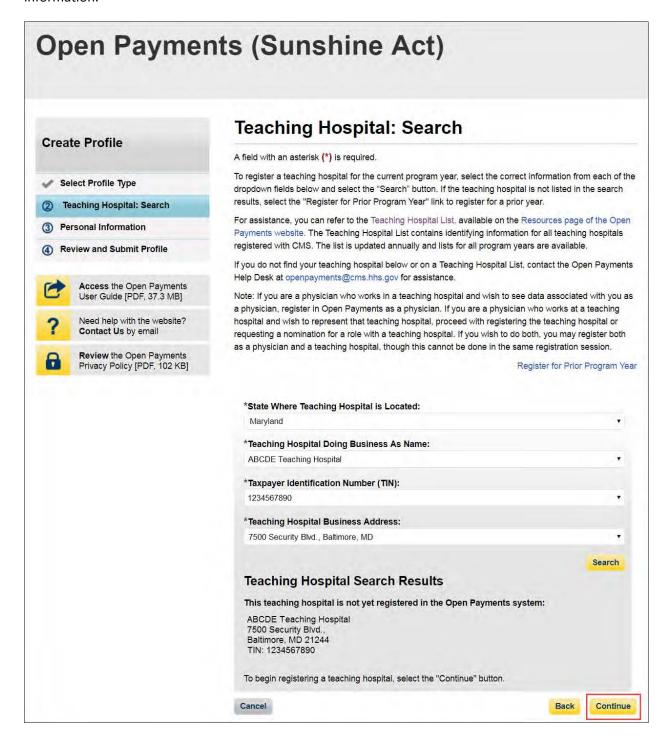
The name of the hospital selected during registration must be the hospital's "Doing Business As" name. In the CMS Teaching Hospital List, the "Doing Business As" name is under the heading of "Hospital Name." (Note that this differs if you register the teaching hospital for Program Year 2013 only. Refer to Section 3.3f 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."

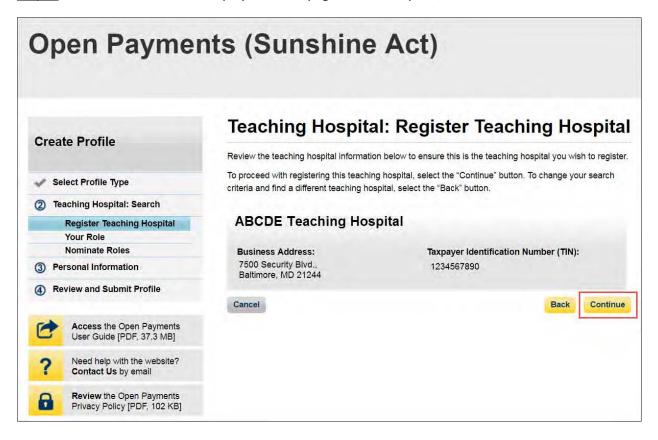
Teaching hospitals are pre-populated into the Open Payments system based on the Open Payments Teaching Hospital List. Teaching hospitals not on this list or prior program year lists will not have payments or other transfers of value reported about them.



<u>Step 5:</u> Review the information displayed on the page. Select the "Continue" button 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.

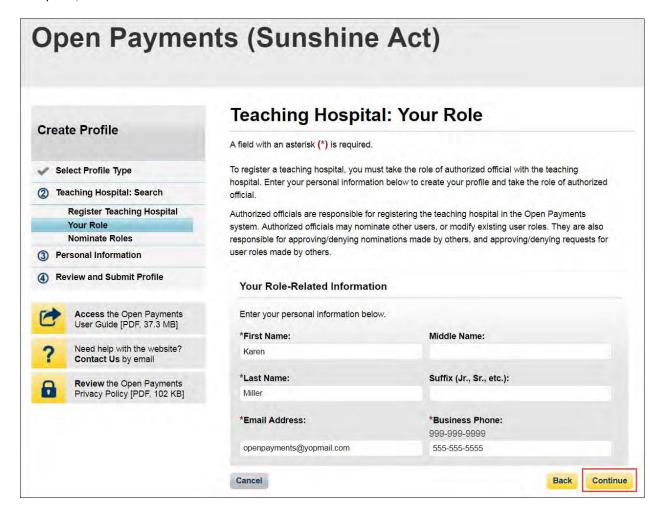


Step 6: Review the information displayed on the page. When complete, select the "Continue" button.

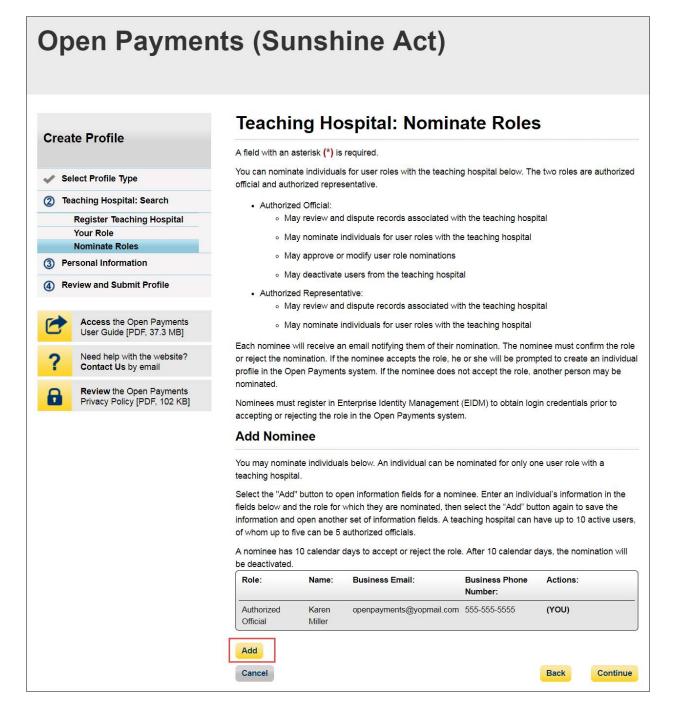


<u>Step 7:</u> Review the information generated by the system related to your role. You must select the role of "Authorized Official" for yourself to proceed with registration. Information on teaching hospital user roles is available in Section 3.4b.

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 the "Continue" button.



<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 the "Continue" button without adding any nominee information and proceed to Step 9.



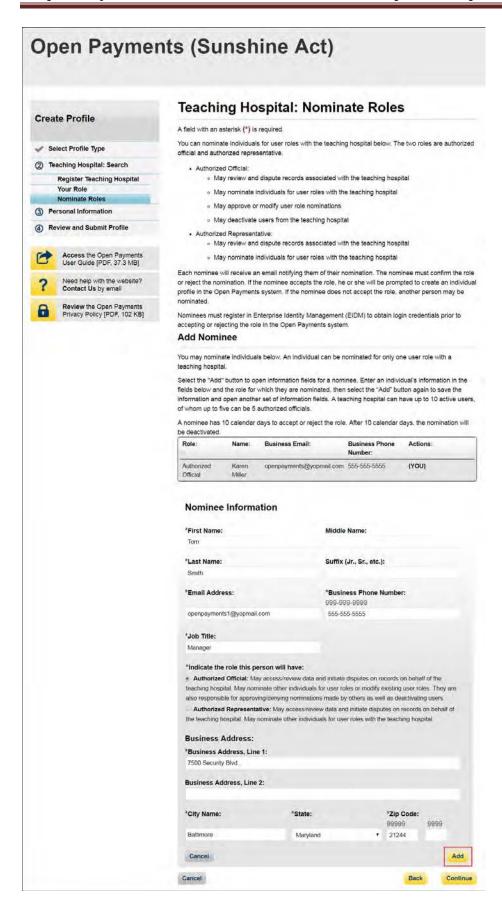
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<u>Step 8a</u>: If you selected "Add," enter the required information for one individual and select either "Authorized Official" or "Authorized Representative" to nominate the individual for the selected role. Information on teaching hospital user roles is available in Section 3.4b. 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.

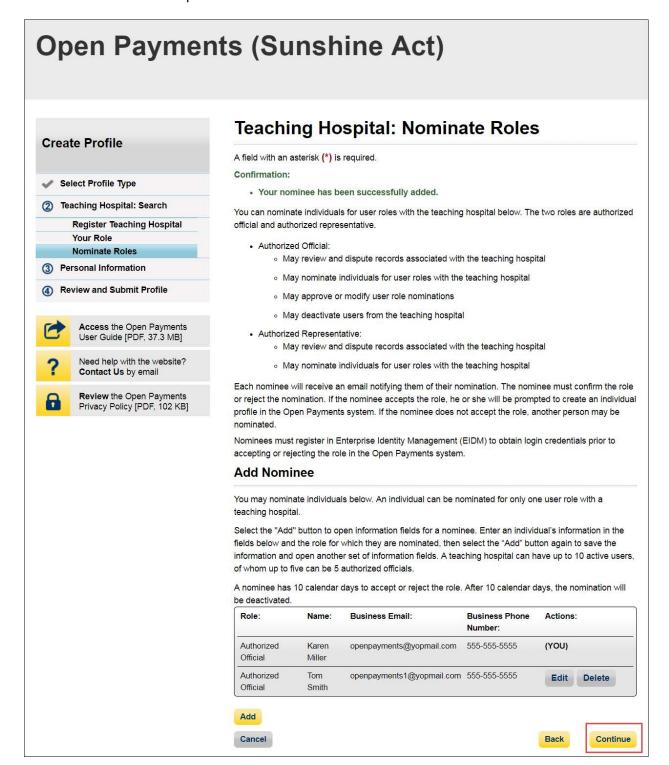
Repeat the process until you have entered all of the individuals you wish to nominate. A teaching hospital may have up to 10 unique active users, 5 of whom can hold the role of authorized official. When you have added all of the individuals you wish to nominate, select "Continue."

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

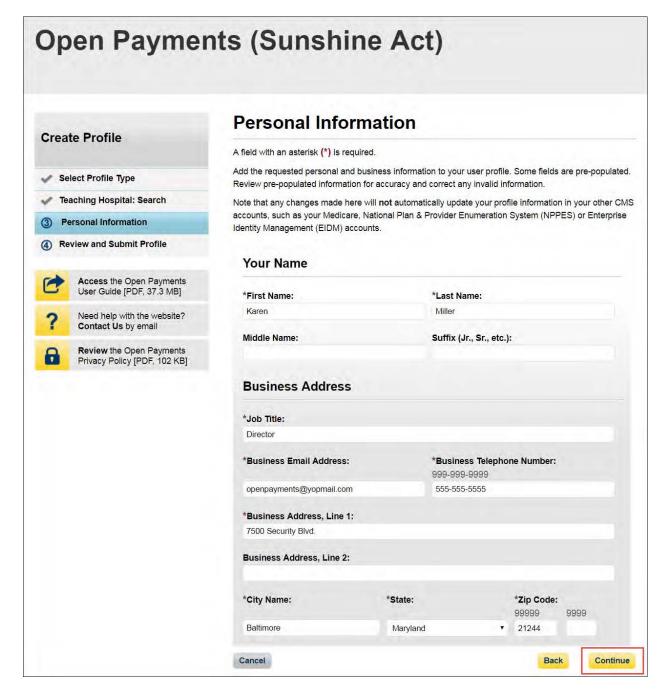
You do not have to nominate additional individuals during initial registration. You can nominate individuals later by updating your teaching hospital profile within the "Manage Teaching Hospitals" tab.



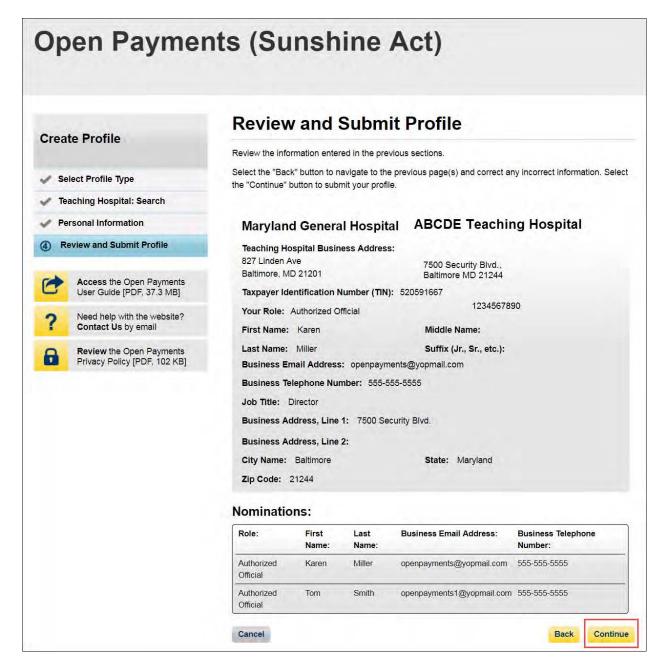
If you entered any nominees, you will see the nominee information displayed on the page. Confirm the information and when complete select the "Continue" button.



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



<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 the "Continue" button.



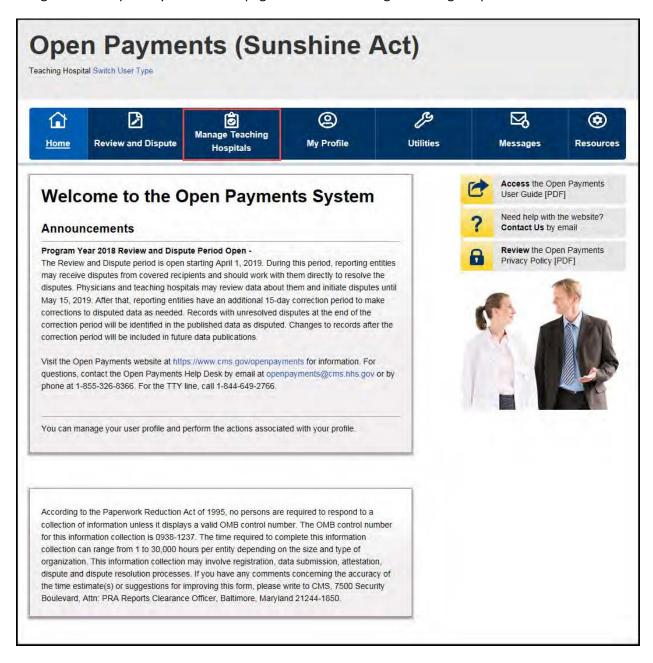
The following message will appear on-screen to confirm your profile has been successfully created. You will have immediate access to the teaching hospital data. If you nominated additional individuals for user roles, an email notification is sent to the nominees that will instruct them on their next steps.



3.3e: 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."

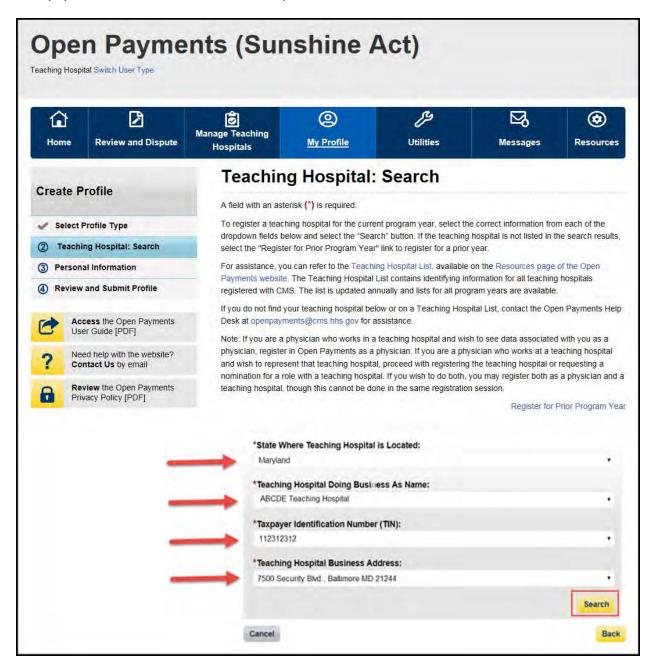
If your teaching hospital is not found, select "Register for Prior Program Year" to search for your teaching hospital in a previous program year. If you can find your teaching hospital only in a prior program year, you may select the teaching hospital and proceed with registration. For instructions on registering a teaching hospital for a prior program year, see Section 3.3f.

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

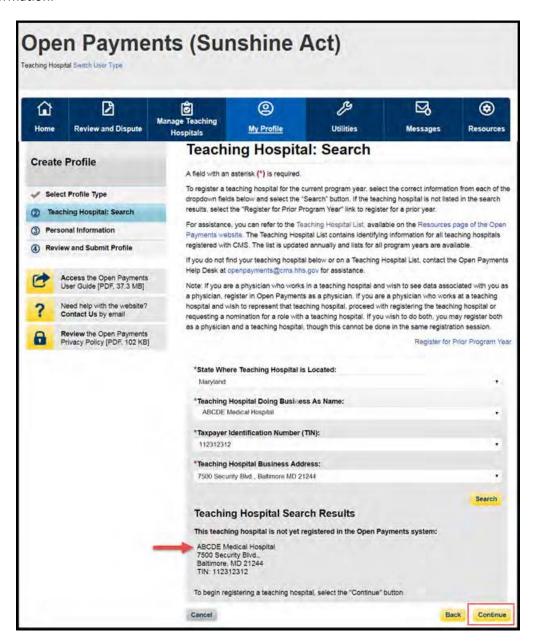
The name of the hospital selected during registration must be the hospital's "Doing Business As" name. In the CMS Teaching Hospital List, the "Doing Business As" name is under the heading of "Hospital Name." (Note that this differs if you register the teaching hospital for Program Year 2013 only. Refer to Section 3.3f 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."

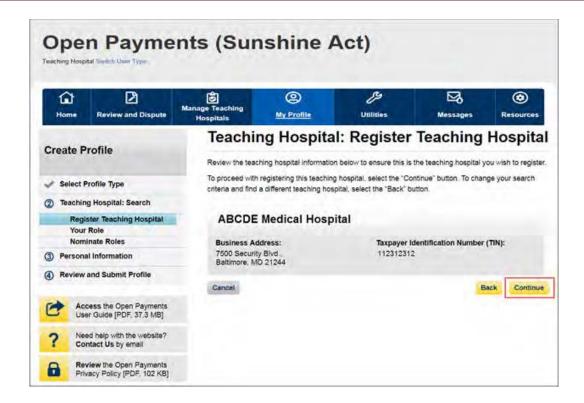
Teaching hospitals are pre-populated into the Open Payments system based on the 2015 Open Payments Teaching Hospital List. Teaching hospitals not on this list or prior program year lists will not have payments or other transfers of value reported about them.



<u>Step 4:</u> Review the information displayed on the page, and select the "Continue" button 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.

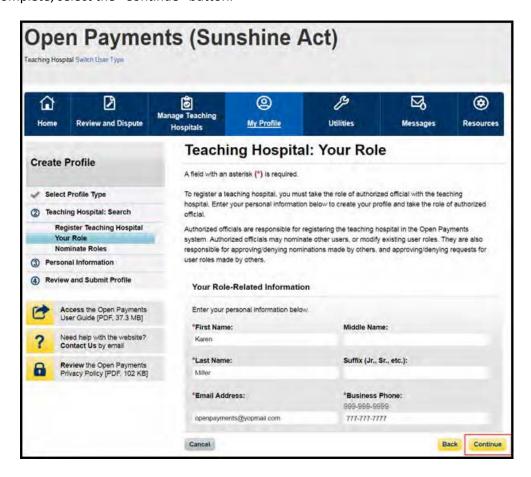


Step 5: Review the information displayed on the page and select the "Continue" button.

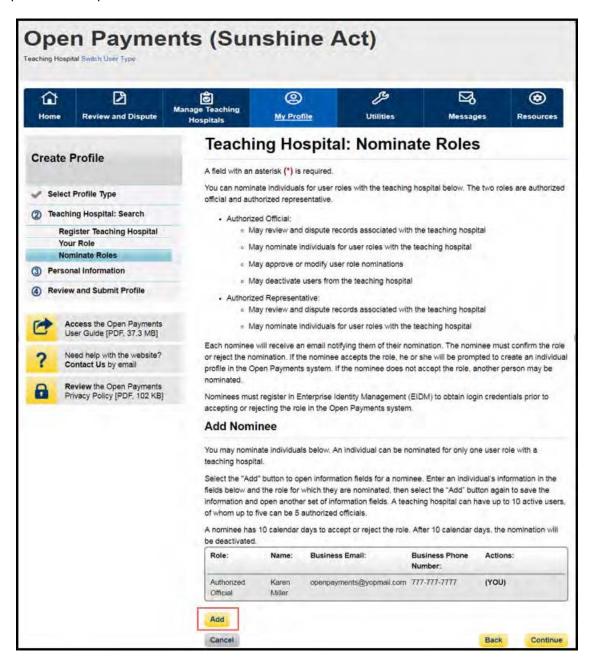


<u>Step 6:</u> Review the information generated by the system related to your role. You must select the role of "Authorized Official" for yourself to proceed with registration. Information on teaching hospital user roles is available in Section 3.4b.

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 the "Continue" button.



<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 the "Continue" button without adding any nominee information and proceed to step 8.



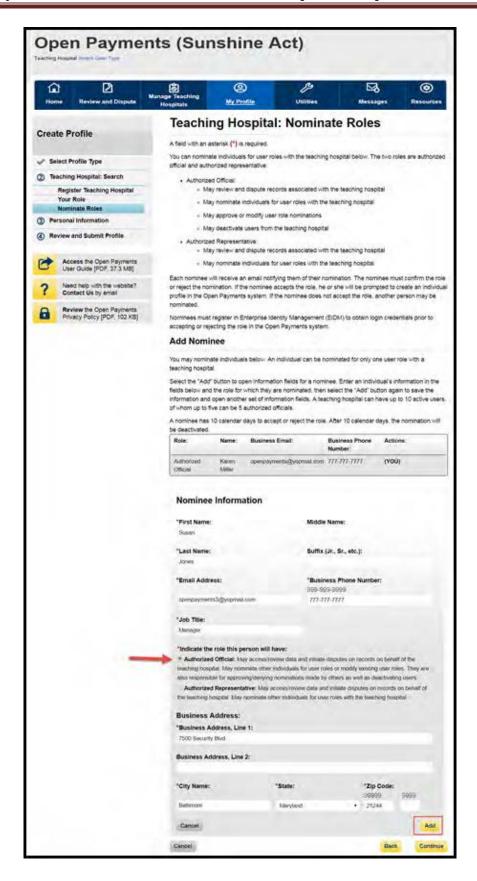
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<u>Step 7a</u>: If you selected "Add," enter the required information for one individual and select either "Authorized Official" or "Authorized Representative" to nominate the individual for the selected role. Information on teaching hospital user roles is available in Section 3.4b. 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.

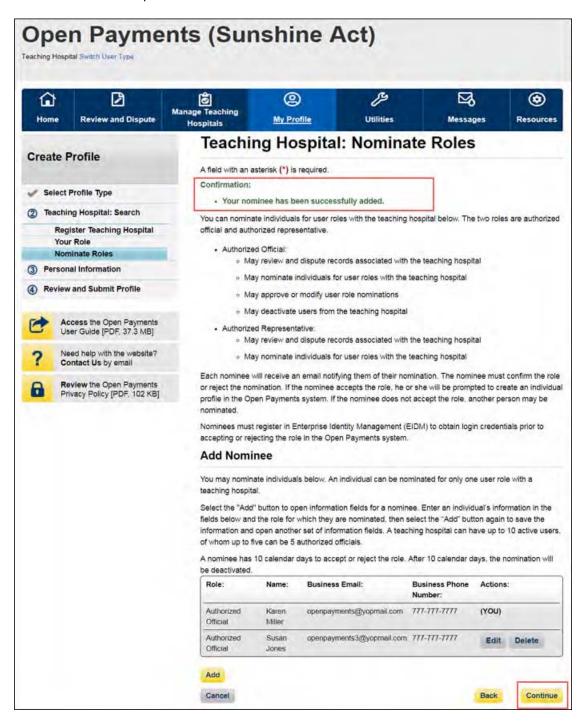
Repeat the process until you have entered all of the individuals you wish to nominate. A teaching hospital may have up to 10 active users, 5 of whom can hold the role of authorized official. When you have added all of the individuals you wish to nominate, select the "Continue" button.

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

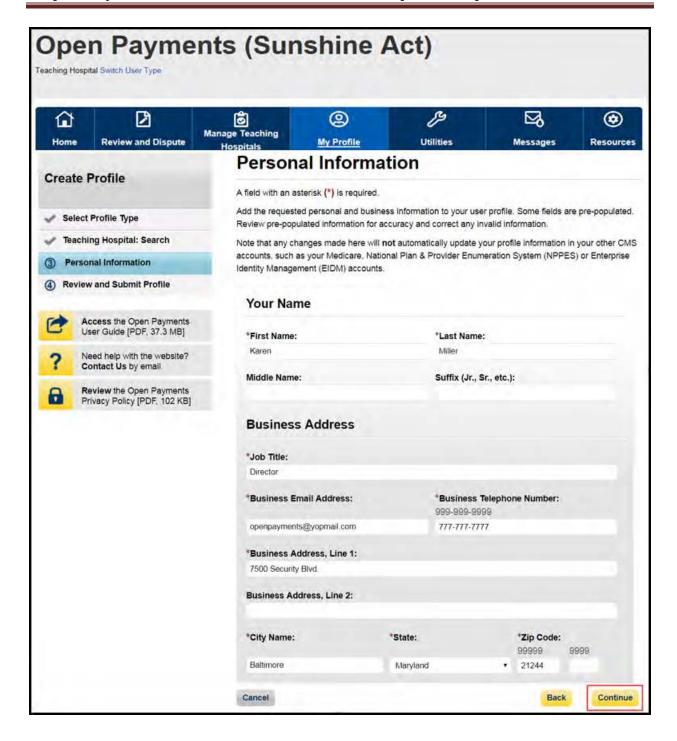
You do not have to nominate additional individuals during initial registration. You can nominate individuals later by updating your teaching hospital profile within the "Manage Teaching Hospitals" tab.



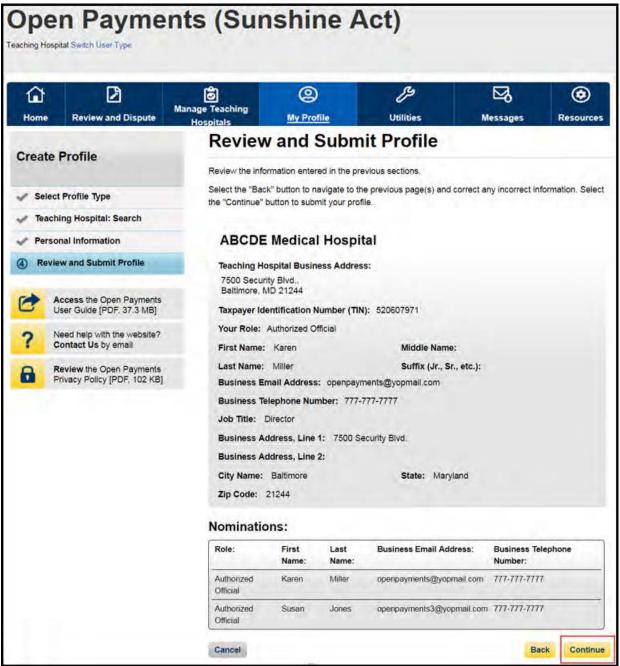
If you entered any nominees, you will see the nominee information displayed on the page. Confirm the information and when complete select the "Continue" button.



Step 8: Enter the required personal information. When finished, select the "Continue" button.



<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 the "Continue" button.



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.



3.3f Registering a Teaching Hospital (Prior Program Year)

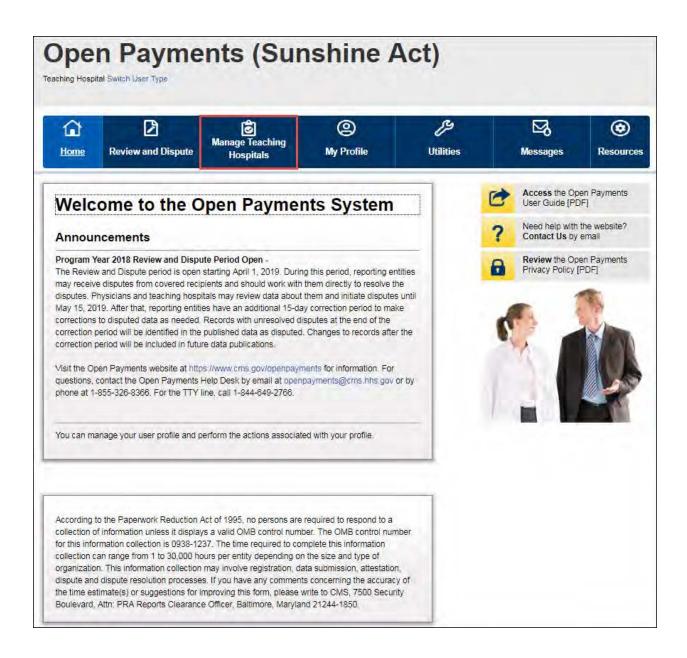
If you wish to register a teaching hospital in Open Payments that does **not** appear on the current program year's CMS Teaching Hospital List, but **does** appear in previous Teaching Hospital Lists, you can register the hospital for a prior program year. Doing so will allow you to view records associated 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:

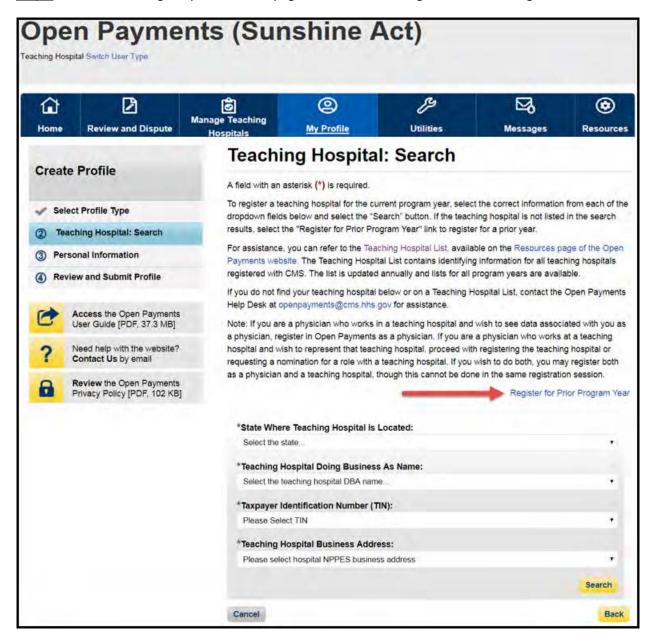
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. Select the "Manage Teaching Hospitals" tab.



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."

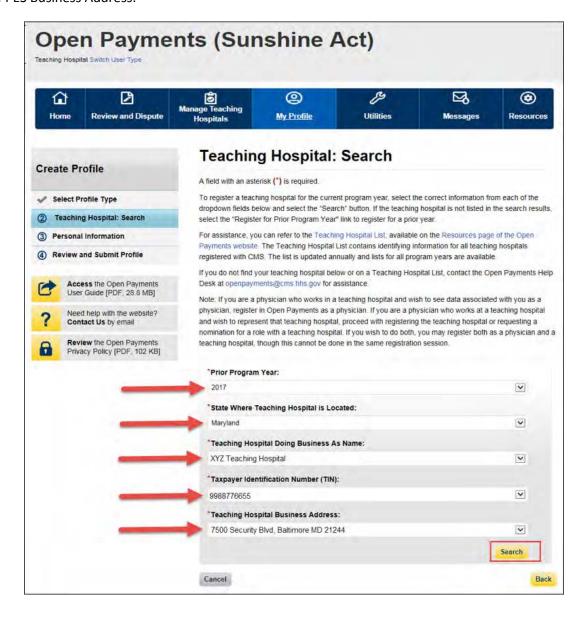


<u>Step 4</u>: Teaching hospitals are pre-populated in the Open Payments system based on the Teaching Hospital List for the program year you selected. Teaching hospitals not found in any program year will not have payments or other transfers of value reported about them for that program year.

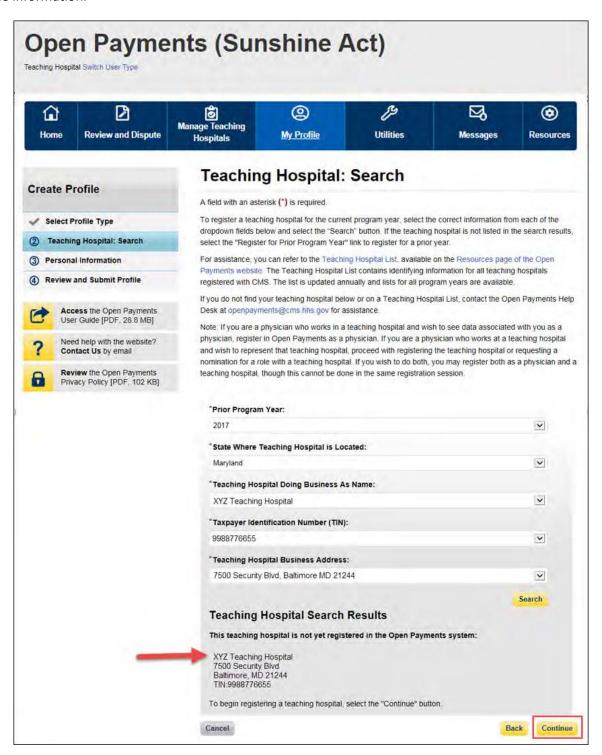
Search for the teaching hospital by selecting the program year you wish to register the hospital for, as well as the state, teaching hospital name, teaching hospital business address, and Taxpayer Identification Number (TIN) from the drop-downs and select "Search."

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."

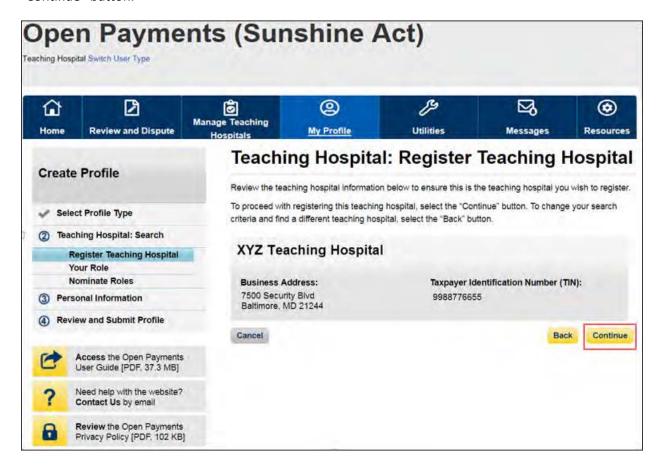
The address selected should be the address listed in the CMS Teaching Hospital List as the hospital's "NPPES Business Address."



<u>Step 5:</u> Review the information displayed on the page, and select the "Continue" button 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.

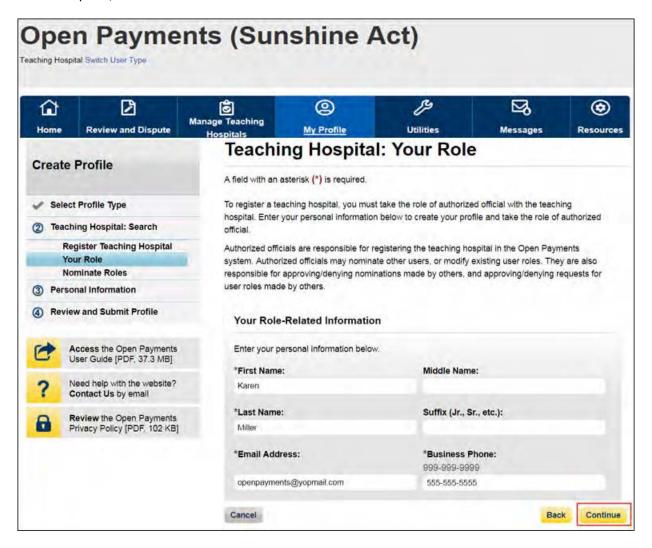


<u>Step 6:</u> Review the teaching hospital information displayed on the page. When complete, select the "Continue" button.

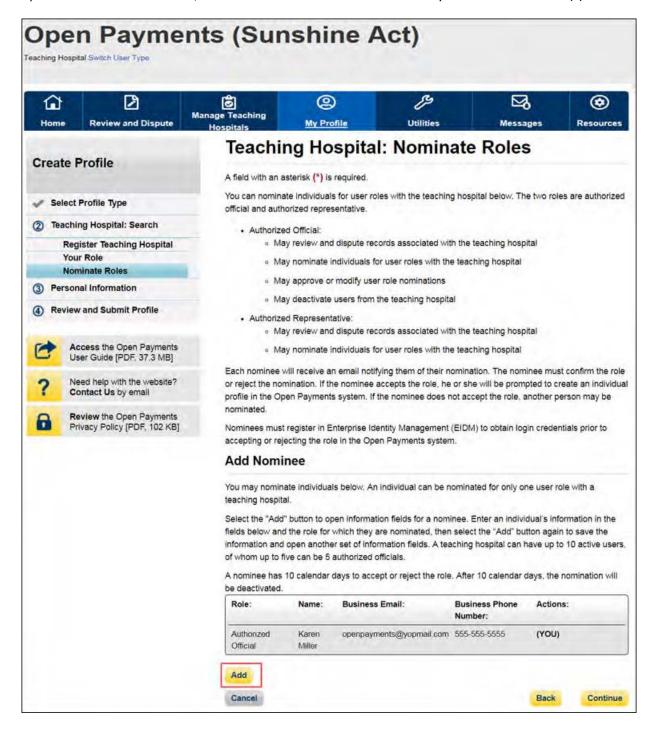


<u>Step 7:</u> Review the information generated by the system related to your role. You must select the role of "Authorized Official" for yourself to proceed with registration. Information on teaching hospital user roles is available in Section 3.4b.

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 the "Continue" button.



<u>Step 8:</u> You may choose to nominate additional users to fill the authorized official or authorized representative roles. To do so, select the "Add" button to nominate any additional individual(s).



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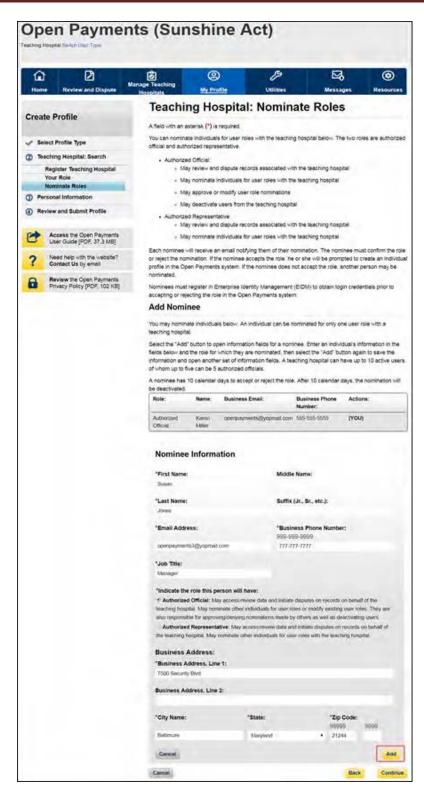
<u>Step 8a</u>: Enter the required information for one individual and select either "Authorized Official" or "Authorized Representative" to nominate the individual for the selected role. Information on teaching hospital user roles is available in Section 3.4b. When you have entered the information, select the "Add" button.

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 the "Continue" button.

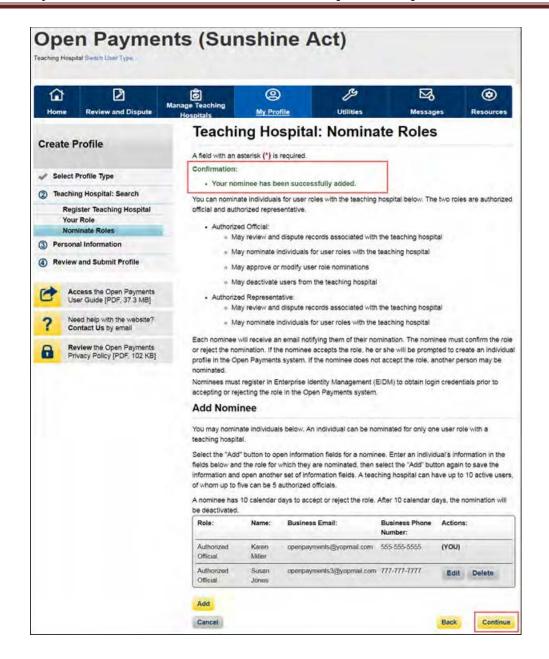
Each nominated individual will receive an email notifying them of their nomination. The nominee must confirm or reject the role within 10 calendar days.

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.

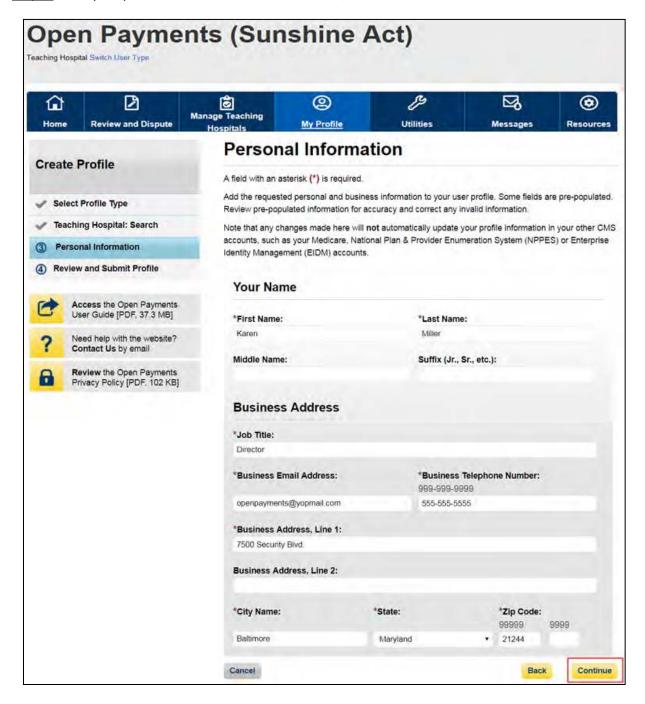
If you choose not to add nominees at this time, select "Continue" without adding any nominee information.



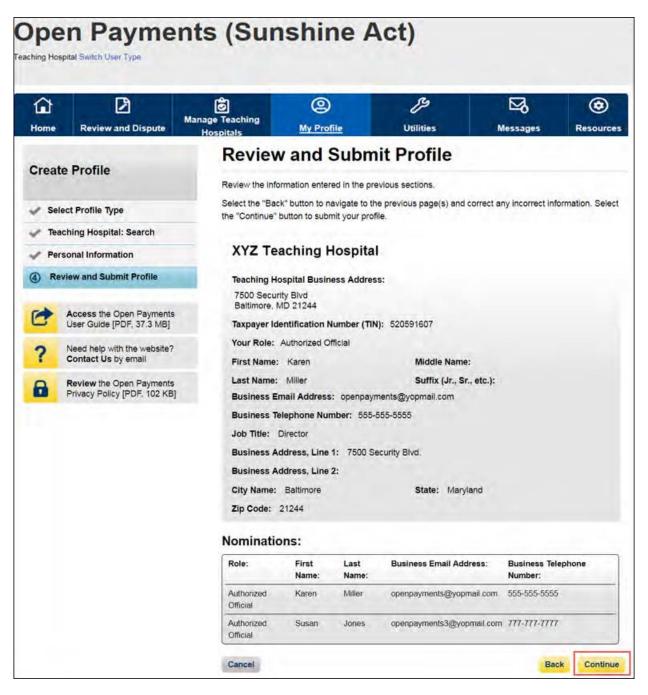
If you entered any nominees, you will see the nominee information displayed on the page. Confirm the information and when complete select the "Continue" button.



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



<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 the "Continue" button.



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.



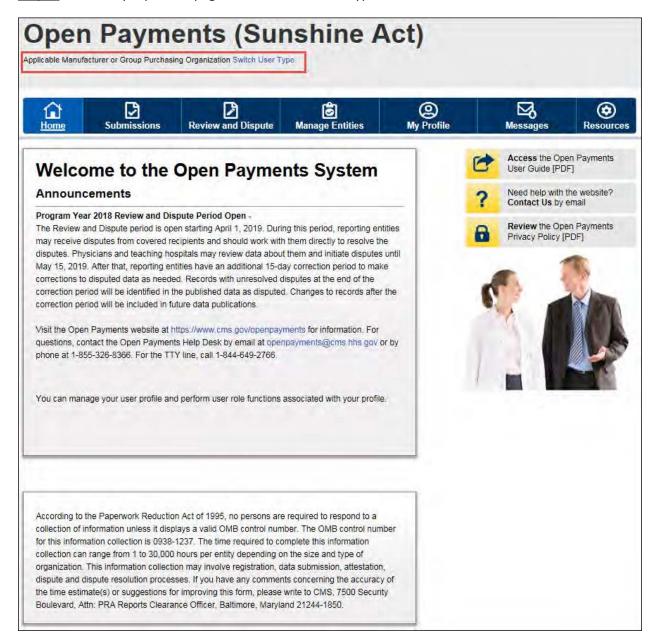
3.3g: Using the Switch User Functionality

The Open Payments system allows you to hold multiple user roles based on your affiliations with multiple entities. You can switch among the applicable manufacturer/applicable GPO, physician, and teaching hospital user types through a "Switch User Type" functionality. Once you have 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.

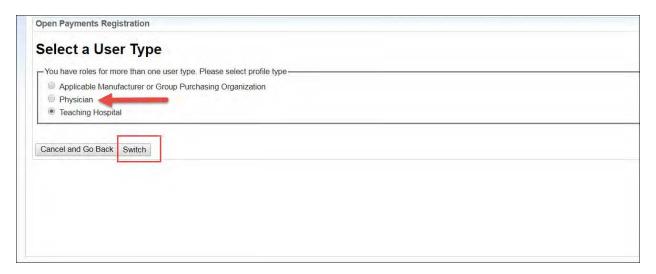
All users have access to the "Switch User Type" functionality. Users who have only a single user type can use the functionality to request roles for and/or register as another user type.

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."



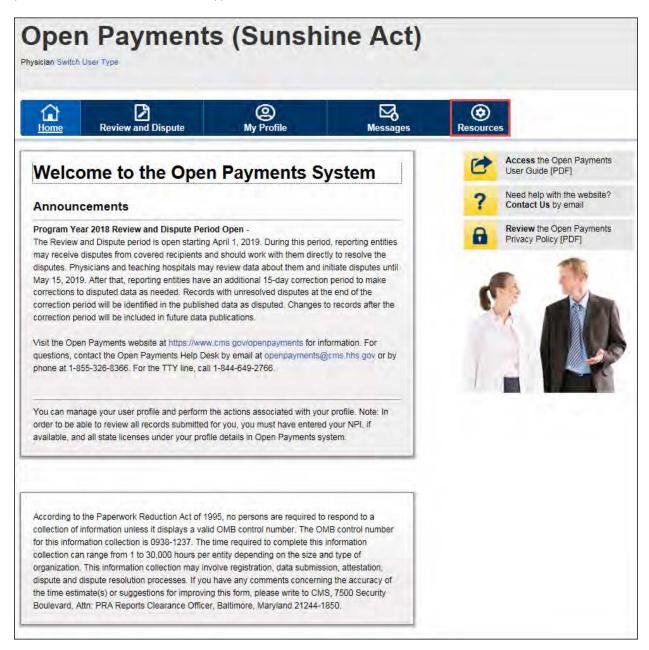
<u>Step 2:</u> Select the user type to which you would like to switch, or which user type you would like to request a role. When finished, select "Switch." If you decide you do not want to change user types, or you selected "Switch User Type" by accident, select "Cancel and Go Back."



<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 3.4: 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.

3.4a: 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 3.7: 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	Physician can grant one or more of the following access levels:	
Representative	 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.) 	
	 <u>Dispute Records</u>: 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 	

3.4b: 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 3.8 below.

Figure 3.8: 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 3.5: Nominations

The nomination process allows you 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 3.9** shows the five steps in the nomination acceptance process.

Figure 3.9: Accepting Nominations Process



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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.

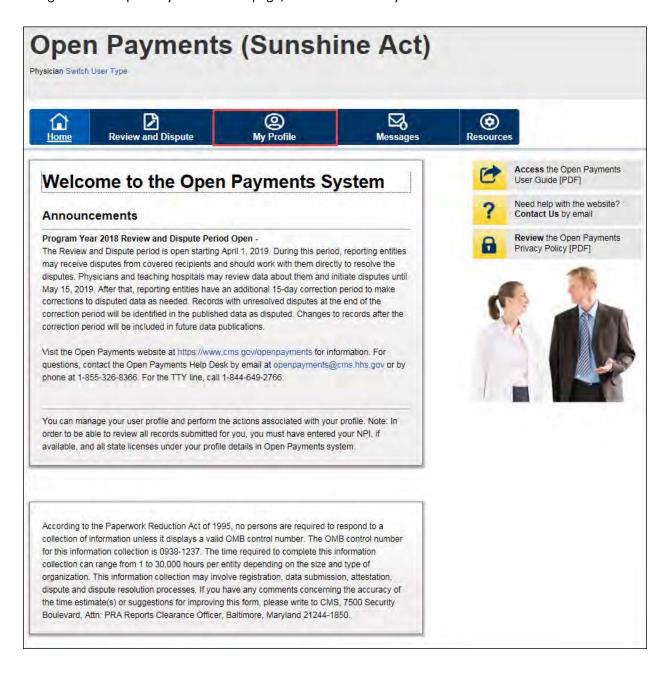
Figure 3.10: User Role Statuses for Physicians and Teaching Hospitals

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	

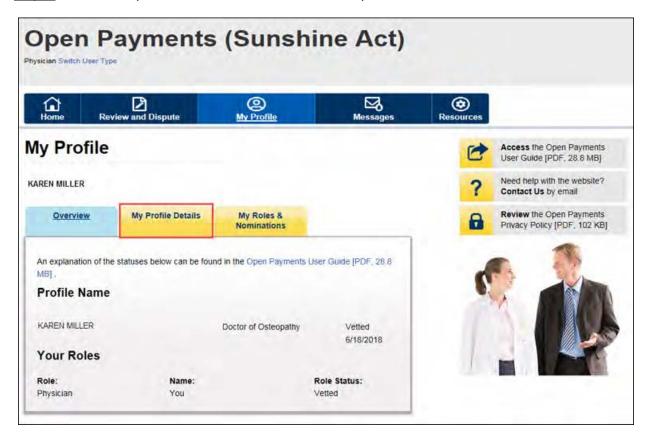
3.5a: Nominating a Physician Authorized Representative (Returning System Users)

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.

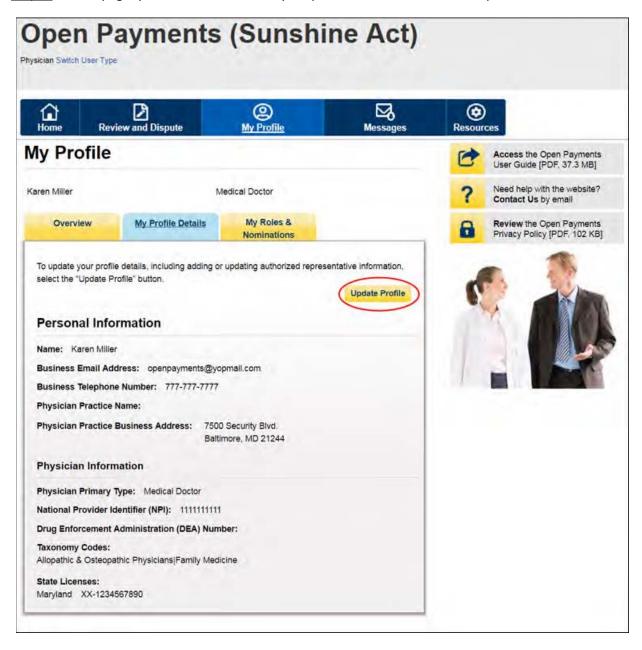
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page, and select the "My Profile" tab.



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."



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<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.

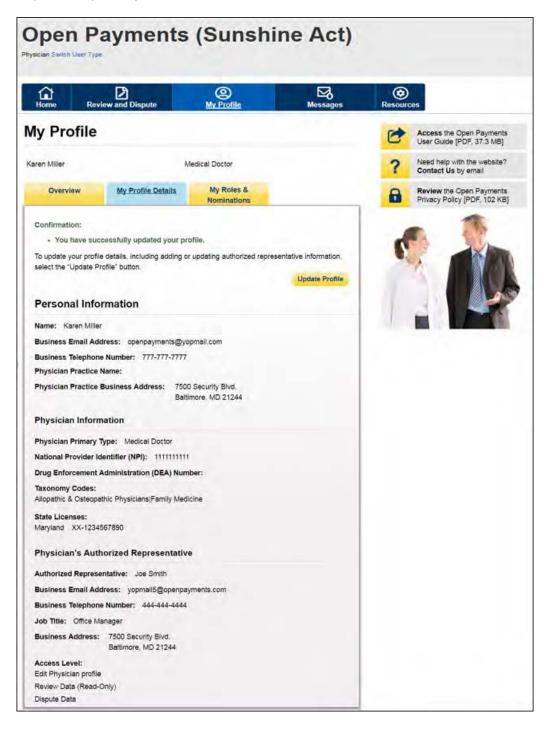
If you still do not wish to delegate an authorized representative, select "Not now" and select "Save Updates." On this page, you may also modify your profile information, such as adding or editing your state license information or physician taxonomy codes. See Section 3.6 for more information on profile 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 3.4. When complete, select "Save Updates."



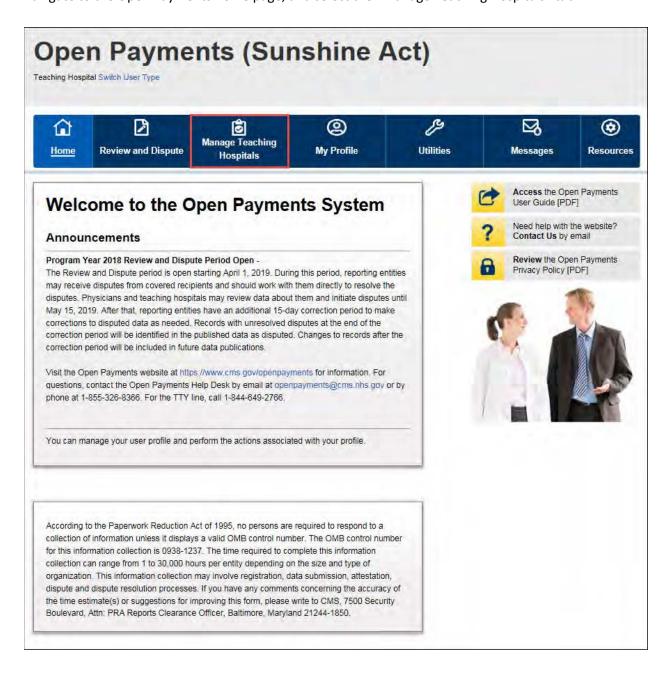
<u>Step 5:</u> The nominee will receive an email notification that they have been nominated for a role in the Open Payments system. The email will contain a nomination ID. Users notified of their nomination for a role must use the nomination ID received in the nomination email to complete their profile 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.



3.5b: 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.



<u>Step 2:</u> Select the teaching hospital for which you wish to nominate a new role.



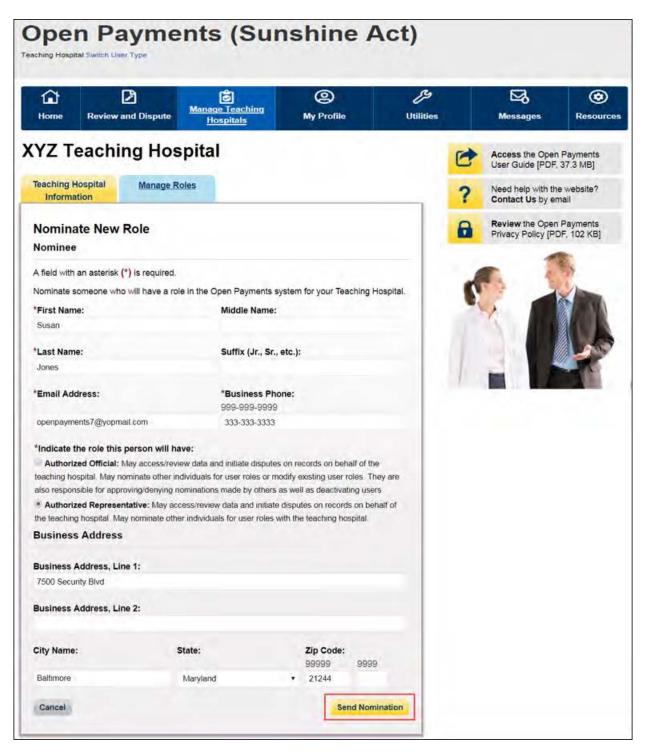
Step 3: Select the "Manage Roles" tab.



Step 4: Select the "Nominate New Role" button.



<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 the "Send Nomination" button.



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.

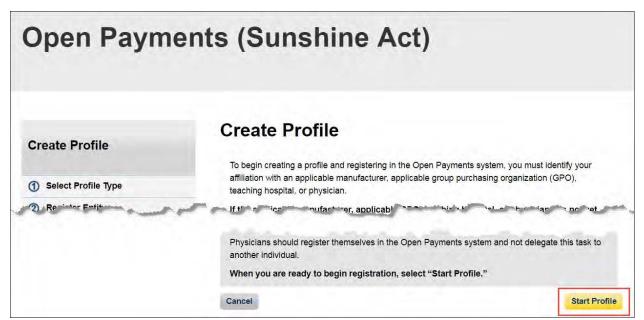
3.5c: Accepting or Rejecting a Nomination (Physician Authorized Representative – First-Time Users)

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.

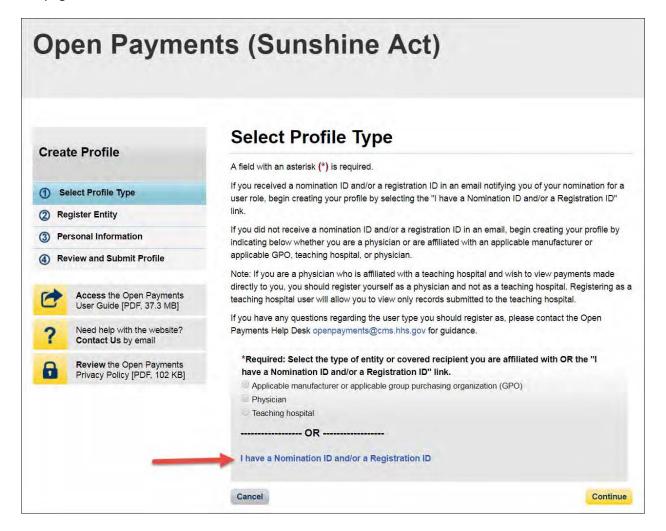
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are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



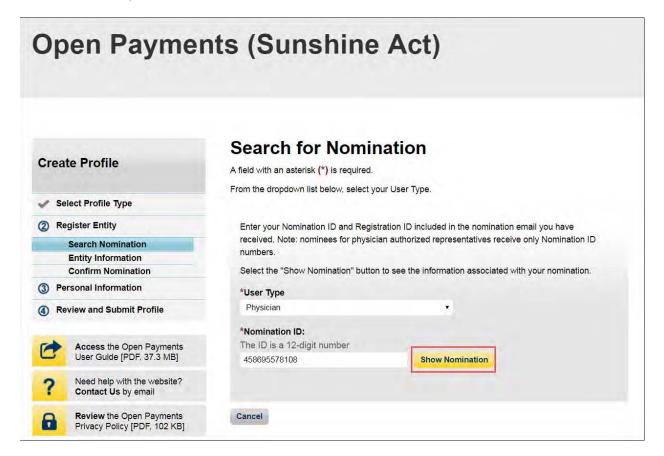
<u>Step 2:</u> The on-screen text contains important information regarding creating the physician and individual profiles. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start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



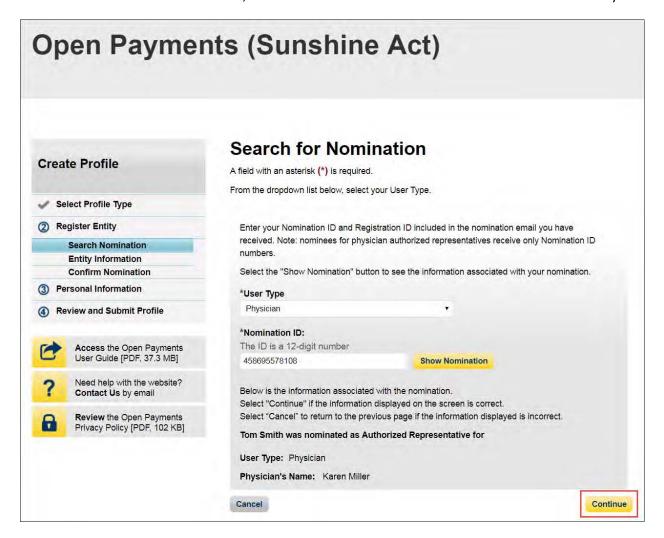
<u>Step 3:</u> Although you are affiliating with a physician, do not select "Physician" on the "Select Profile Type" page. Instead, select the "I have a Nomination ID and/or a Registration ID" link at the bottom of the page.



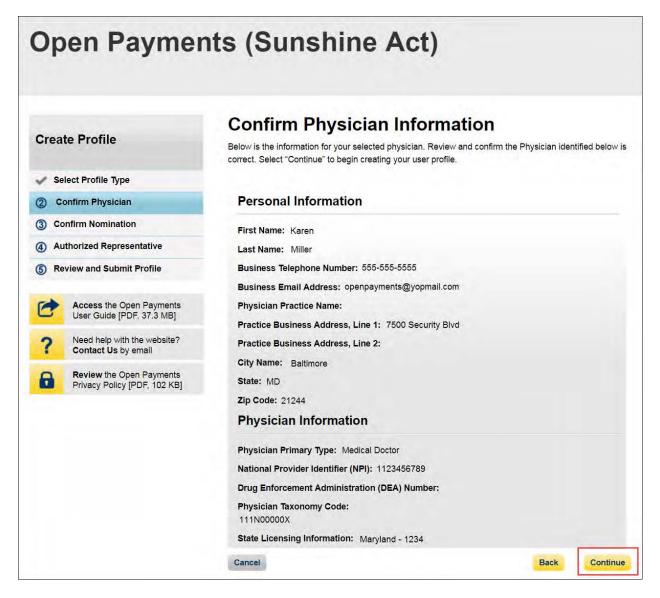
<u>Step 4:</u> Select the User Type "Physician." Enter the nomination ID included in the nomination notification email you received and then select the "Show Nomination" button.



<u>Step 5:</u> Review the nomination information displayed. If the information is correct, select the "Continue" button. If the information is incorrect, select the "Cancel" button and contact the nominator directly.

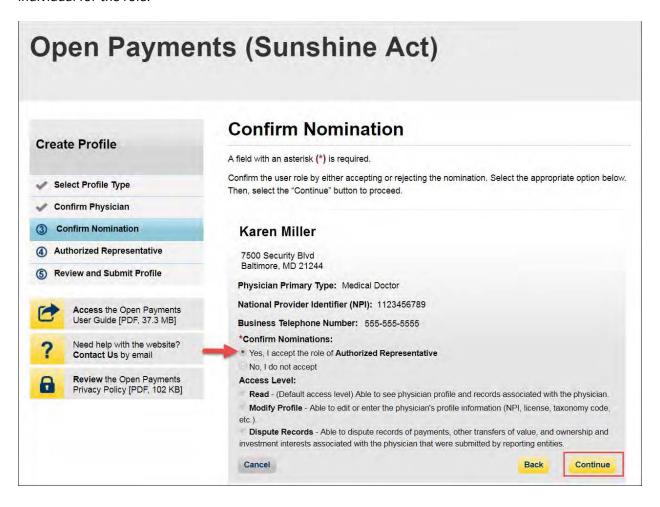


<u>Step 6:</u> Review the physician information displayed on the page. You will not be able to edit the information. Ensure that this is the physician for which you want to accept the user role nomination. If it is not the correct physician, either select the "Back" button at the bottom of the page to return to the previous page to correct the information you have entered, or select the "Cancel" button to end the acceptance process.

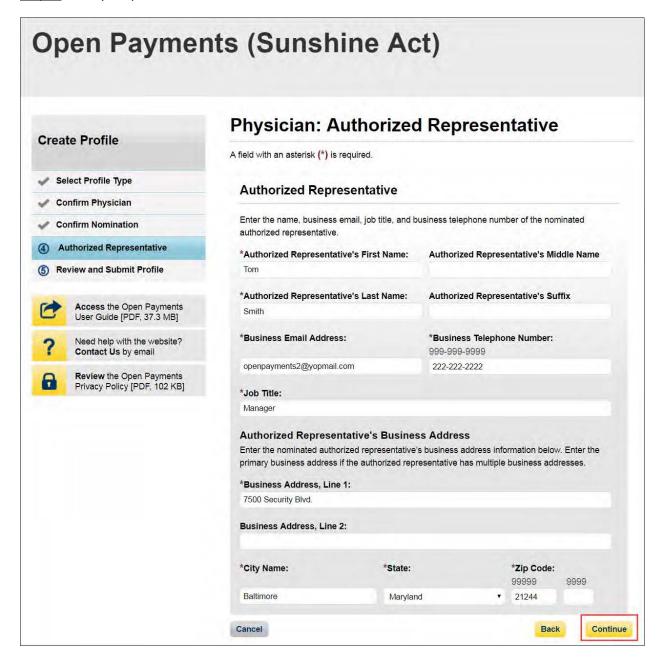


<u>Step 7:</u> Review the nomination information on the page. Select "Yes, I accept the role of Authorized Representative" if you wish to accept the role or "No, I do not accept" if you do not wish to accept the role. If you accept the role and select "Continue," you will continue the nomination confirmation process.

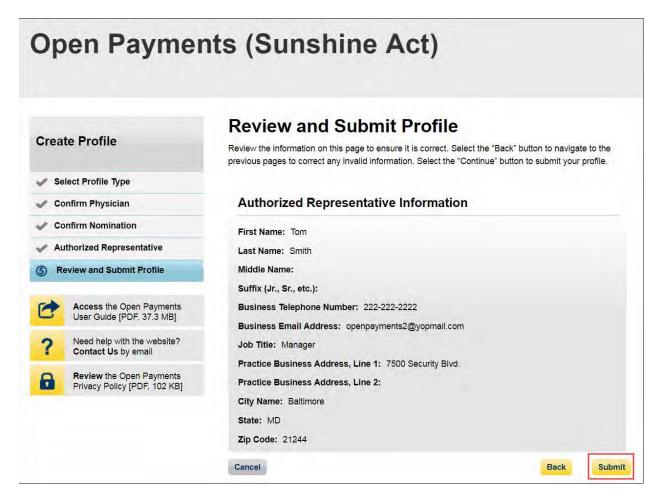
If you reject the role for which you have been nominated, select the "Continue" button after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will 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 the "Continue" button.



<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 the "Submit" button.



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



3.5d: 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.



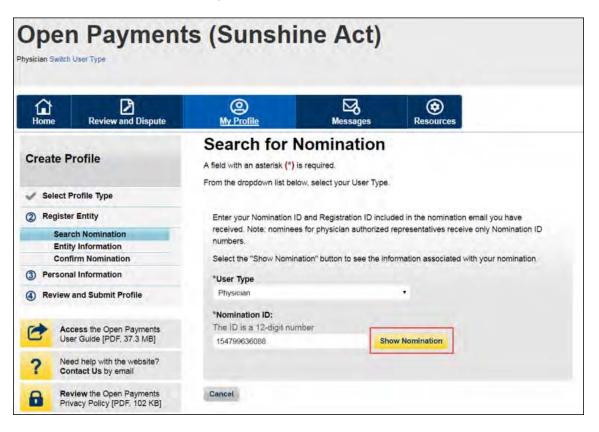
Step 2: From the "My Profile Overview" tab, select the "My Roles and Nominations" tab.



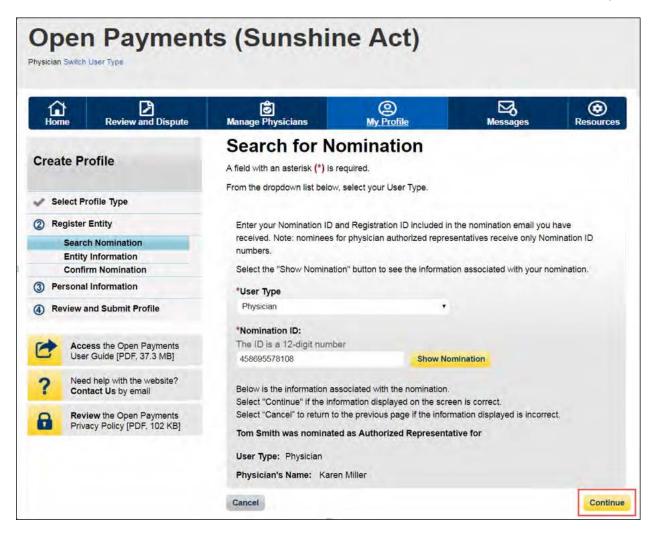
Step 3: From the "My Roles and Nominations" tab, select "Accept/Reject Nominations."



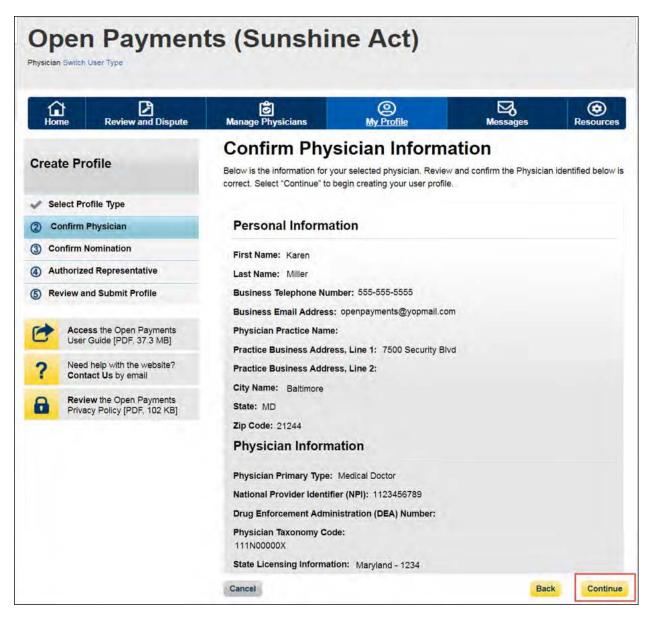
<u>Step 4:</u> The "User Type" should be pre-populated with "Physician." Enter the nomination ID provided in the nomination notification email you received and then select "Show Nomination."



<u>Step 5:</u> Review the nomination information displayed. If the information is correct, select the "Continue" button. If the information is incorrect, select the "Cancel" button and contact the nominator directly.

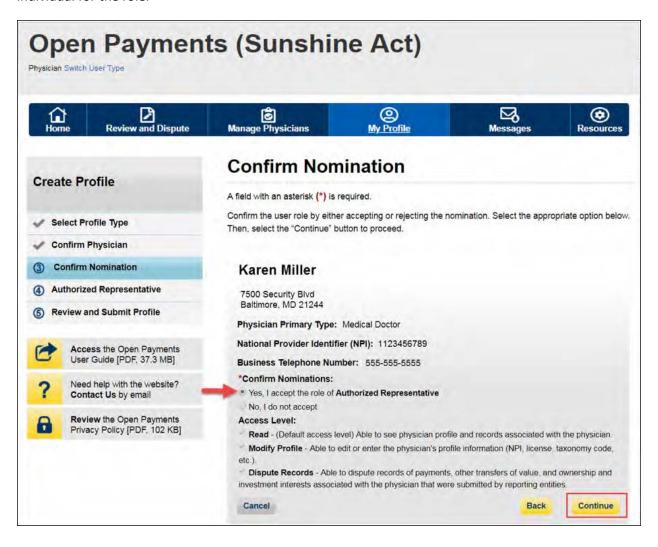


<u>Step 6:</u> Review the physician information displayed on the page. You will not be able to edit the information. Ensure that this is the physician for which you want to accept the user role nomination. If it is not the correct physician, either select the "Back" button at the bottom of the page to return to the previous page to correct the information you have entered, or select the "Cancel" button to end the acceptance process.

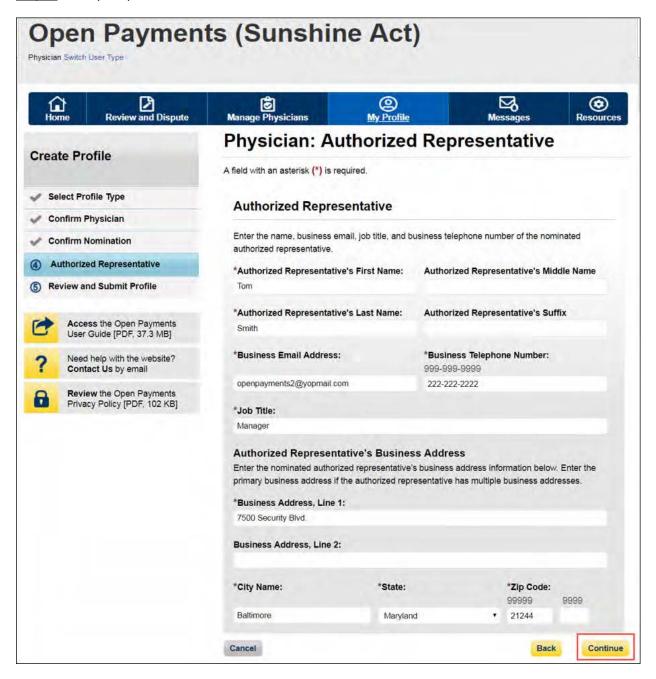


<u>Step 7:</u> Review the nomination information on the page. Select "Yes, I accept the role of" if you wish to accept the role or "No, I do not accept" if you do not wish to accept the role. If you accept the role and select the "Continue" button, you will continue the nomination confirmation process.

If you reject the role for which you have been nominated, select the "Continue" button 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 the "Continue" button.



<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 the "Submit" button.



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



3.5e: 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.

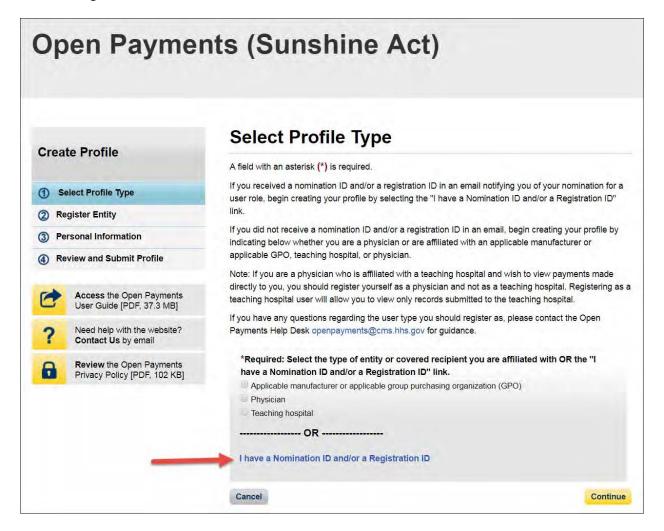
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are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



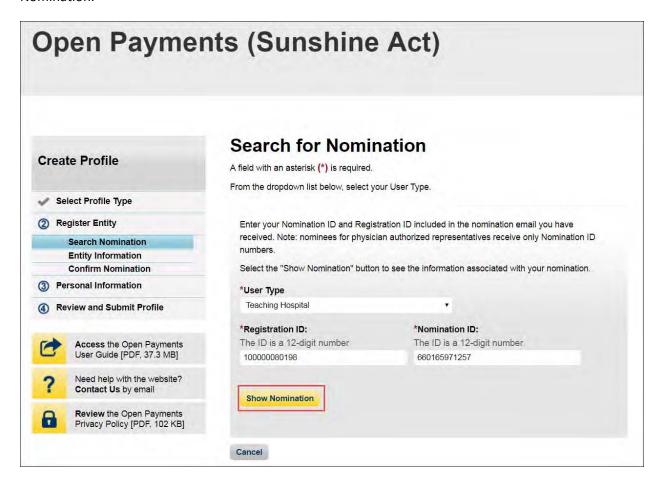
<u>Step 2:</u> The on-screen text contains important information regarding creating the physician and individual profiles. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start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



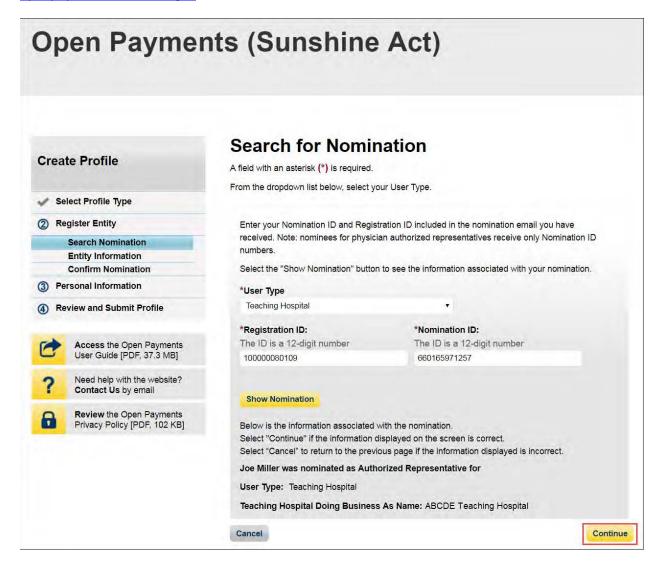
<u>Step 3:</u> On the "Select Profile Type" page, though you are affiliating with a teaching hospital, do not select "Teaching Hospital." Instead, select the link at the bottom of the page, "I have a Nomination ID and/or a Registration ID."



<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."

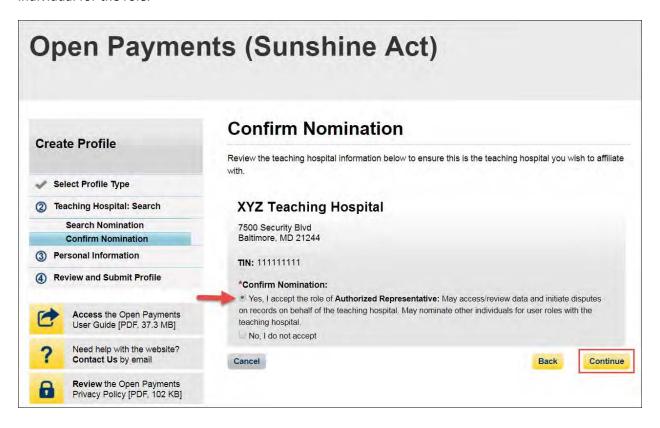


<u>Step 5:</u> Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select the "Cancel" button and contact the Open Payments Help Desk at openpayments@cms.hhs.gov.

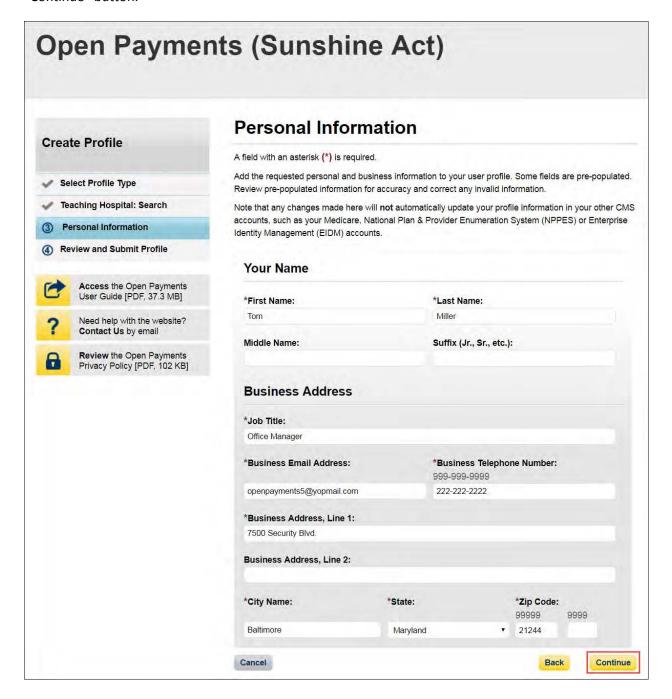


<u>Step 6:</u> Select "Yes, I accept the role of" if you wish to accept the role or "No, I do not accept" if you do not wish to accept the role. If you accept the role and select "Continue," you will continue the nomination confirmation process.

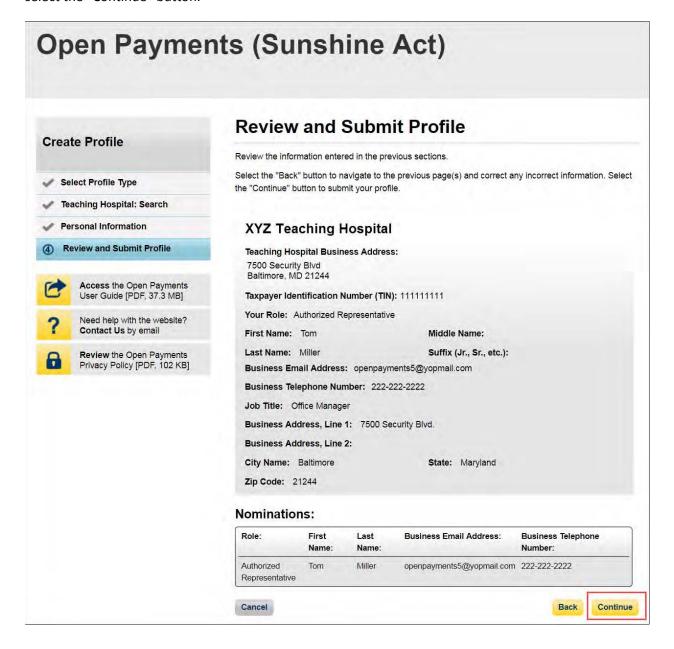
If you reject the role for which you have been nominated, select the "Continue" button after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will 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 the "Continue" button. If the information displayed is incorrect, update the necessary fields. When finished, select the "Continue" button.



<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 the "Continue" button.



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



3.5f: 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.



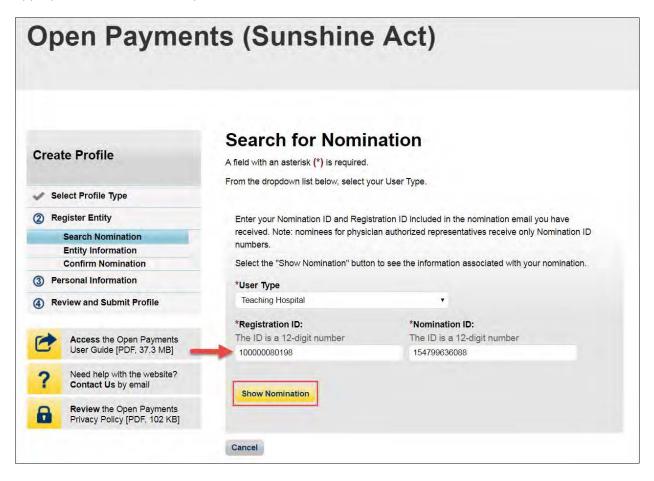
Step 2: Select "My Roles and Nominations."



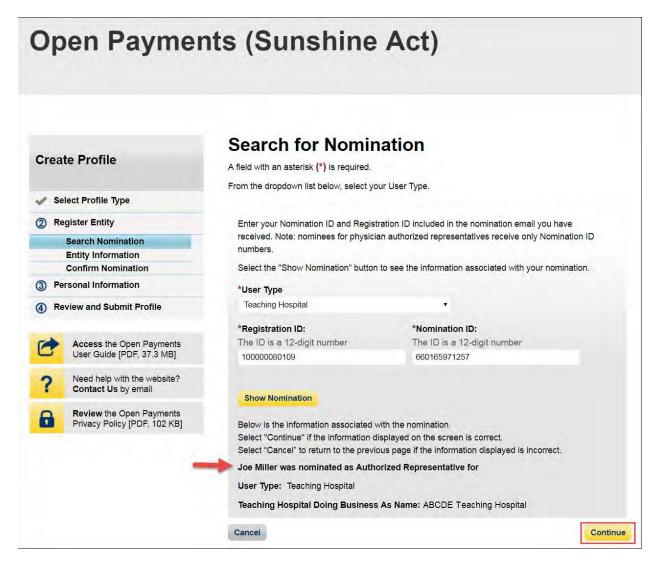
Step 3: Select "Accept/Reject Nominations."



<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."

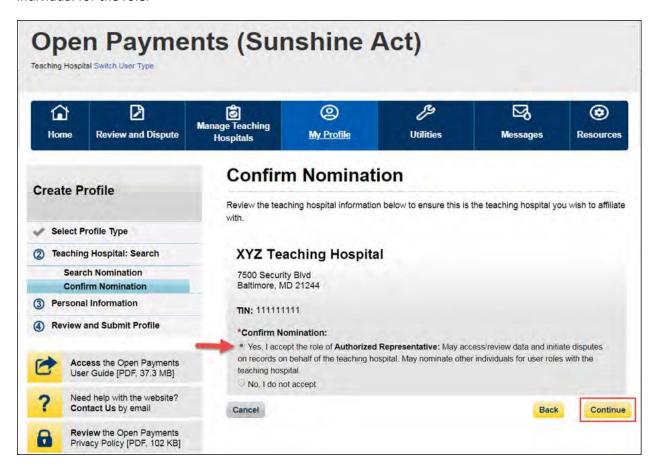


<u>Step 5:</u> Review the nomination information displayed. If the information is correct, select the "Continue" button. If the information is incorrect, select the "Cancel" button and contact the teaching hospital directly.

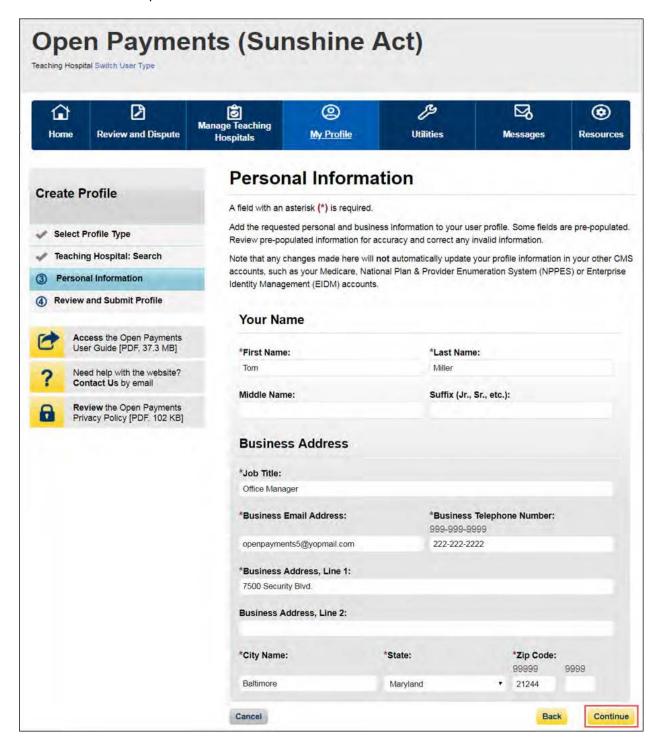


<u>Step 6:</u> Select "Yes, I accept the role of" if you wish to accept the role or "No, I do not accept" if you do not wish to accept the role. If you accept the role and select the "Continue" button, you will continue the nomination confirmation process.

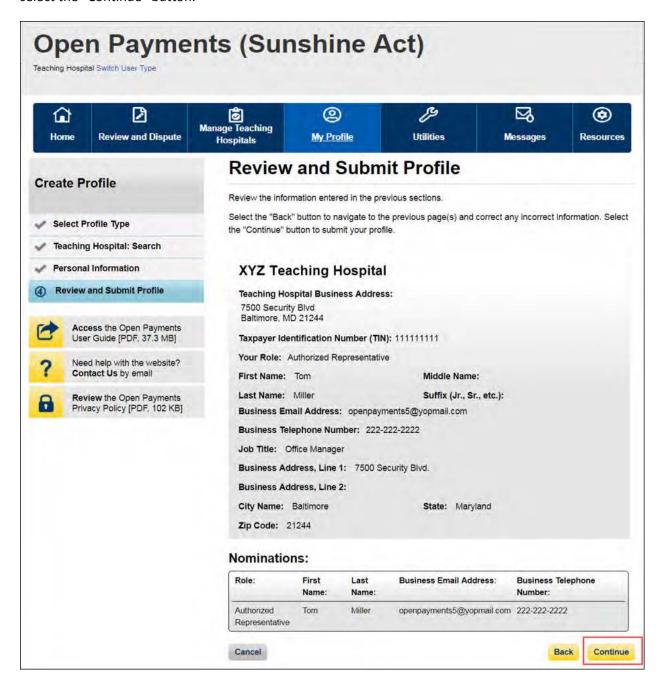
If you reject the role for which you have been nominated, select the "Continue" button after selecting "No, I do not accept" for the role. The system will ask you if you are sure you want to reject this role. If you confirm your choice to reject the role, you will exit the system and the nominator will receive an email that you rejected the nomination. The nominator will then be allowed to nominate another individual for the role.



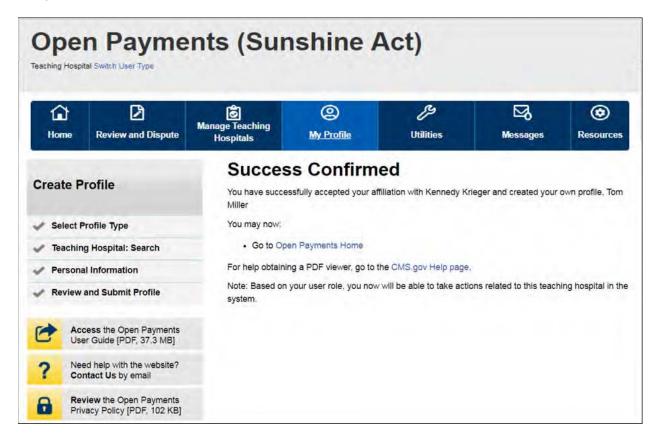
<u>Step 7:</u> Review your personal information and enter in any additional required fields. Select the "Continue" button to proceed.



<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 the "Continue" button.



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



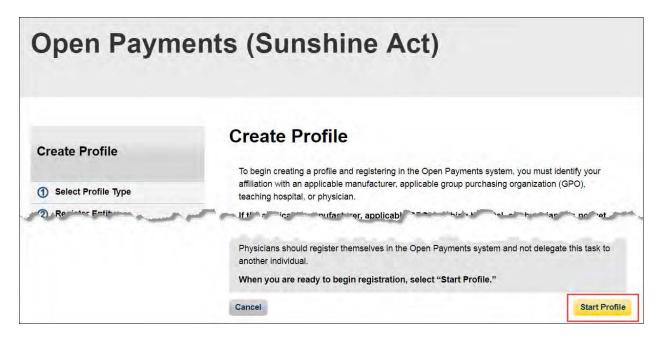
3.5g: Self-Nomination: Requesting a Role (Teaching Hospital - First Time System Users)

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.

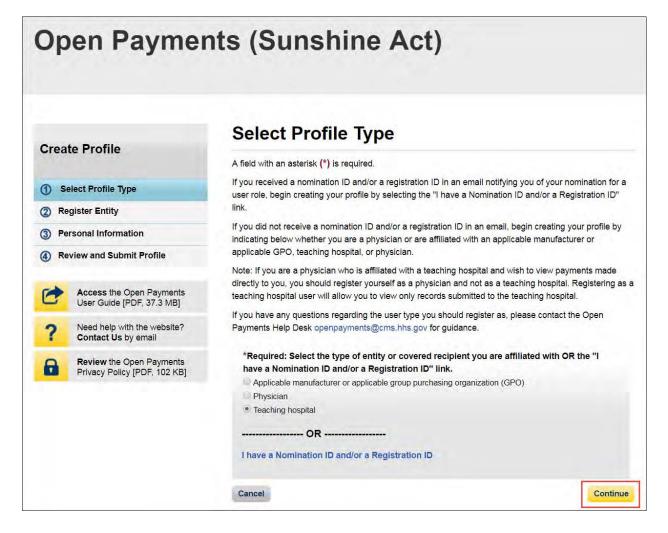
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are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



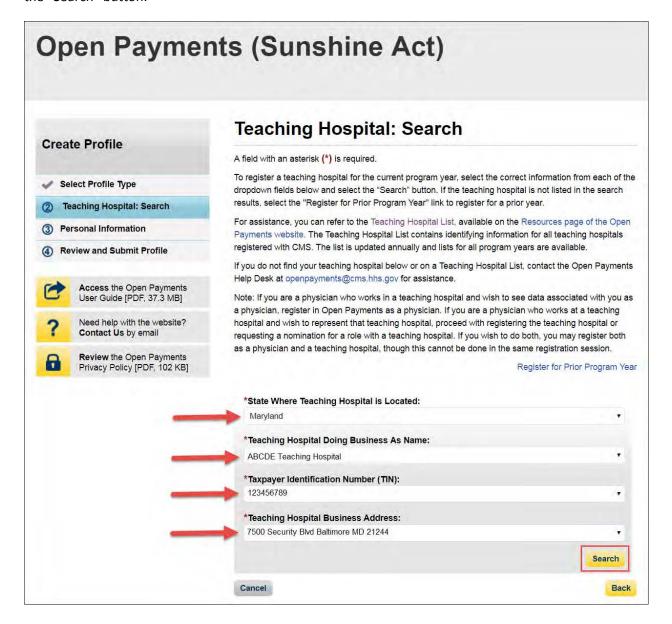
<u>Step 2:</u> The on-screen text contains important information regarding creating the physician and individual profiles. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start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



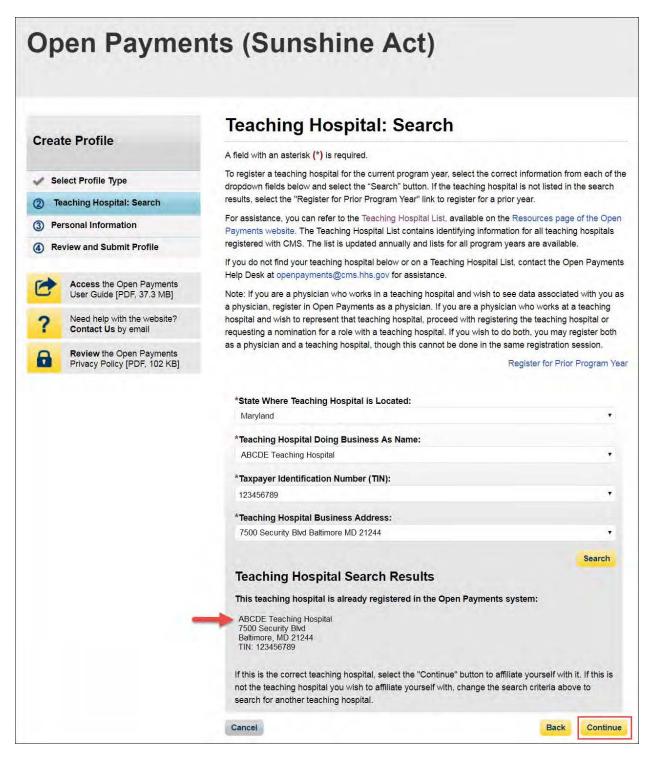
Step 3: Select the profile type "Teaching Hospital." When finished, select the "Continue" button.



<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 the "Search" button.



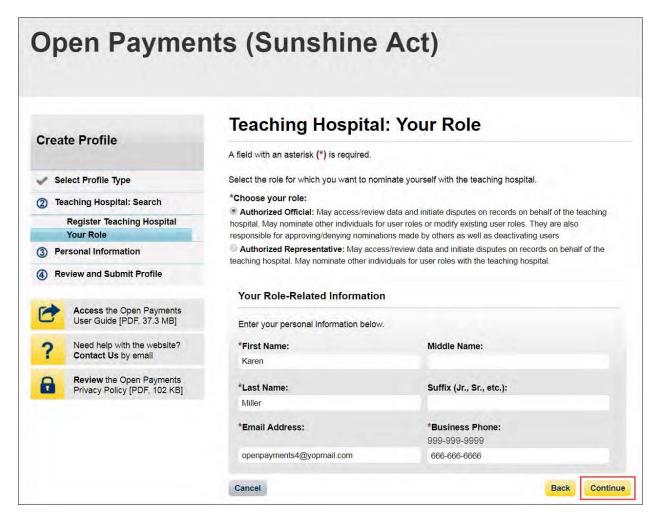
<u>Step 5:</u> Review the returned information displayed on the page. Select the "Continue" button if the information displayed is correct. If the information is not correct, select the "Back" button at the bottom of the page to return to the previous page and edit the search information you entered.



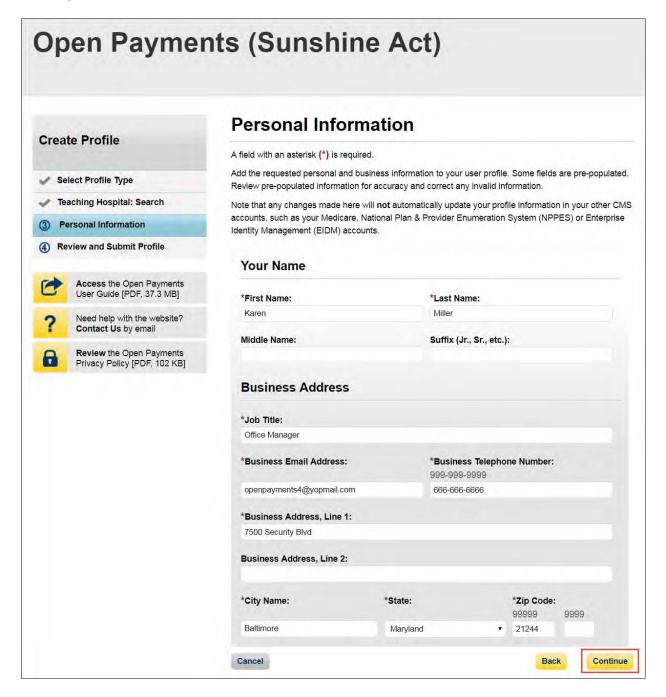
<u>Step 6:</u> Review the information displayed on the page. If the information is correct, select the "Continue" button. If the information is not correct, select the "Back" button at the bottom of the page to select a different teaching hospital.



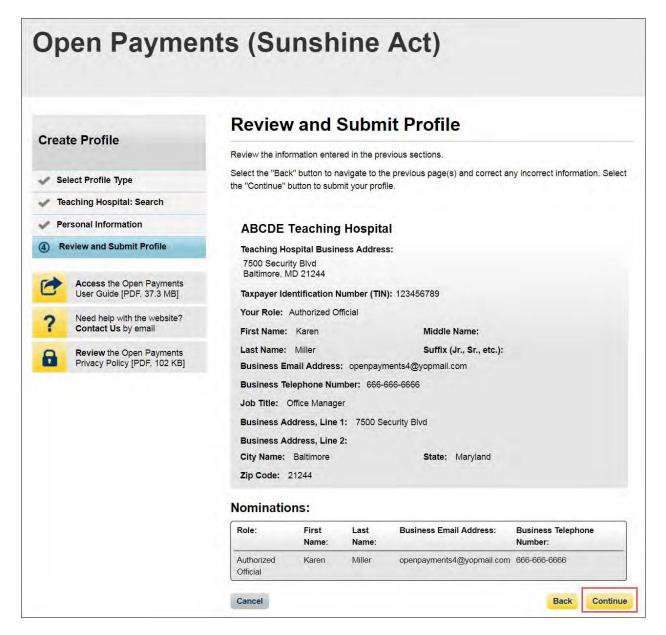
<u>Step 7:</u> Select the role you wish to nominate yourself for in the teaching hospital. Note that as you are not registering the teaching hospital, you may select either role. After you have chosen your role, enter in the role-related information in the data fields. Required fields are marked with an asterisk. Once you have entered in all of the information, select the "Continue" button.



<u>Step 8:</u> Review your information displayed on the page. Enter your job title and business address. When finished, select the "Continue" button.



<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 the "Continue" button.



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.



3.5h: 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.



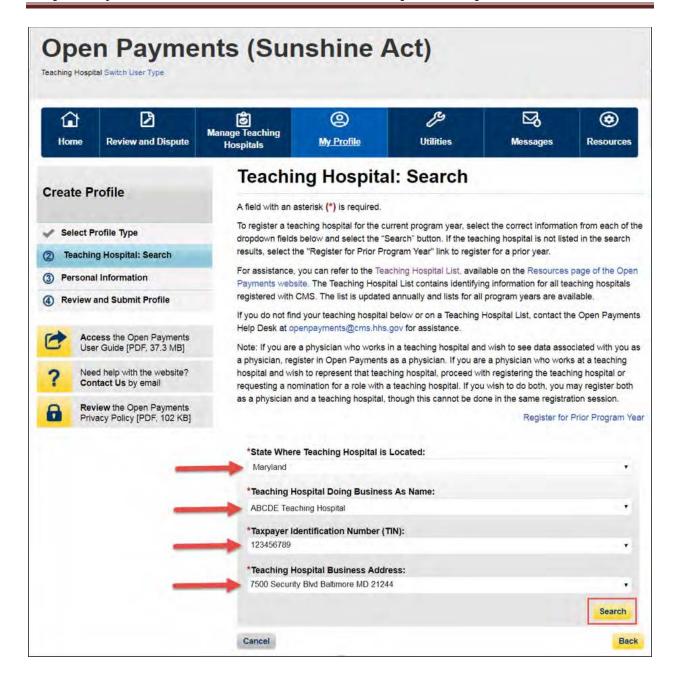
Step 2: Select the "My Roles and Nominations" tab.



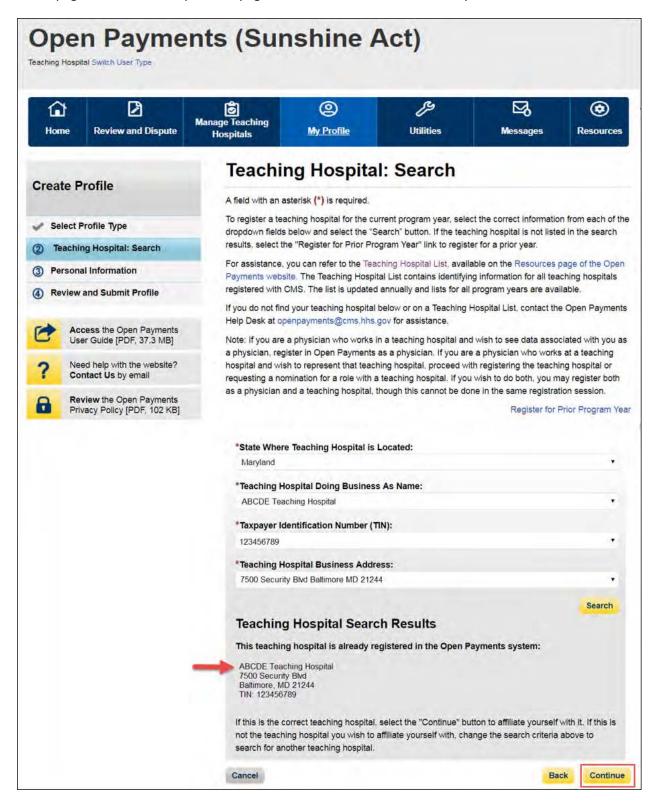
Step 3: From the "My Roles and Nominations" tab, select the "Request a Role" button.



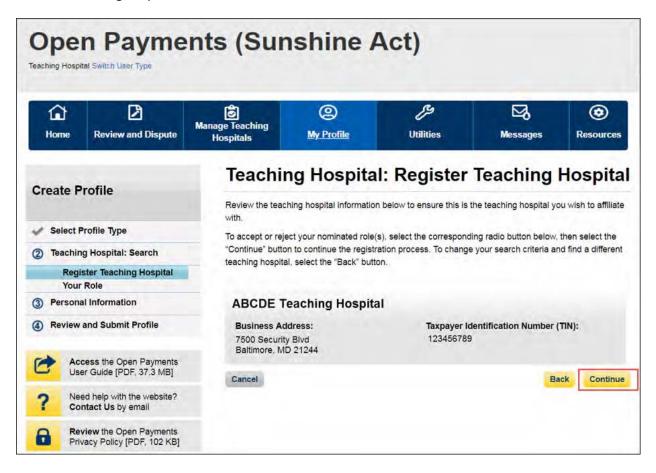
<u>Step 4:</u> Search the database for the correct teaching hospital. To do so, select the teaching hospital's state, name, business address, and Taxpayer Identification Number (TIN) from the drop-downs. When finished, select the "Search" button.



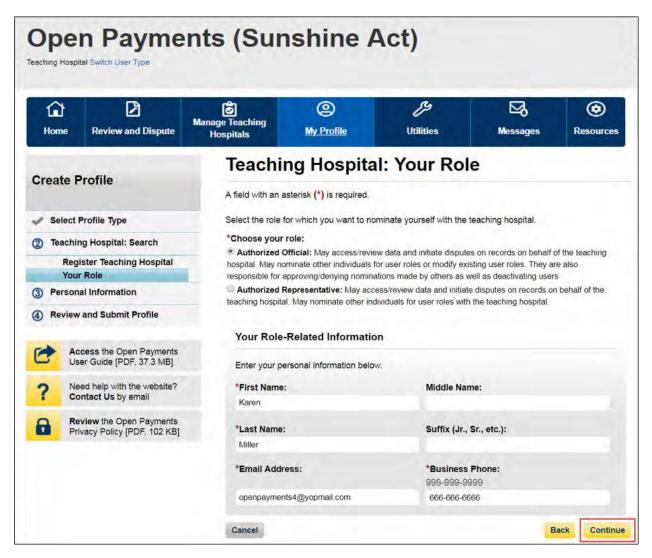
<u>Step 5:</u> Review the returned information displayed on the page. Select the "Continue" button if the information displayed is correct. If the information is not correct, select the "Back" button at the bottom of the page to return to the previous page and edit the search information you entered.



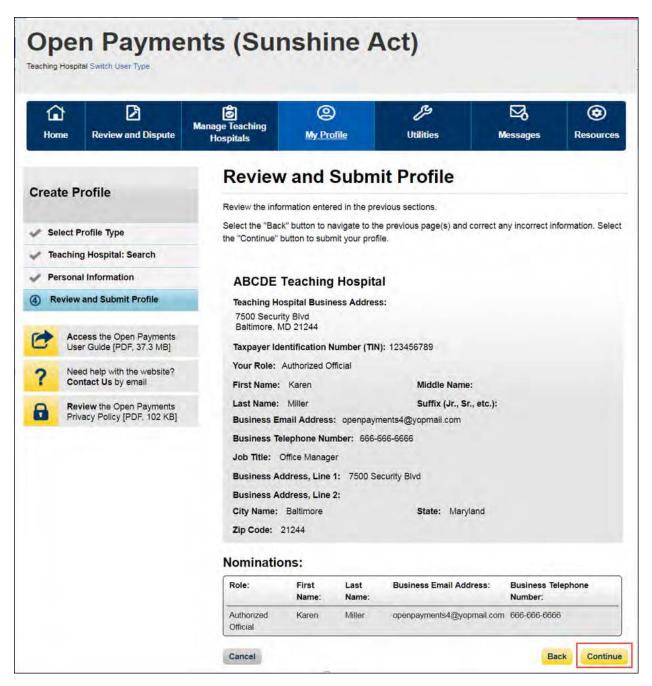
<u>Step 6:</u> Review the teaching hospital information. If the information is correct, select the "Continue" button. If the information is not correct, select the "Back" button at the bottom of the page to select a different teaching hospital.



<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 the "Continue" button.



<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 the "Continue" button.



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.

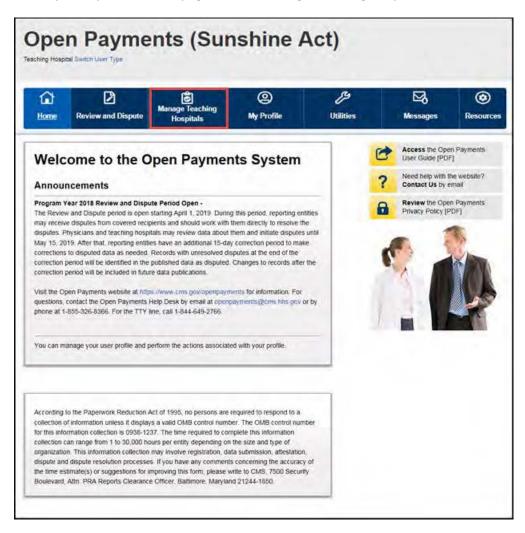
If you are nominating yourself for a role with a teaching hospital that has already been registered but which lacks an active authorized official to approve your self-nomination, please contact the Open Payments Help Desk at openpayments@cms.hhs.gov.



3.5i: 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."



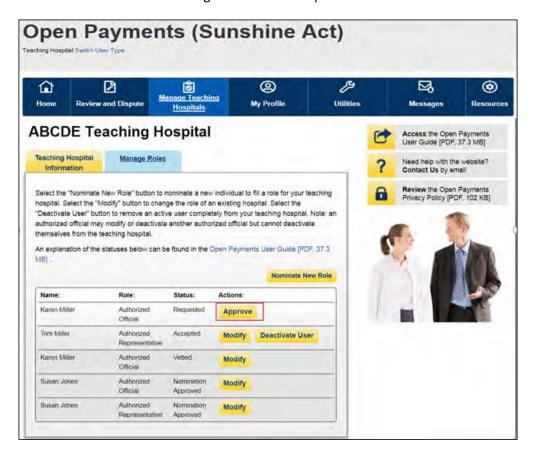
<u>Step 2:</u> On the "Manage Teaching Hospitals" page, select the teaching hospital for which you want to confirm a nomination.



Step 3: Select the "Manage Roles" tab.

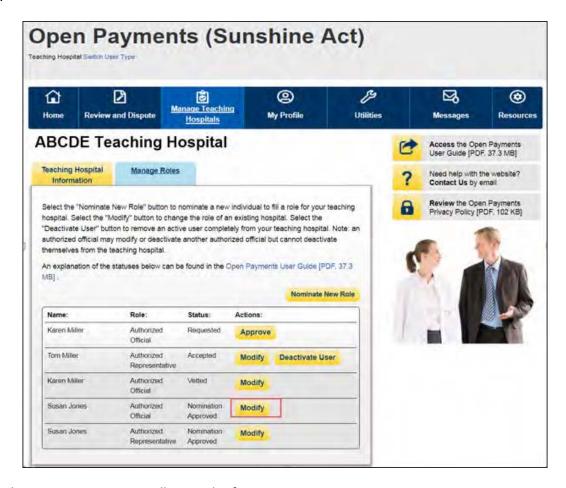


<u>Step 4:</u> To approve a nomination, select the "Approve" button next to a nominee's name. The nominee will receive an email notification informing them of the acceptance of their nomination.

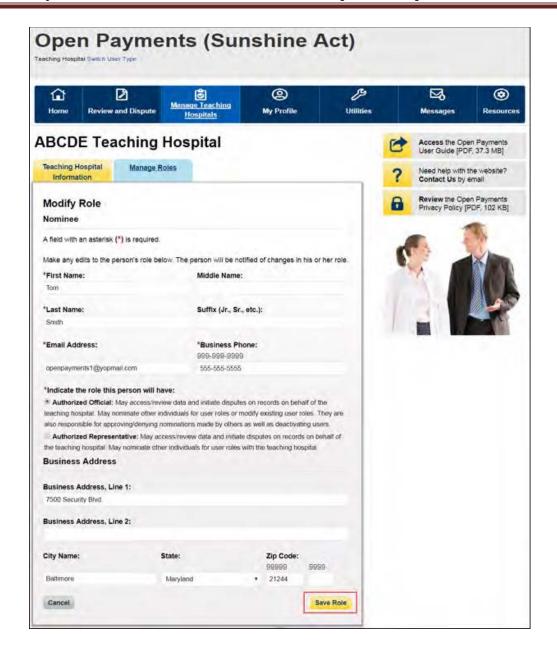


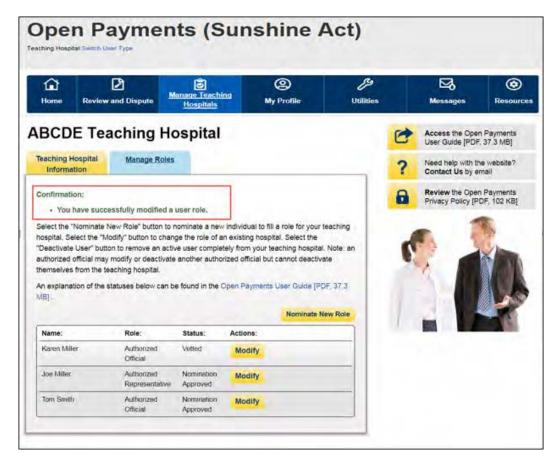


<u>Step 4a</u>: To modify a nomination, select the "Modify" button next to a nominee's name. This will allow you to change the individual's information and/or role. When modifications are complete, select "Save Role."



Note that you cannot remove all user roles from a nominee.





Step 5: You will now see an updated list of nominations on the "Manage Roles" tab.

3.5j: 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.

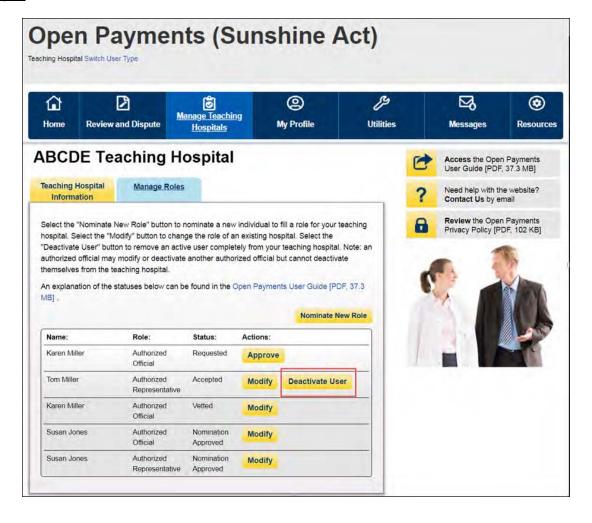
To deactivate an individual's user role, follow these steps.

<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.

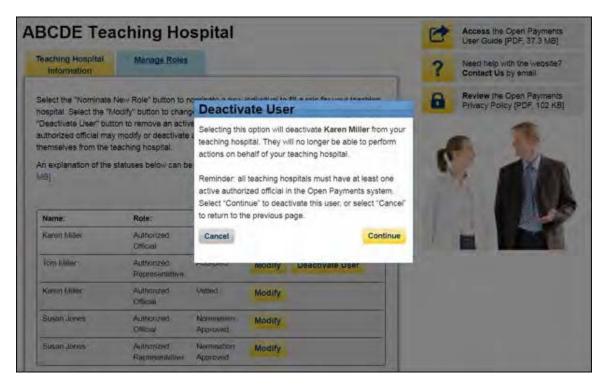
<u>Step 2:</u> You will see a list of all of the teaching hospitals you are associated with. Select the hyperlink for the teaching hospital for which you will be deactivating a user.

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 the "Continue" button to confirm deactivation or the "Cancel" button 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.



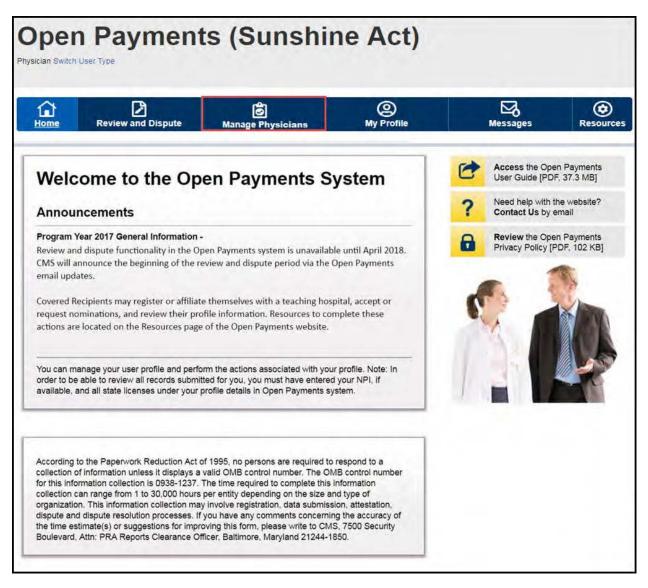
Section 3.6: Updating Profile Information in the Open Payments System

Physician and teaching hospital profiles can be kept current by updating them as information changes. The steps for profile updates are given below.

3.6a: Updating a Physician Profile as an Authorized Representative

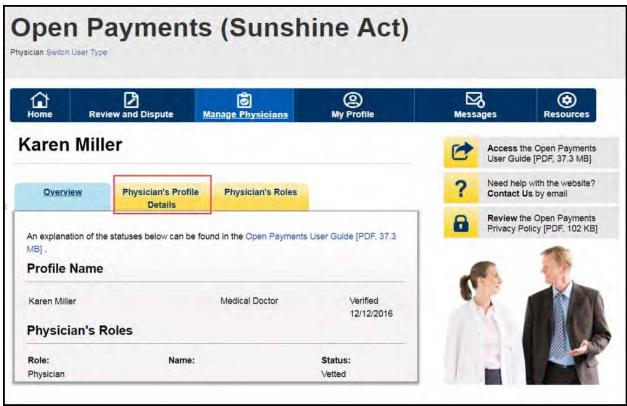
For a physician's authorized representative who holds the level of access of "Modify Profile" to edit their physician's profile, follow these steps.

<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.

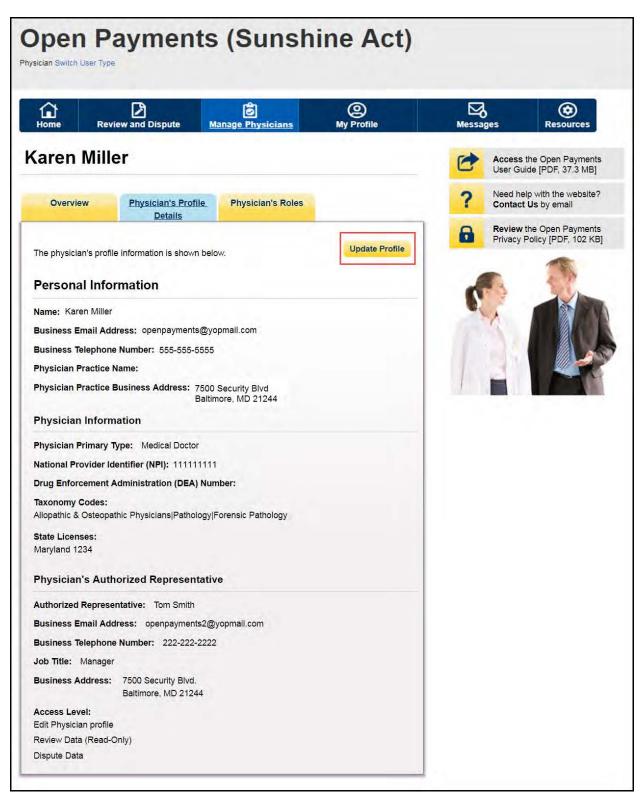


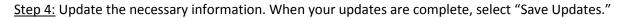
Step 2: Select the physician for which you wish to make updates on the "Manage Physicians" page.





<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.





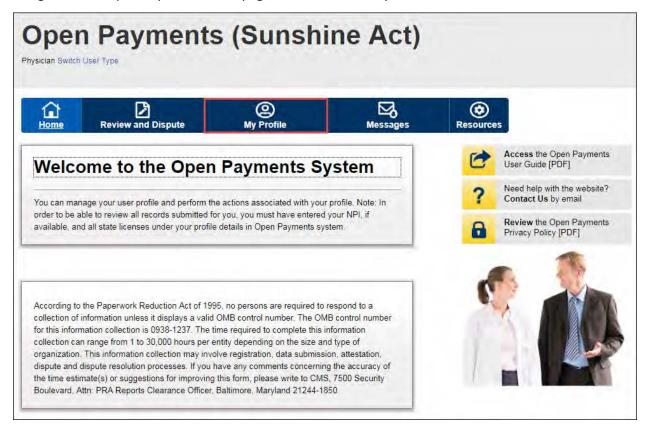


Note: Any updates made to the physicians profile will cause the physician to be re-vetted. Once the updated information has been re-vetted, both the physician and authorized official will be able to perform the necessary actions in the Open Payments system. See Section 3.3c for information on physician vetting.

3.6b: Updating Physician or Physician Authorized Representative Personal Profile

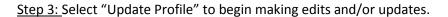
As a user of the Open Payments system, you have the ability to update your personal profile information. You will be able to update your name, business email address, business telephone number, job title, and business address. Steps for updating your profile are explained below.

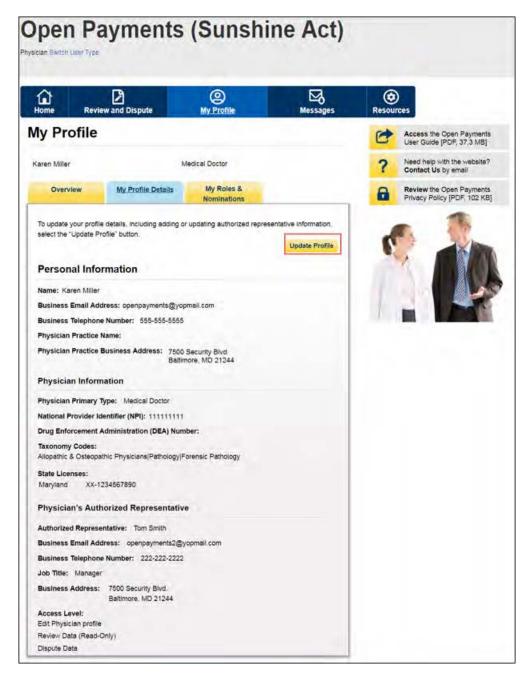
<u>Step 1:</u> Log in to the CMS Enterprise Portal at https://portal.cms.gov using your EIDM credentials, navigate to the Open Payments home page, and select the "My Profile" tab.



Step 2: Select the "My Profile Details" tab. You will be able to view your existing profile information.

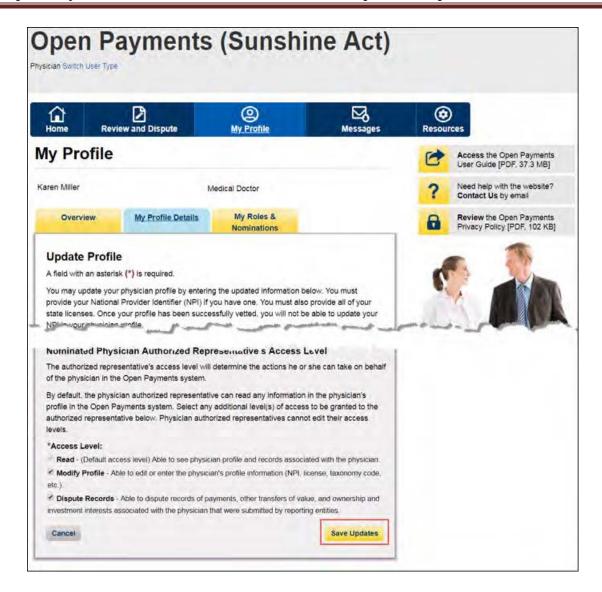






Step 4: Update fields as necessary. When changes are complete, select "Save Updates."

The updated information will now appear on the "My Profile Details" page.



Review and Dispute

Chapter 4: 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 and Dispute Process Overview** provides information on the review and dispute process within the Open Payments system.
- Reviewing Records provides information on how physicians, teaching hospitals, and physician
 principal investigators can review data submitted about them by applicable manufacturers and
 applicable GPOs.
- Affirming Records provides information on how physicians, teaching hospitals, and physician
 principal investigators can affirm data submitted about them by applicable manufacturers and
 applicable GPOs.
- Disputing Records provides information on how physicians, teaching hospitals, and physician
 principal investigators can initiate disputes against data submitted about them by applicable
 manufacturers and applicable GPOs.
- Withdrawing Disputes provides information on how physicians, teaching hospitals, and
 physician principal investigators can withdraw disputes they have initiated against data
 submitted about them by applicable manufacturers and applicable GPOs.

This chapter covers the review and dispute functions for physicians, teaching hospitals, and physician principal investigators.

Section 4.1: Review and Dispute Process Overview

Physicians, teaching hospitals, and physician principal investigators registered in the Open Payments system may review data reported about them by applicable manufacturers and applicable GPOs in the Open Payments system record(s) that were submitted during that calendar year's submission period. This includes records submitted for the previous program year and any records submitted late from prior program years.

During a review, the reviewer may perform two optional actions:

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- If the reviewing physician, teaching hospital user, or physician principal investigator agrees that a record is accurate, they can **affirm** the record. Note: Affirmation is not a required action. Records that have not been affirmed will still be included in the next data publication.
- If the reviewing physician, teaching hospital user, or physician principal investigator believes a record is in error, they can **initiate a dispute** against the record.

These actions can be performed on one record at a time.

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) rather than covered recipient 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.

To resolve a dispute, physicians, teaching hospitals, and physician principal investigators should work directly with reporting entities outside of the Open Payments system. **CMS will not mediate disputes between physicians, teaching hospitals, physician principal investigators, and reporting entities.**The outcome of the resolution will be recorded in the Open Payments system. Dispute resolutions can lead to changes to the submitted data or the dispute may be resolved without changes to the data. In addition, a dispute may be withdrawn by the individual who initiated it.

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.

Note: records that are flagged for a delay in publication by the reporting entity are eligible for review and dispute by physicians, teaching hospitals, and physician principal investigators.

4.1a: Review, Dispute, and Correction Period

Each program year has a scheduled review, dispute, and correction period. The period is 60 days long and divided into two sections.

The 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 from prior program years.

Immediately following the 45-day period is a 15-day correction period for reporting entities to make corrections to records and resolve any active disputes.

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 publication. 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. Refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at https://www.cms.gov/openpayments/About/Resources.html 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.

4.1b: 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 original record disputed under the "Deleted and In Progress Records" tab with status of "In Progress" and the user(s) that have disputes in "Initiated" or "Acknowledged" status will be notified via email that the record is being updated by the entity. Once the record has been re-attested, the record will be available under the "Available for Review and Dispute" tab again.

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 under the "Available for Review and Dispute" tab, the record will be available under the "Deleted and In Progress Records" tab. If the deletion of the record was in response to a dispute, any user(s) that have disputes in "Initiated" or "Acknowledged" status will be notified via email that the record has been deleted by the entity when the record is re-attested. The records that have been deleted will display under the "Deleted and In Progress Records" tab with a "Deleted" status. The newly identified physician, teaching hospital, or physician principal investigator will see the record during the next calendar year's review and dispute period under the "Available for Review and Dispute" tab.

If a reporting entity edits or deletes a disputed record, the Open Payments system will send an email notification to the individual(s) who initiated the dispute(s). If the dispute initiator is a physician's authorized representative, email notifications will be sent to both the authorized representative and the physician.

Refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at https://www.cms.gov/openpayments/About/Resources.html for details on how changes to records affect data publication.

4.1c: Review and Dispute Statuses

Records available for 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.

Records submitted during the submission period that calendar year may be unavailable for review and dispute for one of the following reasons:

- A deleted record can only be viewed under the "Deleted and In Progress Records" tab and cannot be disputed. For deleted records only the record information will display.
 Disputes associated to the record will not be available once the record has been deleted.
- A record undergoing editing by its reporting entity can only be viewed under the "Deleted and In Progress Records" tab and cannot be disputed. Records undergoing editing will display all the dispute statuses and dispute details (where available).

Section 4.2: Reviewing Records

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.

A step-by-step walkthrough for reviewing records follows.

<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. "Review and Dispute Overview" page is displayed.



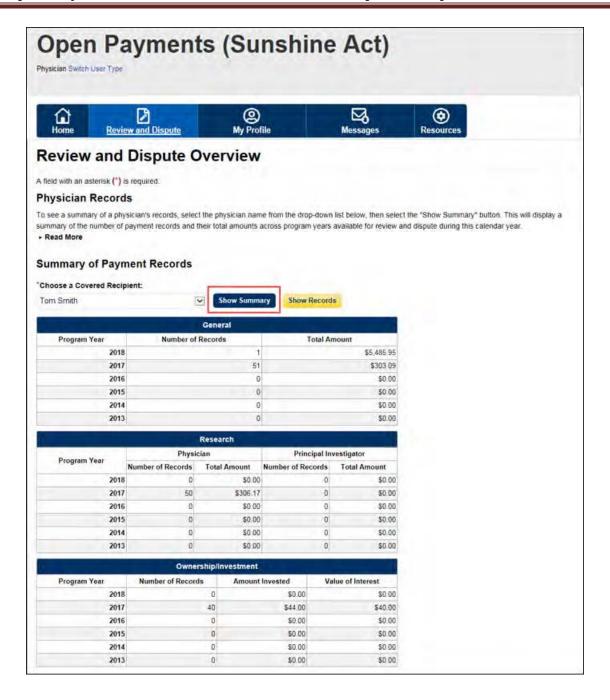
<u>Step 2</u>: On the "Review and Dispute Overview" page, some instructions will be visible. To display all of the instructions, select the "Read More" hyperlink.



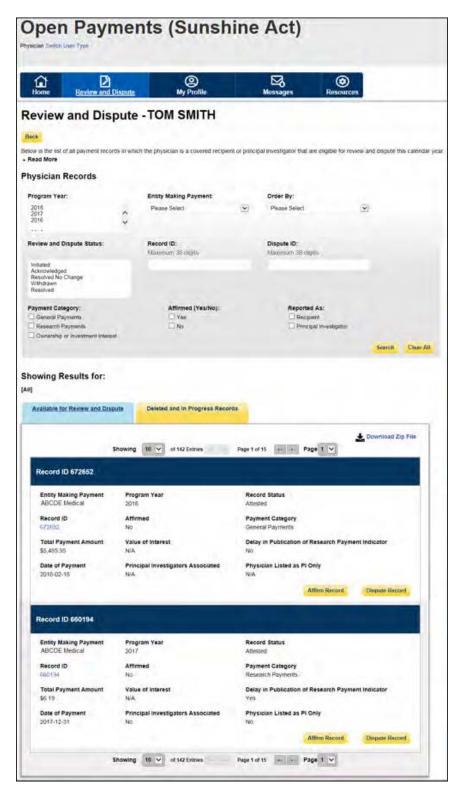
<u>Step 3</u>: Under the heading "Summary of Payment Records," select the covered recipient whose records are to be reviewed from the drop-down menu. To see the summary of payment records for the covered recipient chosen, select the "Show Summary" button. This will bring up the Summary of Payment Records.

The Summary of Payment Records displays the total number of records available for review and dispute for the selected covered recipient and the total dollar amount for those records. The totals are grouped by program year and payment category.

For physicians, the research payment category totals are split to differentiate between the records in which the physician is identified as the covered recipient and the records in which the physician is identified a principal investigator. Note that teaching hospital summaries do not include an Ownership/Investment section, as that payment category is not applicable to them.



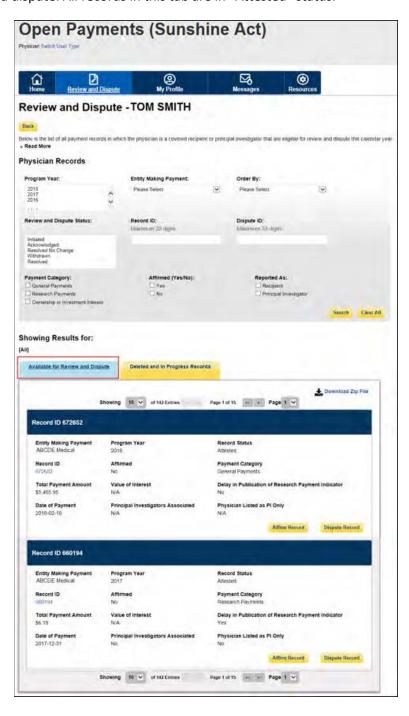
<u>Step 4:</u> Select the "Show Records" button to navigate to the "Review and Dispute" page for the covered recipient.



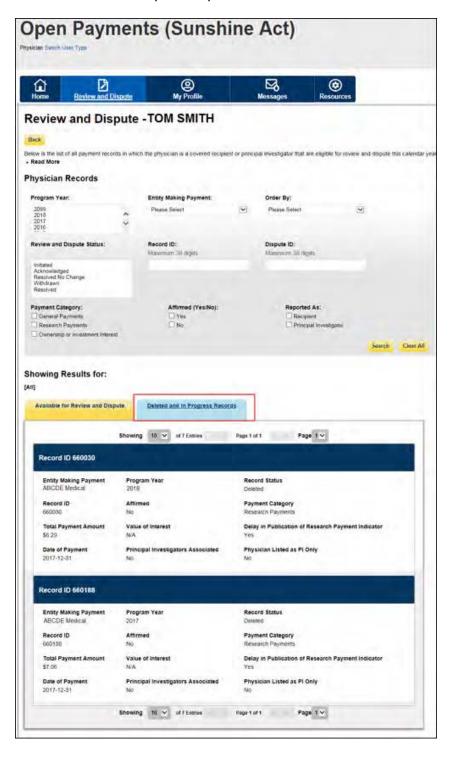
<u>Step 5</u>: The "Review and Dispute" page displays all available records for review. Users can use available filters on the page to narrow search results as desired.

There are two tabs that may contain information related to the disputes attributed to the covered recipient:

• Available for Review and Dispute: This tab displays all records that are currently available for review and dispute. All records in this tab are in "Attested" status.



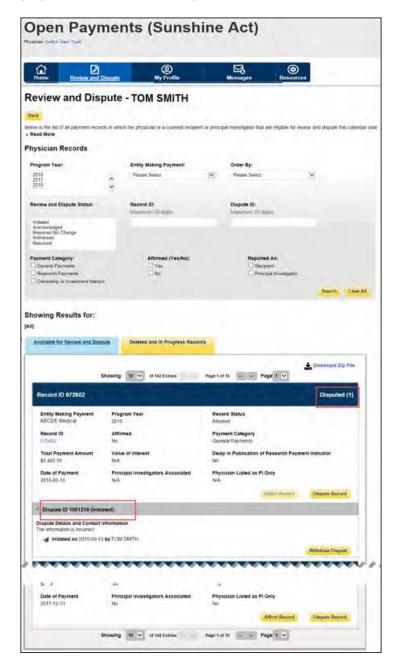
• **Deleted and In Progress Records**: This tab displays all records that were available for review and dispute in the current calendar year but were deleted or are in the process of being edited by the AM/GPOs and are not available for review. Note that review and dispute actions will not be allowed for these records as they can only be viewed.



<u>Step 6</u>: Records on the "Review and Dispute" page are displayed in a card format. To see all of a record's information, select the hyperlinked number under the "Record ID" heading. This will open up the "Record ID" page for that record, which contains the record's details, general information, and reporting entity contact information. The Record Details page also displays any "Active Disputes," if available.



<u>Step 7</u>: Available disputes are displayed as a child record within the payment record on the covered recipient "Review and Dispute" page. Select "Dispute ID" link to view all dispute(s) associated with the record. Each dispute is displayed in an accordion style listed in descending order of Dispute ID. The record header also displays the total number of disputes for the record.



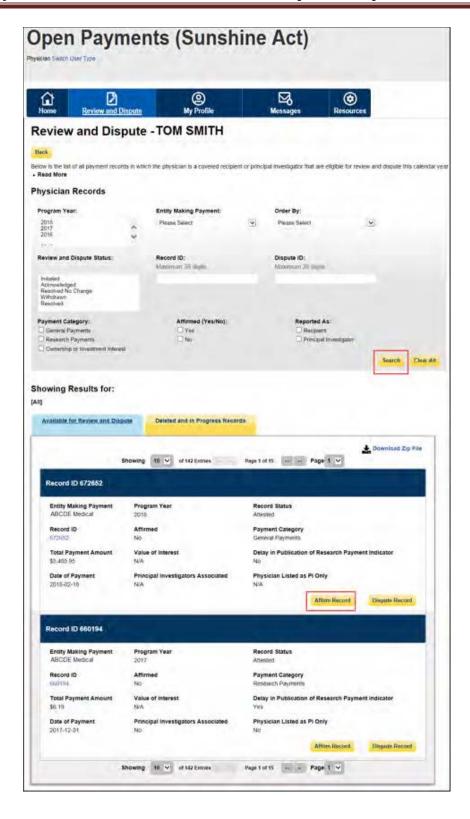
Section 4.3: Affirming Records

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.

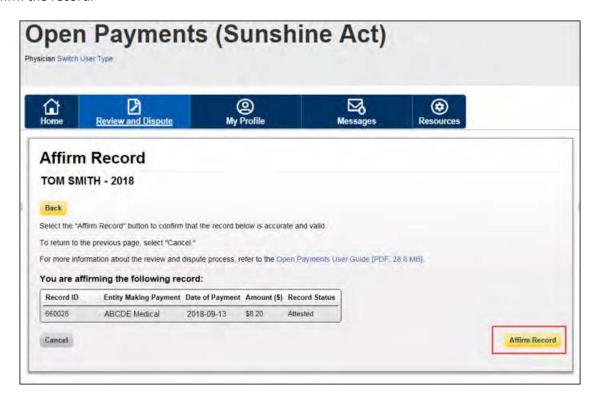
To affirm a record, follow the steps below.

<u>Step 1</u>: On the "Review and Dispute" page, use the filtering tools to help find the records to be affirmed, then select the "Search" button. All records available for affirmation will be under the "Available for Review and Dispute" tab.

Step 2: Select the "Affirm Record" button to open the "Affirm Record" page.

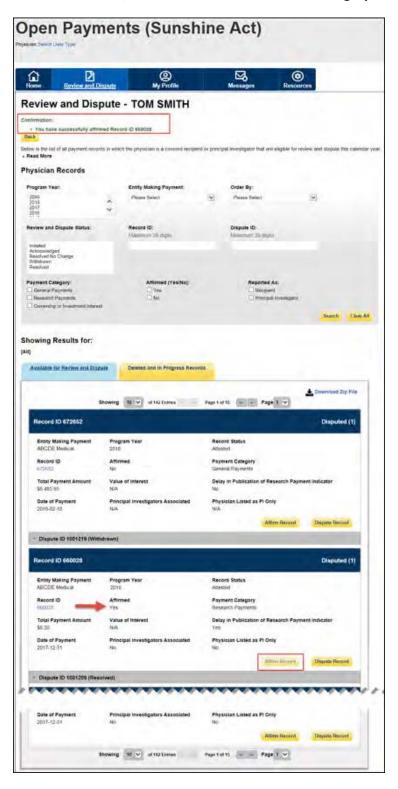


<u>Step 3</u>: Review the information displayed on the "Affirm Record" page. Select "Affirm Record" button to affirm the record.



Step 4: A confirmation message is displayed that the record has been successfully affirmed.

Note: Once a record has been affirmed, the "Affirm Record" button will be grayed out.



Section 4.4: Disputing Records

Records can only be disputed individually. To initiate a dispute on a record, follow the steps below.

<u>Step 1</u>: On the "Review and Dispute" page, use the filtering tools to help find the records to be disputed, then select the "Search" button. All records available for dispute will be under the "Available for Review and Dispute" tab.

Step 2: Select the "Dispute Record" button to dispute the record. This opens the "Dispute Record" page.

Note that when the user selects the "Dispute Record" button to initiate a dispute on a record which has an active dispute (Dispute Status is "Initiated" or "Acknowledged"), the system will display a pop-up window identifying that a dispute has already been initiated against the record with the following messages based on the scenarios explained below:

- The physician (not principal investigator), physician's Authorized Representative (AR) or
 Teaching Hospital's Authorized Representative (AR)/Authorized Official (AO) has ACTIVE
 (Dispute Status is "Initiated" or "Acknowledged") disputes against the record. The Record ID
 header displays "Disputed (# of disputes)" and the following pop-up message is issued when the
 user selects the "Dispute Record" button:
 - "The selected payment record has a dispute that is currently in progress.
 Select Yes to continue with your dispute request.
 Select No to cancel your dispute request."
- The physician is a principal investigator or AR for a physician listed as principal investigator, and has NO ACTIVE disputes against the record. The Record ID header only displays the Record ID and the following pop-up message is issued when the user selects the "Dispute Record" button:
 - "The selected payment record has the physician listed as a principal investigator. A principal investigator is not considered a recipient of a payment but rather is considered associated with the payment. As a result, the dispute can be initiated for the physician's association with the selected research payment(s) but not the date, amount, or other values it contains.
 - Select Yes to continue with your dispute request. Select No to cancel your dispute request."
- The physician is a principal investigator or AR for a physician listed as a principal investigator, and has disputes in status other than "Initiated" or "Acknowledged" against that record. The Record ID header displays "Disputed (# of disputes)" and the following pop-up message is issued when the user selects the "Dispute Record" button:
 - "The selected payment record has the physician listed as a principal investigator. A principal investigator is not considered a recipient of a payment but rather is considered associated with the payment. As a result, the dispute can be initiated for the physician's association with the selected research payment(s) but not the date, amount, or other values it contains.

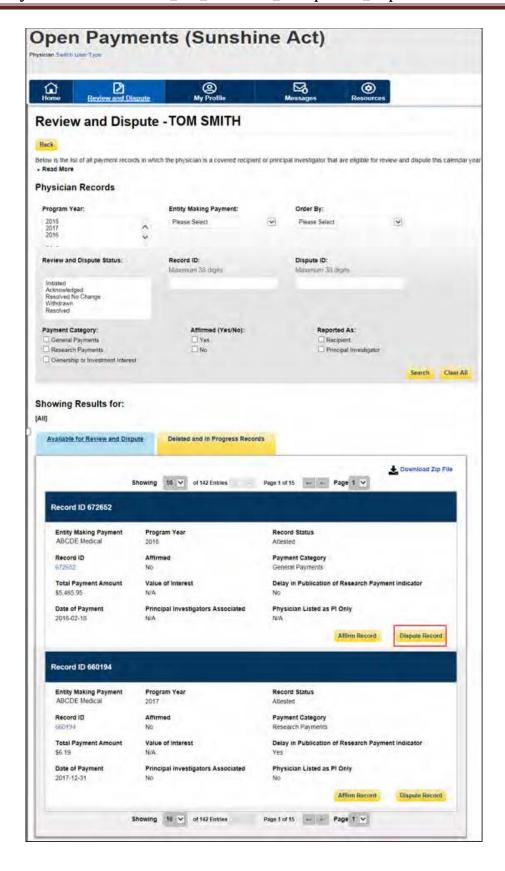
Select Yes to continue with your dispute request. Select No to cancel your dispute request."

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- The physician is a principal investigator or AR for a physician listed as a principal investigator, and has ACTIVE ("Initiated" or "Acknowledged") disputes against the record. The Record ID header displays "Disputed (# of disputes)" and the following pop-up message is issued when the user selects the "Dispute Record" button:
 - o "The selected payment record has a dispute that is currently in progress. Note that the physician is listed as a principal investigator in this record. As a result, the dispute can be initiated for the physician's association with the selected research payment(s) but not the date, amount, or other values it contains.

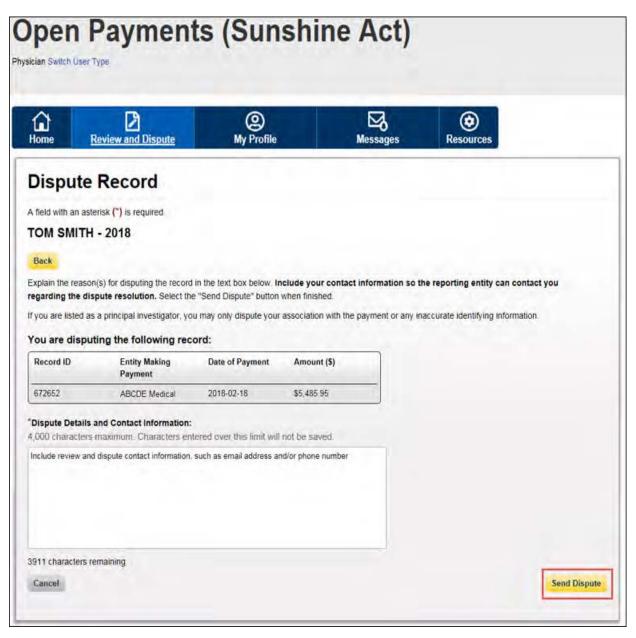
Select Yes to continue with your dispute request.

Select No to cancel your dispute request."

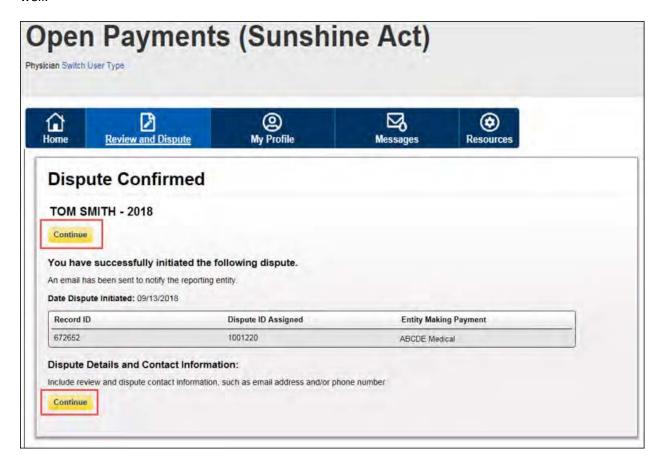


<u>Step 3</u>: Review the information on the "Dispute Record" page. Enter a detailed reason for why the dispute has been initiated in the "Dispute Details and Contact Information" text box before continuing. The text box can contain up to 4,000 characters, including spaces, and allows all special characters on a standard U.S. keyboard (not including ALT+NUMPAD ASCII Key characters). It is recommended that the "Dispute Details and Contact Information" text includes review and dispute contact information, such as an email address and/or phone number, within the text box, to facilitate the resolution of the dispute in a timely manner.

Once the dispute is ready, select the "Send Dispute" button. The Open Payments system will send an email to the reporting entity to notify, that a dispute has been initiated. The email will include the contents of the "Dispute Details and Contact Information" text box.



<u>Step 4</u>: The "Dispute Confirmed" page displays a confirmation message that the dispute has been successfully initiated for that record. The initiator of the dispute will receive an email notification as well.



The covered recipient who initiated the dispute will receive an email notification from the Open Payments system if the reporting entity takes any action on the record. Also, the covered recipient can see any records that are undergoing editing by the entity under the "Deleted and In Progress Records" tab. Records under the "Deleted and In Progress Records" tab will be in either "In Progress" or "Deleted" statuses. The records "In Progress" will display under the "Available for Review and Dispute" tab once the entity has re-attested to them.

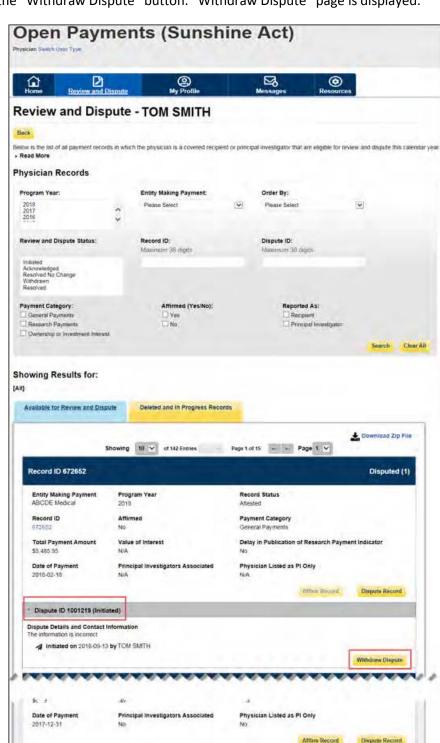
Section 4.5: Withdrawing Disputes

To withdraw a dispute on a record, follow these steps.

<u>Step 1</u>: On the "Review and Dispute" page, use the filtering tools to help find the records to be withdrawn, then select the "Search" button. All records available for withdrawing will be under the "Available for Review and Dispute" tab.

Note: Only records in "Initiated" and/or "Acknowledged" statuses will be available to withdraw.

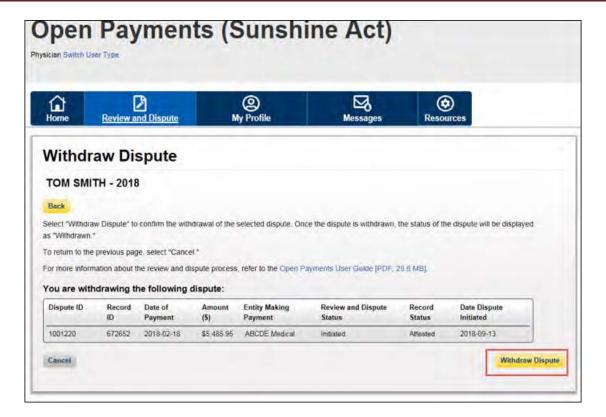
Step 2: Select the "Dispute ID" link to view dispute details.



Step 3: Select the "Withdraw Dispute" button. "Withdraw Dispute" page is displayed.

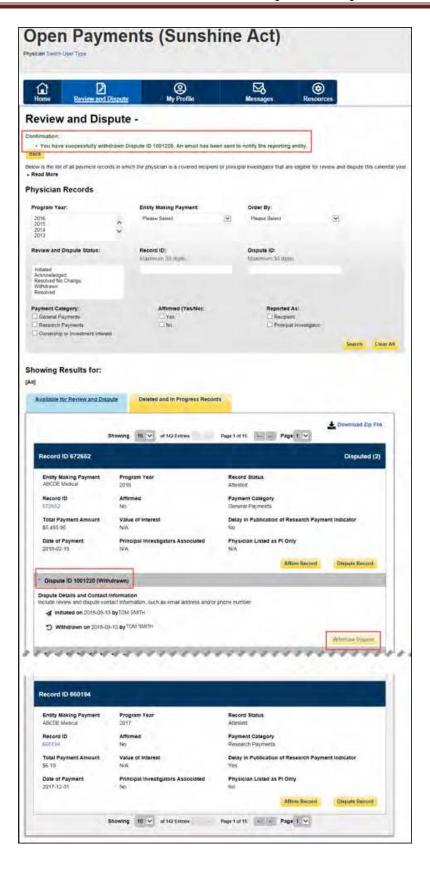
<u>Step 4</u>: Review the information on the "Withdraw Dispute" page and select the "Withdraw Dispute" button.

Showing 10 v of 142 Entries Page 1 of 15 - Page 1 v



Step 5: A confirmation message is displayed that the dispute has been successfully withdrawn.

Note: Once a dispute has been withdrawn, the "Withdraw Dispute" button will be unavailable for selection.



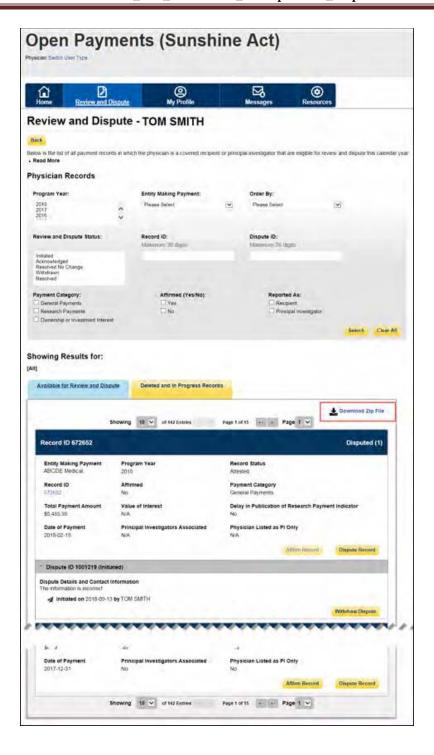
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Section 4.6: Exporting Data

Users can download records associated with them by selecting the "Download Zip File" link on the "Available for Review and Dispute tab of the "Review and Dispute" page.

Records are exported into a pipe ("|") delimited CSV format, compressed into a ZIP file. It will contain all data fields displayed in the table and other data elements related to the dispute, including the status of each record's dispute(s), if applicable.

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.



Chapter 5: Messages and Utilities

This chapter on Messages and Utilities provides detailed information on how to navigate and use the Message and Utilities Tabs.

This chapter is divided into the following sections:

- **Messages Tab** contains information how to search for system generated email messages received by the covered recipient physician or teaching hospital in the past 12 months.
- **Utilities Tab** contains information on how teaching hospitals can use utilities to look up information in the Open Payments system.

Section 5.1: Messages

As a Covered Recipient user, you have the ability to view system generated messages sent to you within the past 12 months.

A system generated email is an email generated by the Open Payments System in response to any action performed in the Open Payments system. For example, during the registration process, once a physician registers on the CMS Open Payments system, an email is sent out to the physician confirming registration. This is a system generated email that is able to be viewed on the "Messages" tab.

The "Messages" tab is accessible from the CMS Open Payments home screen banner on the CMS Open Payments home page. Once you are redirected to the "Messages" tab from the CMS Open Payments home page, you can view the following searchable fields: (1) Teaching Hospital or Physician Name, (2) Record ID, (3) Payment Category, and (4) Message Category. All of these fields are optional to refine your search.

5.1a: Instructions for searching messages

Step <u>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 "Messages" tab.



Step 2: You will be brought to the "Messages" page.

Step 3: You can search results based on the following search criteria:

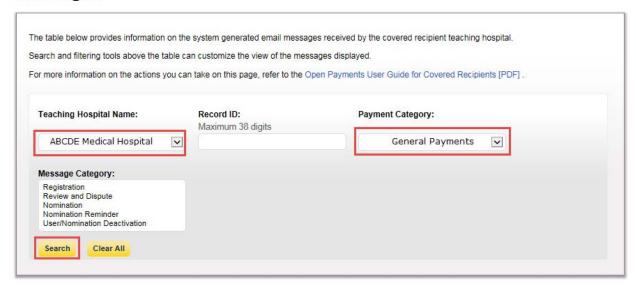
- Teaching Hospital or Physician Name
- Record ID (only applicable for Message Category of "Review and Dispute")
- Message Category
- Payment Category (only applicable for Message Category of "Review and Dispute")

Note: Selecting the "Clear All" button will remove all filter selection.

<u>Step 4:</u> Select the "Search" button to initiate the search. After selecting the "Search" button, a data table with the list of messages will display. This list of messages is sorted by newest to oldest. You will see an expandable row section that displays more details about all messages.



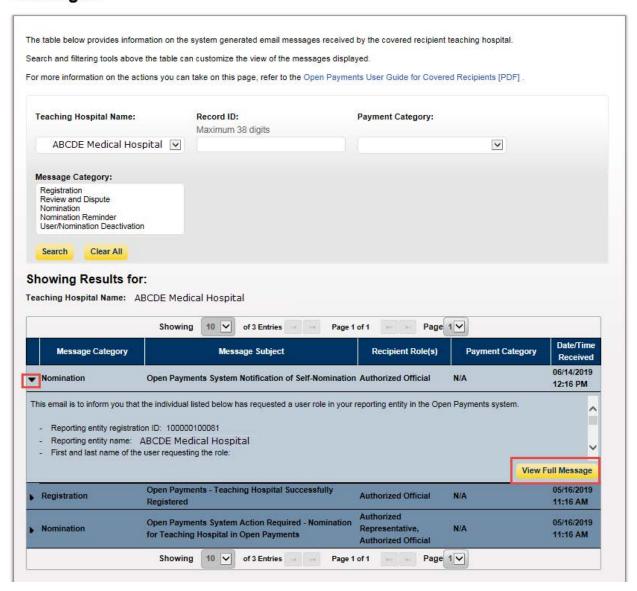
Messages



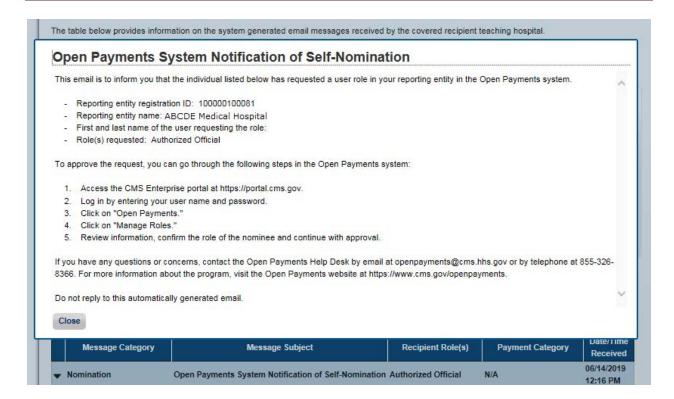
<u>Step 5:</u> Select the expandable arrow next to the message you wish to view. You will see an expandable view of the data pertaining to the message. You will also see a "View Full Message" button to view the full text of the message.



Messages



<u>Step 6:</u> Select the "View Full Message" to view the text of the message. You will see a pop-up window that displays the text.

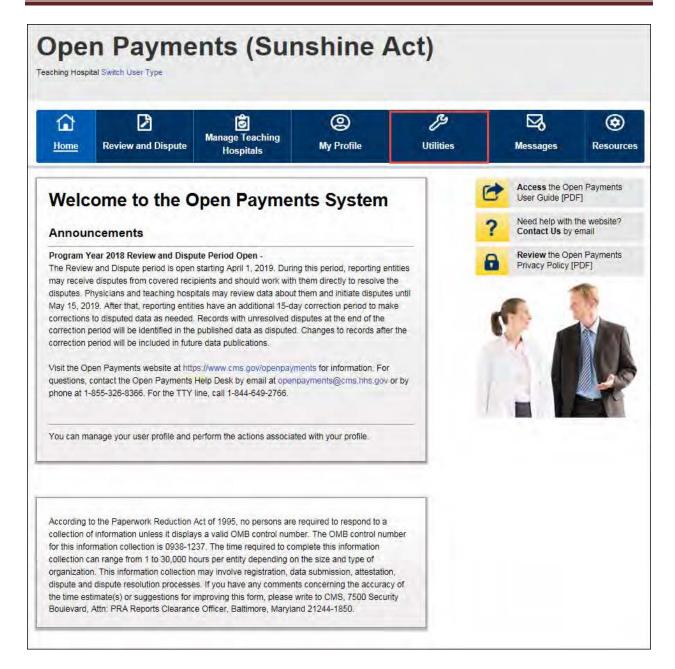


Section 5.2: Utilities

Teaching Hospital users have the ability to look up Physician's Open Payments Profile IDs that correspond to the National Provider Identifier for that physician.

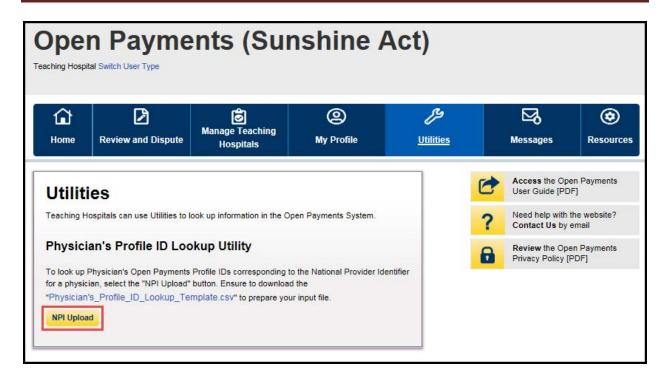
5.2a: Instructions for Teaching Hospital Utility

Step <u>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 "Utilities" tab.



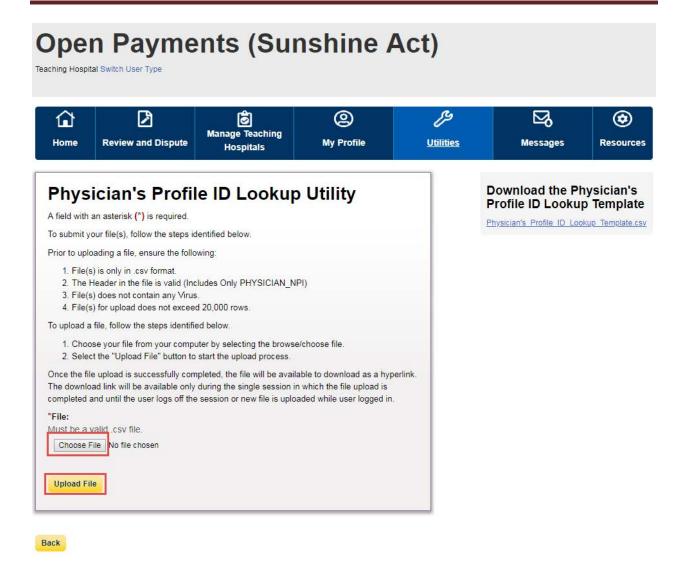
Step 2: You will be brought to the "Utilities" page.

<u>Step 3:</u> On the Utilities page, download and fill out the "Physician's_Profile_ID_Lookup_Template.csv" via the link on the page to prepare your input file, into a pipe ("|") delimited CSV. The file cannot exceed the acceptable limit of 20,000 rows. The Header in the file has to be valid (includes only PHYSICIAN_NPI) and the file should be virus free. Then select the "NPI Upload" button to navigate to the next page.

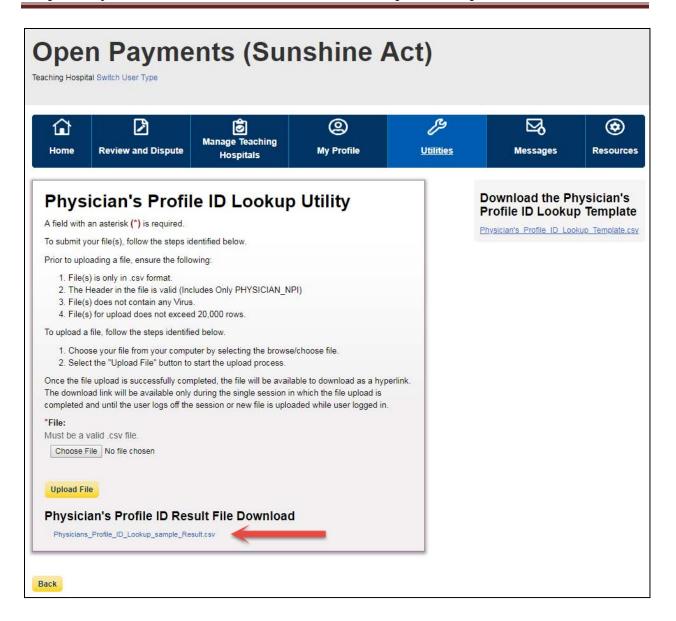


Step 4: Select the "Choose File" button to select the completed input file.

Step 5: Select the "Upload File" button.



<u>Step 6:</u> You will see the results section that displays a downloadable link to the results at the bottom of the page. Select the results link to view more information about physician's profile ID. The result link is available until you upload another file or log out of the Open Payments system.



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
I	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	A
Â	A
Ã	A
Ä	A
Å	A
È	E
É	E
Ê	E
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.