User Guide for Reporting Entities

O P E N   P A Y M E N T S

C R E A T I N G   P U B L I C   T R A N S P A R E N C Y
I N T O   I N D U S T R Y - P H Y S I C I A N
F I N A N C I A L   R E L A T I O N S H I P S

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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 applicable manufacturers and applicable group purchasing organizations (AM/GPOs), collectively referred to as "reporting entities", better understand how to comply with Open Payments (the Sunshine Act), including how to operationalize the collecting and reporting of data.

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

- **Introduction to Open Payments**

- **Introduction to Reporting and Data Collection**

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

- **Data Submission and Attestation**

- **Review, Dispute and Correction**

- **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12.0	June 2017	Update	Updated publication chapter, removed outdated information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
18.0	January 2020	Update	Updated to reflect system updates
19.0	September 2020	Update	Updated to reflect system updates

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

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

Section 1.1: Program Overview

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

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

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

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

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

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

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

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

Applicable manufacturers of covered products, and entities under common ownership with applicable manufacturers who also provide assistance and support, are required to annually report to CMS:

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

- Certain ownership or investment interests held by 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.

  o 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.

  o The republication of eligible records from prior program years, including updates to previously published records made since the previous publication.

  o 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.

  o The second publication of eligible records submitted and attested on or before the submission closing date of the latest program year.

  o 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, also referred to as the "data refresh" 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.

The table below outlines the annual Open Payments Program Timeline.

Table 1: Open Payments Program Year Timeline

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 by 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:

Step 1:
Determine if the entity operates in the United States (including any territory, possession, or commonwealth of the United States). See the reference guide in **Figure 2.**

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

Step 3:
Determine if the entity's products are covered drugs, devices, biologicals, or medical supplies, or covered products. See the reference guide in **Figure 2.**

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

Step 6:   Determine if the entity engages in <u>activities</u> of an applicable GPO. See the reference guide in **Figure 3.**

Step 7:   Determine if the entity's products are covered drugs, devices, biologicals, or medical supplies, or <u>covered products.</u> See the reference guide in **Figure 3.**

Step 8:   If the entity possesses the characteristics illustrated in **Figure 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 3,** the entity is not determined to be an applicable GPO in Open Payments.

Figure 1 provides a reference guide for determining if a drug, device, biological, or medical supply manufacturer is an applicable manufacturer in accordance with Open Payments. **Figure 2** also outlines the characteristics for two types of applicable manufacturers.

Figure 1: Determining if an Entity Is an Applicable Manufacturer

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

Figure 2 provides a reference guide for determining if a drug, device, biological, or medical supply purchasing entity is an applicable GPO in accordance with Open Payments. **Figure 2** also outlines the characteristics of applicable GPOs.

Figure 2: Determining if an Entity Is an Applicable GPO

Characteristic	Group Purchasing Organization IF
Operate in US?	• Entity's physical location is within the United States and/or it conducts activities within the United States. This includes any territory, possession, or commonwealth of the United States.
Activities	• Purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.
Covered products	• Reimbursed by Medicare, Medicaid, or Children's Health Insurance Program AND • If the product is a drug or biological, it requires a prescription (or doctor's authorization) to administer OR • If the product is a device or medical supply, it requires pre-market approval or pre-market notification by the FDA.

Section 1.3: Who Are Entities Reporting On

Applicable manufacturers and applicable GPOs are required to report payments or other transfers of value to covered recipients and physician owners/investors. Covered recipients in Open Payments include physicians (except for physicians who are bona fide employees of the reporting entity) and teaching hospitals. For the purposes of Open Payments, physicians are defined as 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, stepchild, stepbrother, or stepsister; (4) father, mother, daughter, son, brother, or sister-in-law; (5) grandparent or grandchild; or the (6) spouse of a grandparent or grandchild.
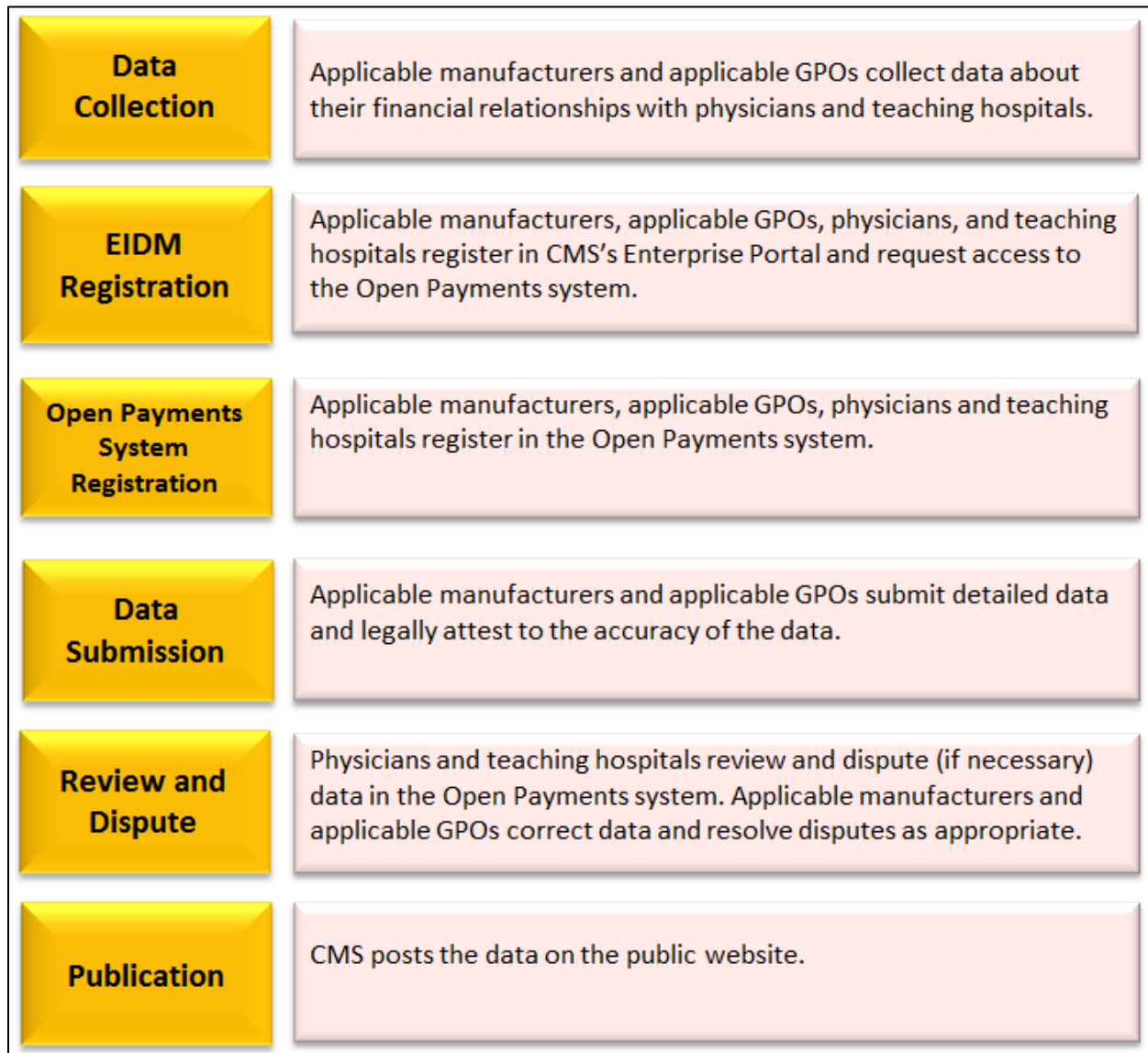
Section 1.4: Open Payments System Overview

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 3** provides a high-level process flow.

Figure 3: High-Level Process Flow for Open Payments

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

1.4a: Open Payments Browser Requirements

The Open Payments system is a web-based application and should be run only on Internet Explorer (version 8 or higher) 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 openpaymentsnnotifications@cms.hhs.gov.

1.4d: Accessibility Guidance

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

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

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

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

1.4d (2): Useful JAWS Keystrokes

The keystrokes given in **Figure 4** 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 4: Useful JAWS Keystrokes

Key	What it finds	Why this is useful
F	Form field	The F key allows users to move from form field to form field. The majority of pages in the Open Payments website are made of forms. The F key allows JAWS users to determine what fields are on the Open Payments form pages quickly.

Key	What it finds	Why this is useful
H	Heading	The H key allows users to move from heading to heading. Headings define the structure of many pages. Moving between sections of an Open Payments page allows for a quick guide to page structure and a way to access sections easily.

Section 1.5: Additional Information and Resources

CMS supports Open Payments system users through a number of different methods. These include webinars, Frequently Asked Questions (FAQs), step-by-step quick reference guides (QRGs), and technical support provided by the Open Payments Help Desk.

1.5a: Open Payments Website

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

1.5b: Open Payments Resources

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

1.5c: Open Payments Help Desk
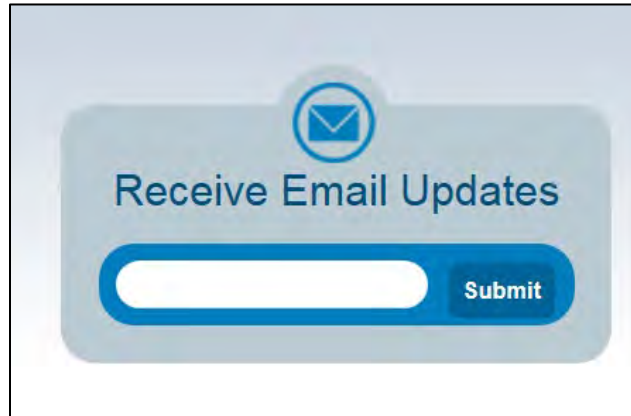
The Open Payments Help Desk serves as the single point of contact for all Open Payments-related inquiries. The Help Desk offers guidance on Open Payments, actions users can take in the system, and technical support. You can submit inquiries to openpayments@cms.hhs.gov or call 1-855-326-8366. **For the 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.
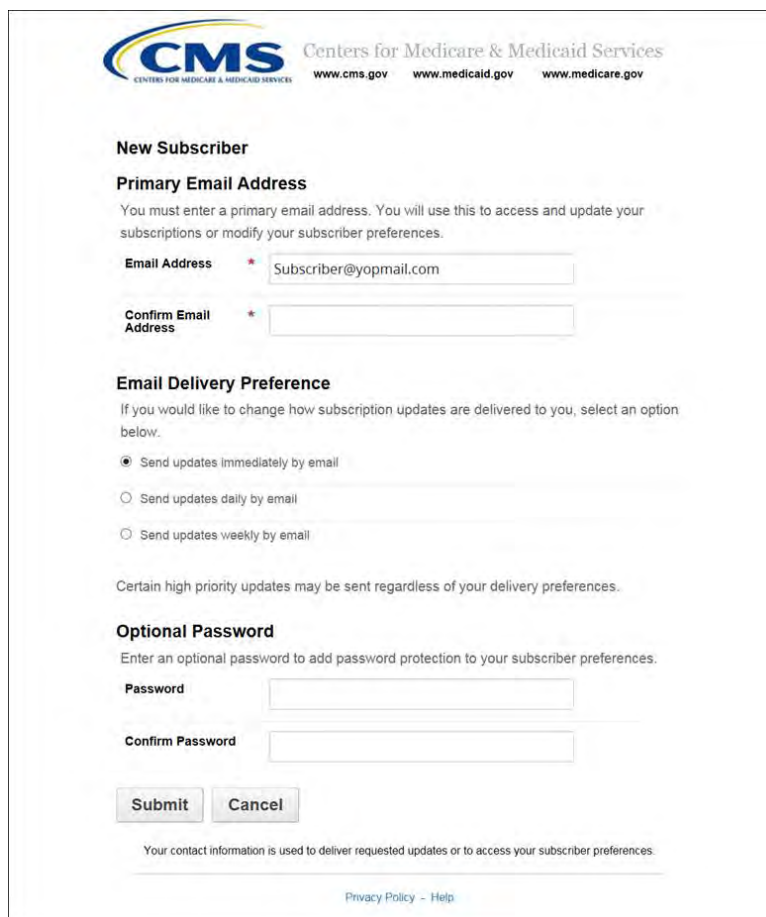
Figure 5: Receive Email Updates

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

Figure 6: New Subscriber screen on the CMS website

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.

Figure 7: Checkboxes for selecting email updates on Quick Subscribe screen

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 2016-2020. Both are available on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html. These documents provide specific, detailed descriptions of the information that must be collected by reporting entities to document general, research, and physician ownership/investment interest payments.

Section 2.1: General Payments Reporting and Data Collection

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

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

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

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

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

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

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

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

Figure 8: Open Payments system "Resources" tab for submitters displaying available reporting templates

Due to changes in record formats, there are two general payments sample file for Program Years (PY) 2013-2015, and PY 2016 -2020.

Section 2.2: Research Payments Reporting and Data Collection

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

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

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

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

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

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

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

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

Due to changes in record formats, there are two research payments sample files, one for PY 2013-2015 and, one forPY 2016-2020.

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

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

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

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

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

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

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

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

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

Registration

Chapter 3: Applicable Manufacturer and Applicable GPO Registration

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

This chapter is divided into the following sections:

- **Two-Step Registration Process Overview,** which provides information about the registration process. Registration includes user registration in EIDM via the CMS Enterprise Portal, as well as registration in the Open Payments system.

- **EIDM Registration**, which provides details on registering for EIDM and requesting access to the Open Payments system.

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

- **Registering Applicable Manufacturers and Applicable GPOs for the Open Payments System**, which contains instructions for registering, logging in to the system, and managing the applicable manufacturer or applicable GPO registration and user roles.

- **Entity Recertification**, which contains instructions for recertifying reporting entity information in the Open Payments system for entities that registered for the prior calendar year.

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

Section 3.1: Two-Step Registration Process Overview

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

Prior to registration in the Open Payments system, you must successfully register in EIDM to obtain log in credentials. Once you have registered in EIDM, you are able to register in the Open Payments system.

Open Payments registration is completed in two steps, illustrated in Figure 10. First, users must obtain EIDM credentials and request access to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov. Second, you must register your reporting entity in the Open Payments system. If your reporting entity is already registered, you can register as an individual and affiliate with the reporting entity.

Figure 9: Applicable Manufacturer and Applicable GPO Registration
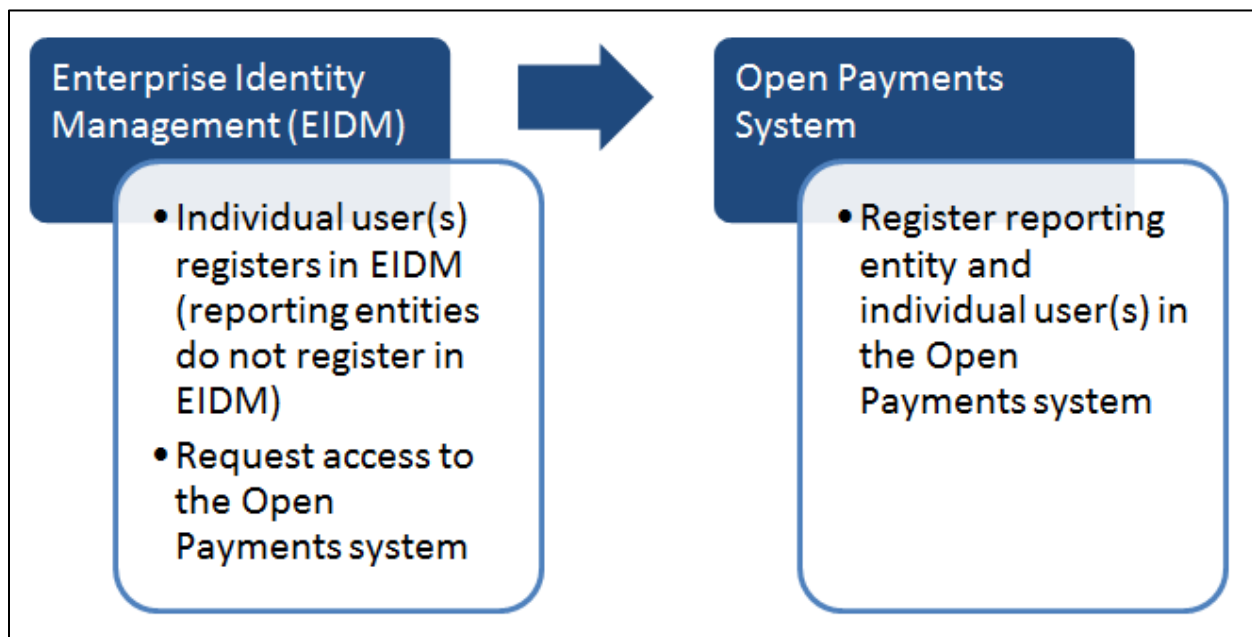
Section 3.2: Enterprise Identity Management (EIDM) Registration and Open Payments Access

Enterprise Identity Management (EIDM) is an identity management and services system that (1) serves as an identity proofing tool to verify a person's identity and (2) provides you with access to CMS applications, including Open Payments. 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.

To begin the registration process, access EIDM via the CMS Enterprise Portal at https://portal.cms.gov. A list of EIDM FAQs is available on the CMS portal at https://portal.cms.gov/wps/portal/unauthportal/help/, 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 to 3.2c: Requesting Access to Open Payments with EIDM Credentials for instructions on how to request access to the Open Payments application.

EIDM will lock your account if no account activity is reported 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 by phone at 1-855-326-8366. For the TTY line, call 1-844-649-2766.

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

3.2a: System Requirements

CMS screens are designed to be viewed at a minimum screen resolution of 1024 x 768. For optimal performance, screen resolution should be set to 1920 x 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 Firefox

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.

Figure 10: CMS Enterprise Portal Public Landing Page
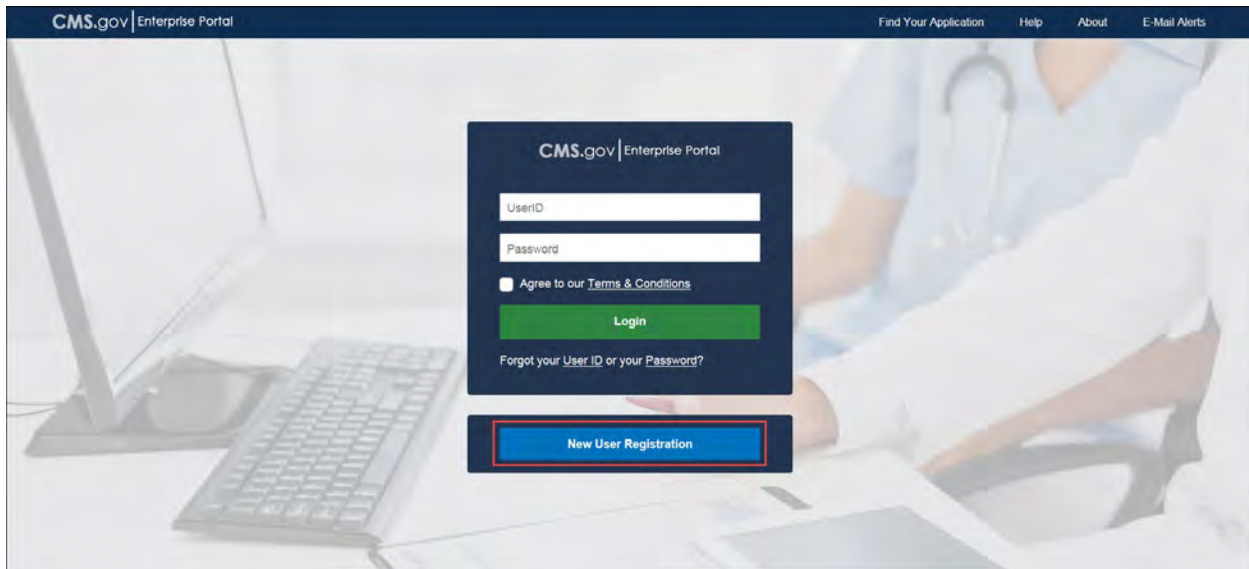
Step 1: On the "Choose Your Application" page, select "Open Payments: Physician Payments Sunshine Act" from the drop down list and agree to the Terms and Conditions of the CMS Enterprise Portal page, then select the "Next" button to continue.

Figure 11: Choose Your Application page
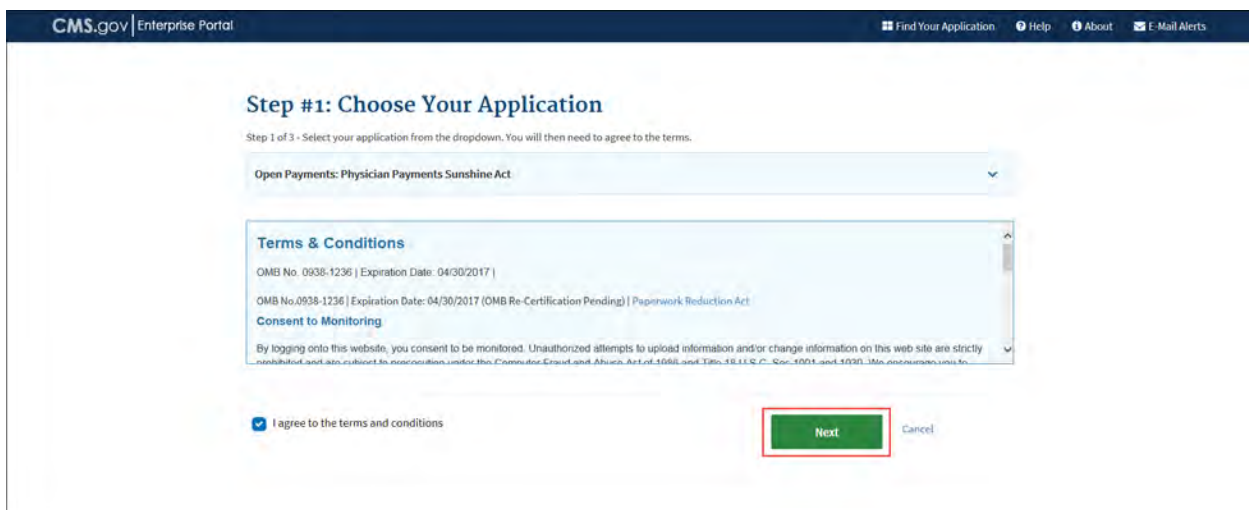
Step 2: On the "Register Your Information" page enter your personal user information. Be sure to enter all information in all required fields. **Note: Selecting the "Cancel" button will cause you to lose all data entered.** Select the "Next" button when all information has been entered.

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

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

Figure 12: Register Your Information page

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.

Step 3: 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.

Figure 13: Create User ID, Password & Challenge Questions page

- 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: ? <> () ' " / \ &

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

Figure 14: Registration Summary page

Step 5: 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 you to the CMS Enterprise Portal home page. Note that profile configuration can take up to 24 hours. If you 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.

Figure 15: Confirmation page

Step 6: Request access to the Open Payments system. Proceed to 3.2c: Requesting Access to Open Payments with EIDM Credentials 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.

Step 1: 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.

Figure 16: CMS.gov Enterprise Portal landing page
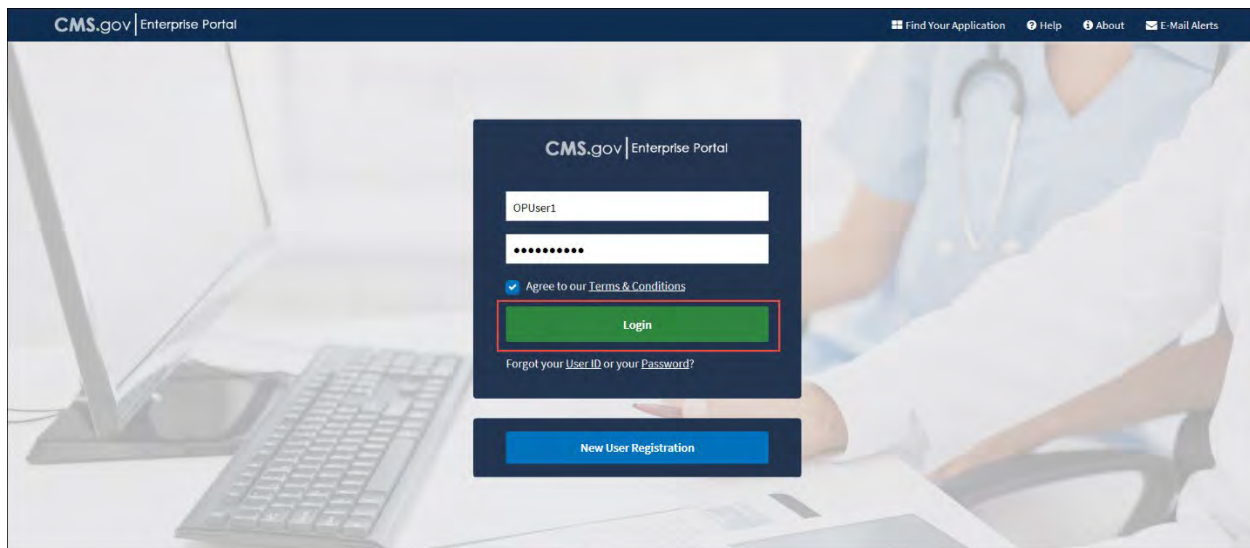
Step 2: Upon initial login, the CMS Enterprise Portal "My Portal" page is displayed. Select the "Request/Add Apps" tile.

Figure 17: My Portal Page

Step 3: 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.

Figure 18: My Access Page
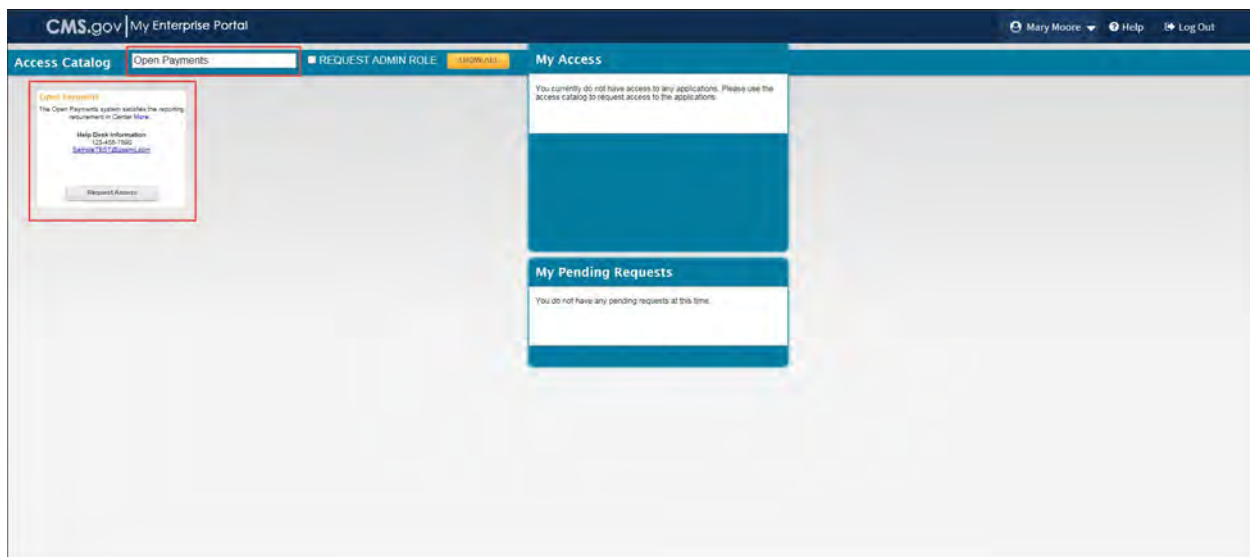
Step 4: On the "Request New System Access" page, "OPENPAYMENTS-Open Payments Application" will be pre-populated for "System Description" drop-down menu. Select a role to request access. Select

"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.

Figure 19: Request New System Access Page
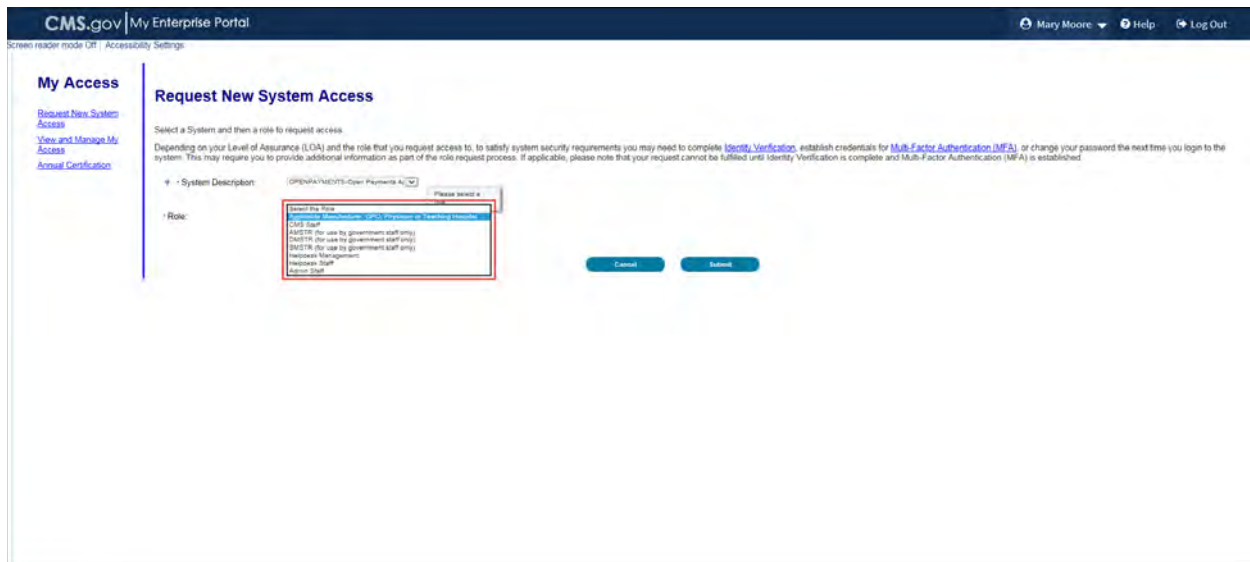
Step 5: Once you have requested access to the Open Payments application, you will then be asked to review the identity verification information. Select the "Next" button once you have reviewed the information.

Figure 20: Identity Verification Information Page
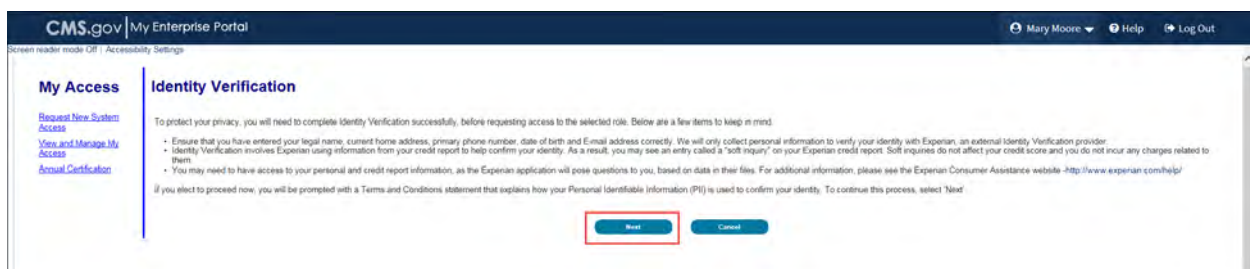
Step 6: Accept the Terms and Conditions by selecting the checkbox. Select the "Next" button.

Figure 21: Terms and Conditions Page

Step 7: 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.

Figure 22: Your Information Page

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 you 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).**

Figure 23: Verify Identity Page

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

Figure 24: Successful Confirmation Message Page
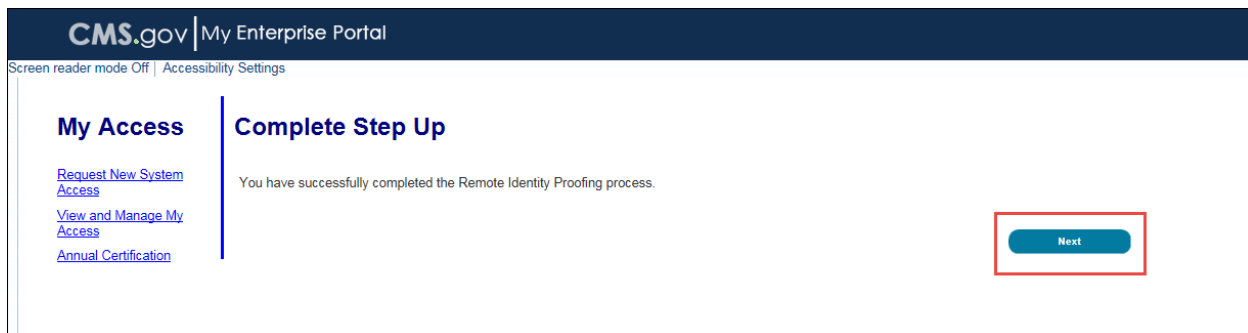
Note: If identity verification fails, you must call the Experian Verification Support Services number provided with the on-screen notification; or, contact Experian Proofing Support Services at 1-866-578-5409. You will need to have incident ID given to them by EIDM. If you do not have this number you will fail again.

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: Following step 9 you will 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.

Figure 25: Multi-Factor Authentication Information Page
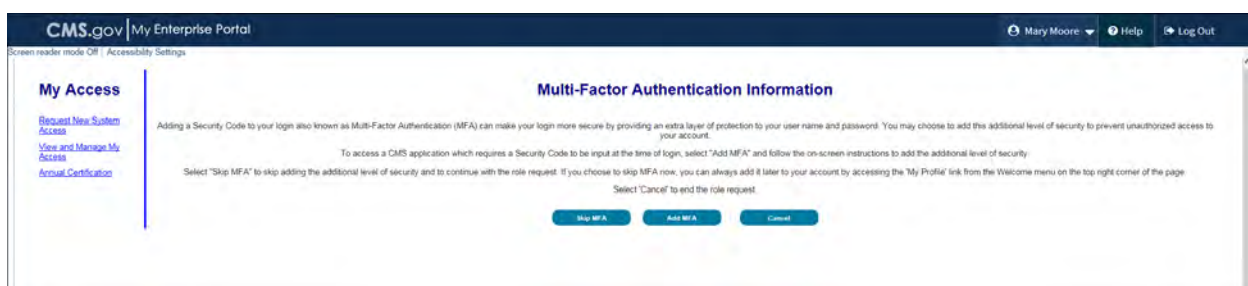
Step 11: **To proceed without MFA**, select "Skip MFA." A confirmation screen will be displayed that you have successfully requested access to the Open Payments system. Access to the Open Payments system will be instantaneous. After you register, you will need to log out of the Enterprise Portal and then log back in before the link to the Open Payments system will appear in the menu bar at the top.

Figure 26: Multi-Factor Authentication Information Page

Figure 27: Successful Completion! Page
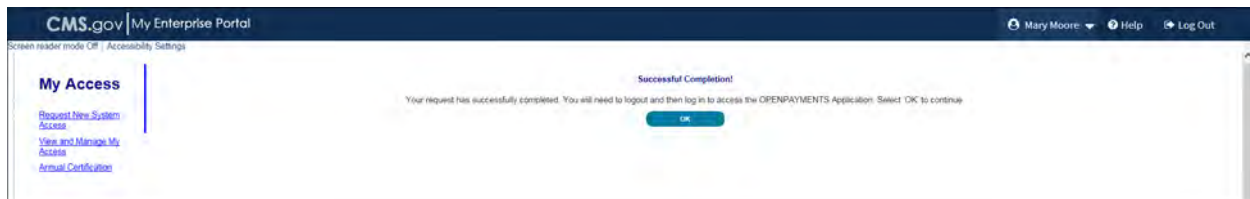
Step 11a: **To proceed with MFA,** select, "Add MFA."

Figure 28: Multi-Factor Authentication Information Page

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.

Figure 29: Register Your Phone, Computer, or Email Page
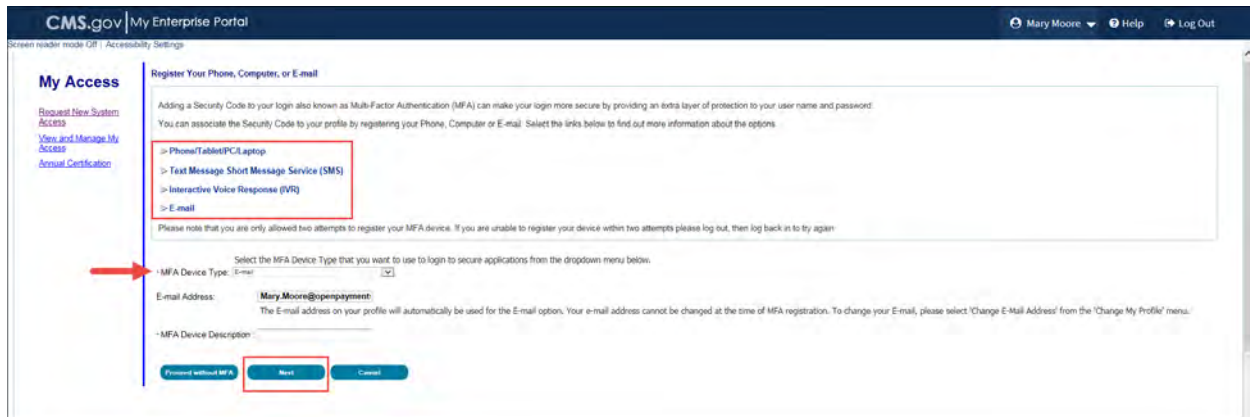
You will receive a confirmation that the MFA device you entered has been successfully registered.

Select the "OK" button to continue.

Figure 30: Register Your Phone, Computer, or Email Page
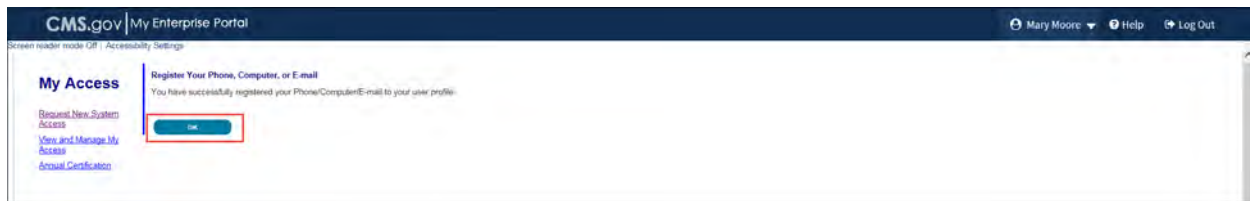
A confirmation screen will be displayed with "Successful Completion!" message "Your request has successfully completed. You will need to logout and then log in to access the OPENPAYMENTS Application. Select 'OK' to continue."

Figure 31: Successful Completion! Page
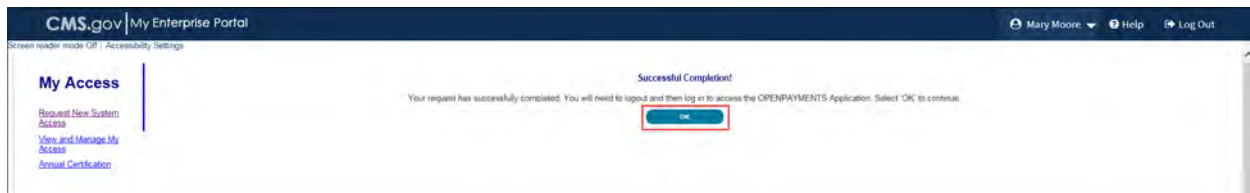
"My Access" page displays the System(s) and Roles(s) you have access to.

Figure 32: View and Manage My Access Page
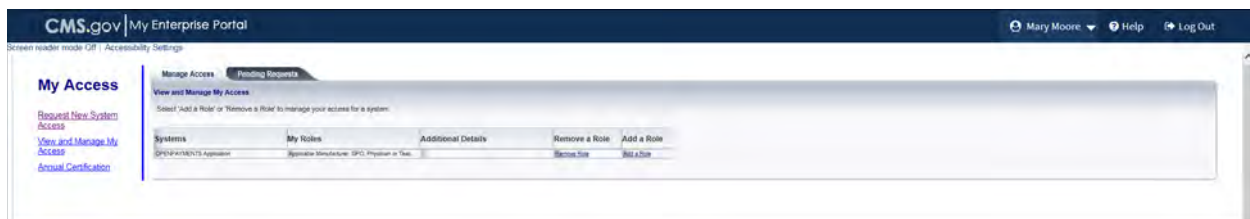
Section 3.3: Open Payments Users and User Roles

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

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

There are the four user roles for applicable manufacturers and applicable GPOs:

- **Officer**: A person who manages the applicable manufacturer or applicable GPO in the Open Payments system, manages all user roles and is permitted to view and download the compliance communications associated with the reporting entity.

- **Submitter**: A person who submits data on payments, other transfers of value, and/or ownership and investment interests for the applicable manufacturer or applicable GPO. The submitter also receives all notifications of disputes initiated by covered recipients against the reporting entity's submitted data.

- **Attester**: A person who attests to the accuracy of the data that has been submitted for the applicable manufacturer or applicable GPO.

- **Compliance**: A person who views and downloads compliance communications uploaded and sent by the CMS Compliance Team to the applicable manufacturer or applicable GPO

The roles, responsibilities, and access levels for the roles are shown in **Figure 33,** below.

Figure 33: Open Payments User Roles

User Roles	Functions	Requirements
Officer	- Manage the reporting entity's profile in the Open Payments system - Nominate (approve) other individuals for submitter, attester, officer, and compliance roles	- Must be an officer as designated by the applicable manufacturer or applicable GPO - If nominated, must either accept or reject the nomination

User Roles	Functions	Requirements
	• Modify nominations and user roles for other users associated with reporting entity • Deactivate other users from the reporting entity • May view and download compliance communications for their reporting entity	
Submitter	• Submit data in the Open Payments system on behalf of the applicable manufacturer or applicable GPO • May nominate individuals for user roles • May edit payments or other transfers of value and ownership/investment interests submitted to the Open Payments system • Receives emails regarding data disputed by physicians and teaching hospitals	• Not required to be an officer of the applicable manufacturer or applicable GPO • If nominated, must either accept or reject the nomination
Attester	• Attest to accuracy of the data in the Open Payments system on behalf of the applicable manufacturer or applicable GPO • May nominate individuals for user roles	• Must be an officer of the applicable manufacturer or applicable GPO as required in the Open Payments Final Rule at 42 C.F.R. § 403.908(e) • If nominated, must either accept or reject the nomination
Compliance	• May view and download compliance communications for their reporting entity	• Not required to be an officer of the applicable manufacturer or applicable GPO • If nominated, must either accept or reject the nomination

Section 3.4 Registering Applicable Manufacturers and Applicable GPOs

Once your reporting entity has decided who should fill the required user roles, you can begin Open Payments registration. During registration, you will enter the required information for your reporting entity profile, user personal profile, and nominees for each user role. Reporting entity registration has five steps, as shown in **Figure 34.** Details on these steps are included later in this section.

Figure 34: Entity Registration

The authorized official enters all required information to create the entity's profile. The authorized official should be highly placed within the entity (e.g., a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable GPO. Specific titles may vary depending on the management structure of the reporting entity.

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

Refer to Section 3.3: Open Payments Users and User Roles for more information on user roles.

Figure 35 and **Figure 36** detail which fields are required and which fields are optional when creating an entity and user profile. It is important to have this information on-hand prior to beginning the registration process.

Figure 35: Entity Profile Fields

Fields	Required or Optional?
Reporting Entity Type	Required
Reporting Entity Legal Name	Required
Business Type	Required
Doing Business As (DBA) Name	Required
Reporting Entity Business Address	Required
Reporting Entity Business Phone Number	Required
Reporting Entity Type of Ownership	Required
Taxpayer Identifier Number (TIN)/ Employer Identification Number (EIN)	Required
Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS)	Optional
Food and Drug Administrator (FDA) Establishment Identifier (FEI)	Optional
Uniform Resource Locator (URL) of Parent Company*	Required

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Fields	Required or Optional?
Consolidated Report Indicator (Y/N) (default N)	Required
Primary Point of Contact Name	Required
Primary Point of Contact Business Phone Number	Required
Primary Point of Contact Title at the Entity	Required
Primary Point of Contact Email Address	Required
Backup Point of Contact Name	Required
Backup Point of Contact Business Phone Number	Required
Backup Point of Contact Title at the Entity	Required
Backup Point of Contact Email Address	Required
Contact Information for Review and Dispute	Required

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

Figure 36: User Profile Fields

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

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

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

Important Notes:

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

- The Open Payments system will log out all users after 30 minutes of inactivity.

- Never use the navigation buttons on your browser toolbar. Only use the navigation buttons (i.e., "Back" button) within the Open Payments system itself.

3.4a: Registering a Reporting Entity (First-Time System Users)

Step 1: 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.

Figure 37: Open Payments Home Screen

Step 2: 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.

Figure 38: Open Payments system landing page for first-time system users

Step 3: The on-screen text contains important information regarding creating the reporting entity and individual profile. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile" at the bottom of the page when you are ready to continue.

Figure 39: Create profile page

Step 4: Select the profile type "Applicable manufacturer or applicable group purchasing organization (GPO)" and select "Continue."

Figure 40: Select Profile Type page

Step 5: Once your entity type is selected, provide the reporting entity's Taxpayer Identification Number/Employer Identification Number (TIN/EIN). This will be the reporting entity's Employer Identification Number (EIN), a nine-digit number used by the entity for tax reporting. The format for the TIN/EIN is 99-9999999. Enter the reporting entity's TIN/EIN in the space provided and select "Find."

Figure 41: Find and Entity page

Step 6: The system will perform a search for that TIN/EIN to determine if it has already been registered.

If the TIN/EIN returns a match, your reporting entity has already been registered. You may choose to proceed by nominating yourself for a role with that entity by selecting the reporting entity name, or you may select "Cancel" to exit entity registration. See Section 3.6d for instructions on how to complete the self-nomination process.

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

Figure 42: Find an Entity page

Open Payments (Sunshine Act)

Create Profile

✓ Select Profile Type

② Register Entity

③ Personal Information

④ Review and Submit Profile

↱ Access the Open Payments User Guide [PDF, 37.3 MB]

? Need help with the website? Contact Us by email

🔒 Review the Open Payments Privacy Policy [PDF, 102 KB]

Find an Entity

A field with an asterisk (*) is required.

To find an entity in the Open Payments system, enter the entity's Taxpayer Identification Number (TIN)/Employer Identification Number (EIN) below.

If the Entity's TIN/EIN Is Not Found

If the TIN/EIN entered does not return any results, the entity has not yet been registered within the Open Payments system. You may register the entity by selecting the "Register Your Entity on Open Payments" link. Note: You must also register yourself for the officer user role when registering an entity. You may hold more than one user role.

If the Entity's TIN/EIN Is Found

If the TIN/EIN search returns results, check the results to see if the entity you wish to register with is listed. If the entity is not listed, you may register the entity by selecting "Other." If the search results contain the entity you wish to associate yourself with, you may select that entity and proceed with creating your personal profile and nominating yourself for a role with that entity.

Required: Enter the TIN/EIN of the entity.

*Enter TIN/EIN:
99-9999999

34-5678901   Find

No entity with that TIN/EIN is registered on Open Payments

Register your Entity on Open Payments

Cancel   Back

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<u>Step 7:</u> Enter the reporting entity's 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. Take care to use proper field formatting required by the system. For example, when entering the entity phone number and Taxpayer Identification Number/Employer Identification Number (TIN/EIN), you must include the hyphen ("-") in the proper place within the field to pass field validation.

URL is also a required field. If the reporting entity you are registering does not have a website, enter the generic URL of https://www.cms.gov into this field. When you are done, select "Continue." Selecting the "Cancel" button will cause you to lose all data entered.

Additional Information on the fields for entity registration:

• The **Consolidated Report Indicator** indicates whether or not the applicable manufacturer or applicable GPO intends to submit a consolidated report. Consolidated reporting allows the reporting entity to submit bulk data files across multiple registered entities. Applicable manufacturers or applicable GPOs should select "yes" if another applicable manufacturer or applicable GPO under common ownership with the registering entity is submitting a report on its behalf. The option selected in the "Consolidated Report Indicator" is a system indicator only and does not commit you to submitting a consolidated report. See Section 4.12 for more on consolidated reporting.

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

  o **Applicable manufacturer**

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

    − applicable manufacturer-drugs/biologicals

    − applicable manufacturer-devices/medical supplies

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

    − applicable manufacturer-physician-owned distributor

    − applicable manufacturer-hospital-owned distributor

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

  o **Applicable GPO**

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

    − GPO-drugs/biologicals

    − GPO-devices/medical supplies

    − GPO- drugs/biologicals and devices/medical supplies

    − GPO-physician-owned

- GPO-hospital-owned

- GPO-hospital and physician-owned

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

- GPO-government-owned

• The **Primary** and **Backup Points of Contact** are individuals who will serve as the points of contact for the reporting entity and CMS. These must be separate individuals. They do not have to be registered in the Open Payments system.

• The **Contact Information for Review and Dispute** field is to provide contact information for individual(s) from your entity who will assist with the dispute resolution process. Individuals listed as contacts for review and dispute do not have to be registered in the Open Payments system. You may also include additional instructions for physicians and teaching hospitals in this field. The contents of the "Contact Information" box will be visible on your entity's profile page as well as the "Record ID" pages of all records the entity has submitted.

Figure 43: Register Entity page

Step 8: Enter the required information and select your user roles. For a description of user roles, see Section 3.5. When registering a new reporting entity, you must select the role of officer for yourself. The system will not allow you to proceed if this role is not selected. You may also select the role of submitter and/or attester and/or compliance for yourself. When you are done, select the "Continue" button.

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

Figure 44: Your Role page

Step 9: You may nominate additional individuals for the officer, submitter, attester, and compliance roles at this step. To add a nomination, select the "Add" button and proceed to Step 10. If you do not wish to nominate additional individuals, select the "Continue" button and proceed to Step 11.

If you will not be fulfilling all four user roles yourself, you must nominate at least one other individual to fill each of the remaining roles. **At least one individual must be identified for officer, submitter, and attester roles in the Open Payments system during initial entity registration.** The system will not allow you to proceed without at least one individual associated with each user role except compliance. The system will allow registering an entity without assigning a user for compliance role.

Refer to Section 3.3: Open Payments Users and User Roles for more information on user roles.

Figure 45: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles page

Step 10: If you selected "Add," the page will expand to show nominee information fields that will need to be completed. Fill in the information for the individual being nominated. Once you are done, select the "Add" button at the bottom of the page again. This will add the nominee information to the reporting entity's profile, as well as open another set of information fields to enter an additional nominee.

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

Figure 46: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles page

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

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

Figure 47: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles page

Step 11: Review any pre-populated information for accuracy and enter other personal information. Required fields are marked with an asterisk (*). You will not be able to proceed with registration until all of the required fields have been completed. Once your personal information has been entered, select the "Continue" button.

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

Figure 48: Enter Personal Information page

Step 12: Review the information entered for your reporting entity and personal profile. Select the "Back" button at the bottom of the page to go back and edit any information. Once you have reviewed the information and determined it to be correct, select the "Continue" button.

Figure 49: Review and Submit Profile Page

The following message will appear on-screen to confirm your reporting entity and personal profile have been successfully created. An email notification with the entity's registration ID will be sent to you, the individuals you nominated for user roles during registration, and the individuals listed as points of contact for the reporting entity.

Figure 50: Success Confirmed Page

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

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

If the reporting entity's registration is unsuccessful, Open Payments will send an email notification to the officer(s) and points of contact stating the entity could not be successfully verified and registered. Contact the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance. **For the TTY line, call 1-844-649-2766.**

3.4b: Registering an Entity (Returning System Users)

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

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

Figure 51: Open Payments system landing page for returning system users.

Step 2: Select "Register New Entity."

Figure 52: Manage Entities page

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

Figure 53: Select Profile Type page

Step 4: Once your entity type is selected, provide the reporting entity's Taxpayer Identification Number/Employer Identification Number (TIN/EIN). This will be the entity's Employer Identification Number (EIN), a nine-digit number used by the entity for tax reporting. The format for the TIN/EIN is 99-9999999. Enter the entity's TIN/EIN in the space provided and select "Find."

Figure 54: Find and Entity page
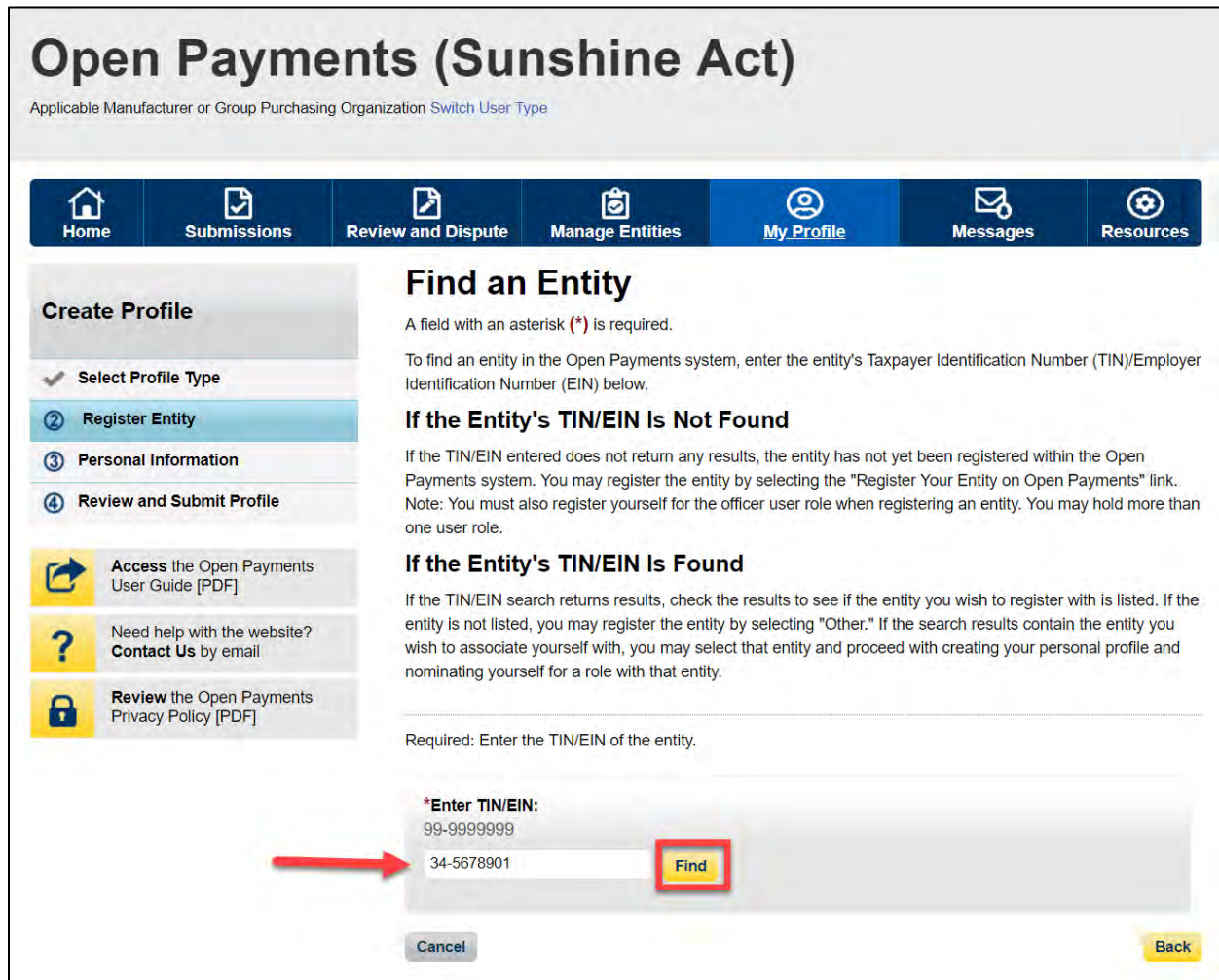
Step 5: The system will perform a search for that TIN/EIN to determine if it has already been registered.

If the TIN/EIN returns a match, your reporting entity has already been registered. You may choose to proceed by nominating yourself for a role with that reporting entity by selecting the entity name, or you may select "Cancel" to exit entity registration. See Section 3.6d for instructions on how to complete the self-nomination process.

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

Figure 55: Find an Entity page

Step 6: Enter the reporting entity information. All required fields will be marked with an asterisk (*). You will not be able to proceed with registration unless all of the required fields have been completed.

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

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

When you are done, select the "Continue" button. Selecting the "Back" button will cause you to lose all data entered.

Additional Information on the fields for entity registration:

- The **Consolidated Report Indicator** indicates whether or not the applicable manufacturer or applicable GPO intends to submit a consolidated report. Consolidated reporting allows the reporting entity to submit bulk data files across multiple registered entities. Applicable manufacturers or applicable GPOs should select "yes" if another applicable manufacturer or applicable GPO under common ownership with the registering entity is submitting a report on its behalf. The option selected in the "Consolidated Report Indicator" is a system indicator only and does not commit you to submitting a consolidated report. See Section 4.12 for more on consolidated reporting.

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

  o **Applicable manufacturer**

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

    - applicable manufacturer-drugs/biologicals

    - applicable manufacturer-devices/medical supplies

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

    - applicable manufacturer-physician-owned distributor

    - applicable manufacturer-hospital-owned distributor

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

  o **Applicable GPO**

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

    - GPO-drugs/biologicals

    - GPO-devices/medical supplies

    - GPO- drugs/biologicals and devices/medical supplies

    - GPO-physician-owned

    - GPO-hospital-owned

    - GPO-hospital and physician-owned

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

    - GPO-government-owned

- The **Primary** and **Backup Points of Contact** are individuals who will serve as the points of contact for the reporting entity and CMS. These must be separate individuals. They do not have to be registered in the Open Payments system.

- The **Contact Information for Review and Dispute** is to provide contact information for individual(s) from your entity who are assisting with the dispute resolution process. You may also include additional instructions for physicians and teaching hospitals. The contents of the "Contact Information" box will be visible on your entity's profile page as well as the "Record ID" pages of all records the entity has submitted.

Figure 56: Register Entity page

Step 7: Enter the required information and select your user roles. For a description of user roles, see Section 3.3. When registering a new reporting entity, you must select the role of officer for yourself. The system will not allow you to proceed if this role is not selected. You may also select the role of submitter, attester, and/or compliance for yourself. When you are done, select "Continue."

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

Figure 57: Your Role page

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

If you will not be fulfilling all four user roles yourself, you must nominate at least one other individual to fill each of the remaining roles. **At least one individual must be identified for officer, submitter, and attester roles in the Open Payments system during initial entity registration.** The system will not allow you to proceed without at least one individual associated with each user role except compliance. The system will allow registering an entity without assigning a user for compliance role.

Figure 58: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles page

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

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

Figure 59: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles page

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Repeat the process until you have entered in all individuals you wish to nominate at this time. An entity can have up to 12 unique users with a maximum of five holding the role of officer and maximum of two holding the role of compliance. Note that individuals can be nominated for user roles after registration is complete.

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

Figure 60: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles page

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

Figure 61: Review and Submit Profile page

The following message will appear to confirm your reporting entity and personal profile have been successfully created. An email notification with the entity registration ID will be sent to the identified officer(s) and points of contact.

Figure 62: Success Confirmed page

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

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

If the reporting entity's registration is unsuccessful, Open Payments will send an email notification to the officer(s) and points of contact stating the entity could not be successfully verified and registered. Contact the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance. For the TTY line, call 1-844-649-2766.

Section 3.5: Entity Recertification

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

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

During recertification, you either confirm that the details of the entity's profile in the Open Payments system are accurate or update the entity's profile information if its profile in Open Payments is inaccurate or outdated. Note that only users who hold the role of officer in the reporting entity can recertify. If you do not have an active officer for your entity, you will need to contact the CMS Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance. For the TTY line, call 1-844-649-2766.

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

To recertify a reporting entity, follow these steps.

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

Figure 63: Open Payments system landing page for returning system users

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

Figure 64: Manage Entities Page

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

Figure 65: Entity Information page

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

Figure 66: Entity Information page in an editable view

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

Figure 67: Manage Entities page showing entity successfully updated confirmation message
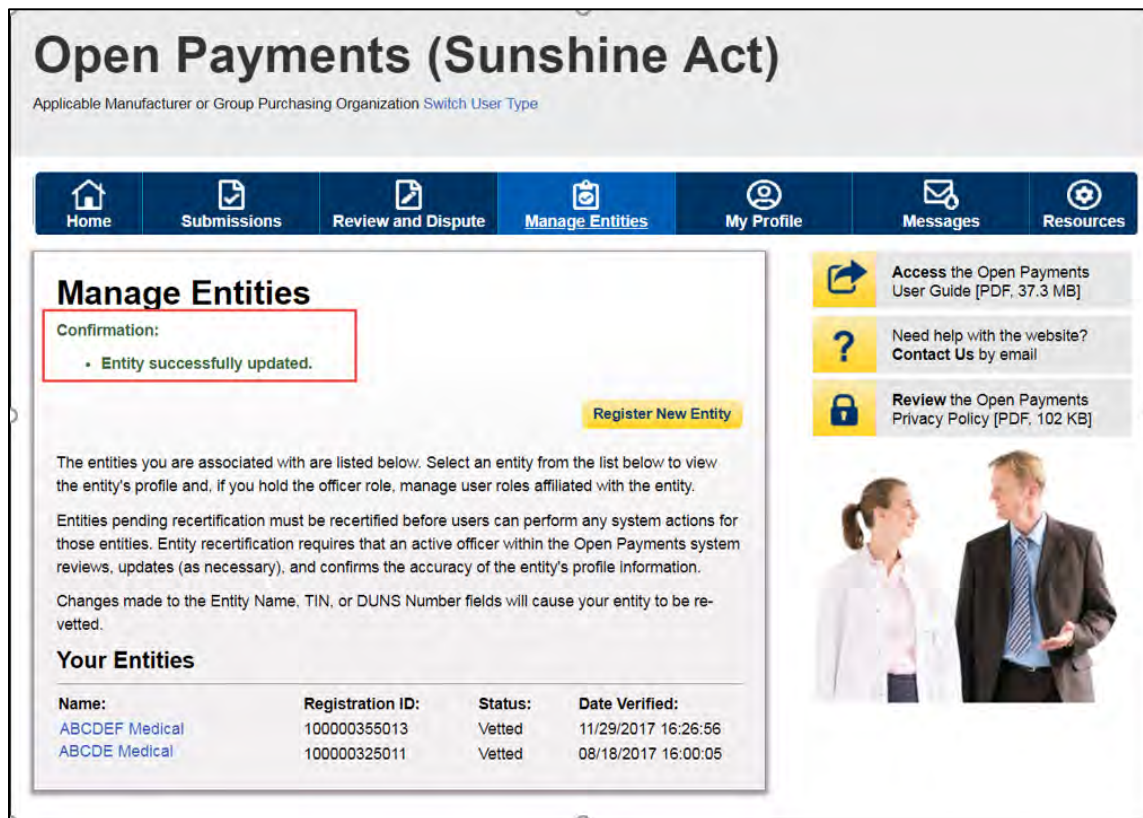
Changes made to the Entity's Legal Name, State, Country, TIN, or DUNS Number fields will trigger your entity to be re-vetted. Updating any of the remaining fields will not trigger the vetting process. You will be able to perform the submission and review and dispute functions once your entity is successfully re-vetted.

Section 3.6: Nominations

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

1. Nominated by an existing Open Payments user for a role with a reporting entity; or

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

You may nominate other individuals for specific user roles within the Open Payments system. The system will generate an email notification to the nominee once their nomination has been approved by an officer.

During initial reporting entity registration, the authorized official must nominate at least one user for each of the three roles (officer, submitter, and/or attester). It is not mandatory to nominate user for the compliance role during initial registration. This process is shown in the entity registration process shown in Section 3.3. Reporting entities can also nominate individuals after registration is complete. The process for this is shown in Section 3.6a.

You can hold multiple roles. Entities may nominate up to 12 unique users with a maximum of five holding the role of officer and a maximum of two holding the role of compliance. To nominate an individual for a role, the following information must be input into the Open Payments system about that individual:

- First name

- Last name

- Job title

- Business address

- Business phone

- Email address

Once you receive the nomination notification, you must access the Open Payments system via the CMS Enterprise Portal and either accept or reject the nomination. You have 10 calendar days to accept or reject the nomination. If you do not take action on your nomination within 10 days, the nomination will expire. The process for accepting or rejecting your nomination(s) is shown in Sections 3.6b and 3.6c.

If the nomination is accepted, you will be able to complete a user profile, gain access to the entity's profile, and perform the duties of your role. An email notification, generated by the Open Payments system, will be sent informing all users holding the role of officer with the entity that the nomination has been accepted. If you reject the nomination, you will not be able to perform the actions on that reporting entity's behalf and the reporting entity's officers will receive an email notification of the rejection. You will need to have EIDM credentials in order to access the Open Payments system and accept or reject your nominations.

If you have been nominated for multiple user roles with a reporting entity, an officer with that entity must confirm all of your user role nominations before you can begin performing actions in the system.

Reporting entities may have third parties submit payments or other transfers of value on their behalf. In this case, the officer would nominate the third party to fulfill the submitter role. See Section 4.13 for more information on third-party data submission.

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

Figure 68: Self-Nomination Process
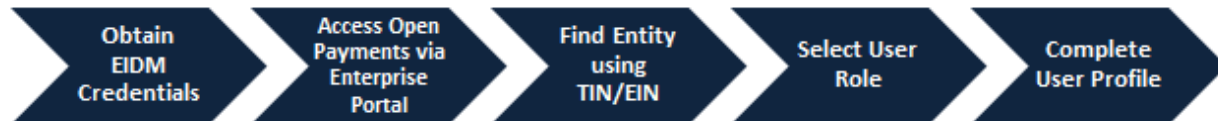
To self-nominate for a role in the Open Payments system, you must access the Open Payments system via the CMS Enterprise Portal, and use the reporting entity's TIN/EIN in order to find the reporting entity in the Open Payments system.

Once you have submitted their nomination request, the officer for that reporting entity will receive an email notification asking to approve the nomination. If the officer approves the nomination, the nominee will receive an email notification and be granted access to the system. Section 3.6d provides instructions for self-nomination and Section 3.6f provides instructions for officers with the reporting entity on how to approve or reject self-nominations.

Note: If the entity no longer has a user in the system who holds the officer user role to approve a self-nomination, the self-nominator can contact the Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance to nominate himself or herself as an officer. **For the TTY line, call 1-844-649-2766.** If the entity does not have an officer and the user wants to nominate themselves for a non-officer role, the nomination will not be approved until the reporting entity has an active officer.

You can also be deactivated from a reporting entity. Deactivation removes your association with a reporting entity in the Open Payments system, including removing your access to that reporting entity's information and records. It does not remove you from the Open Payments system. Section 3.6g provides information and instructions on user deactivation. In the "My Profile" page of the Open Payments system, user roles are listed with a status. An explanation of those statuses is in the table below.

Figure 69: User Role Statuses for Reporting Entities

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

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

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

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

Figure 70: Open Payments system landing page for returning system users

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

Figure 71: Manage Entities Page

Step 3: Select the "Manage Roles" tab.

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Figure 72: Manage Entities Page

Step 4: Select "Nominate New Role."

Figure 73: Entity's Manage Roles tab

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

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

Figure 74: Nominate New Role page

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

Figure 75: Entity's Manage Roles tab confirming success of nomination

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

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

3.6b: Accepting a Nomination (First Time System Users)

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

You will have 10 calendar days to accept or reject a nomination. If you have not taken action on your nomination within 10 days, the nomination will expire. If you want a user role after the nomination expires, then you will have to nominate yourself for a user role (see Section 3.6d for instructions on self-nomination).

The process for accepting nominations is outlined in **Figure 76,** below.

Figure 76: Accepting Nominations
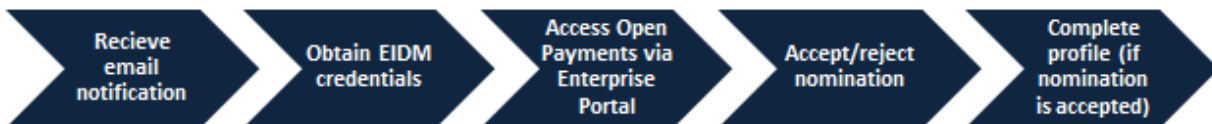
To accept a nomination in the Open Payments system, follow the steps below:

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

Figure 77: Open Payments system landing page for first-time system users

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

Figure 78: Create Profile page

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

Figure 79: Select Profile Type page

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

Figure 80: Search for Nomination page

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

Figure 81: Search for Nomination page

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

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

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

Figure 82: Confirm Entity page

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

If you reject all roles for which you have been nominated, select the "Continue" button after selecting "No, I do not accept" for all roles. The system will ask you if you're sure you want to reject these roles. If you confirm your choice to reject the roles, you will not be able to perform any actions on behalf of the reporting entity and the nominator will receive an email notifying him or her that you rejected the nominations. The nominator will then be allowed to nominate other people for the roles.

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

Figure 83: Confirm Nomination Page

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

Figure 84: Enter Personal Information page

Step 9: You will be asked to review the information you have entered. To correct any errors, select the "Back" button at the bottom of the page to return to previous pages and make your corrections. If the information is correct, select "Continue."

Figure 85: Review and Submit Profile page.

The following message will appear on-screen to confirm your nomination has been successfully accepted. Notification emails will be sent to all of the users who hold the role of officer with that entity that you have accepted your nomination.

Figure 86: Success Confirmed page

Open Payments (Sunshine Act)

Create Profile

✔ Select Profile Type

✔ Register Entity

✔ Personal Information

✔ Review and Submit Profile

Access the Open Payments User Guide [PDF, 37.3 MB]

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

🔒 **Review** the Open Payments Privacy Policy [PDF, 102 KB]

Success Confirmed

You have successfully accepted your affiliation with Love Touch Cleaning Service and created your own profile, Tom Smith.

You may now go to Open Payments Home

For help obtaining a PDF viewer, go to the CMS.gov Help page.

3.6c: Accepting a Nomination (Returning System Users)

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

Figure 87: Open Payments system landing page for returning system users

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

Figure 88: My Profile page

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

Figure 89: My Roles and Nominations tab

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

Figure 90: Search for Nomination page

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

Figure 91: Search for Nomination page

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

Figure 92: Confirm Entity page

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

If you reject all roles for which you have been nominated, Select the "Continue" button after selecting "No, I do not accept" for all roles. The system will ask you if you are sure you want to reject these roles. If you confirm your choice to reject all roles, you will not be able to perform any actions on behalf of the

entity and the nominator will receive an email notifying him or her that you rejected the nominations. The nominator will then be allowed to nominate other people for the roles.

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

Figure 93: Confirm Nomination page

Step 8: Review the reporting entity information and personal profile. Select the "Back" button at the bottom of the page to go back and edit any personal information. If the entity information is not correct, select "Cancel" and contact your reporting entity's authorized official. If the information is correct, select "Continue."

Figure 94: Review and Submit Profile Page

The following message will appear on-screen to confirm your acceptance of one or more user roles. Notification emails will be sent to all of the users who hold the role of officer with that entity that you have accepted your nomination.

Figure 95: Success Confirmed Page

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

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

Figure 96: Open Payments system landing page for first-time system users

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

Figure 97: Create Profile Page

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

Figure 98: Select Profile Type page

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

Figure 99: Find an Entity page

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

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

Figure 100: Find an Entity page

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

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

Figure 101: Confirm Entity page

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

Figure 102: Your Role page

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

Figure 103: Enter Personal Information page

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

Figure 104: Review and Submit Profile page

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

Figure 105: Success Confirmed page

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

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

Figure 106: Open Payments system landing page for returning system users

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

Figure 107: My Profile page
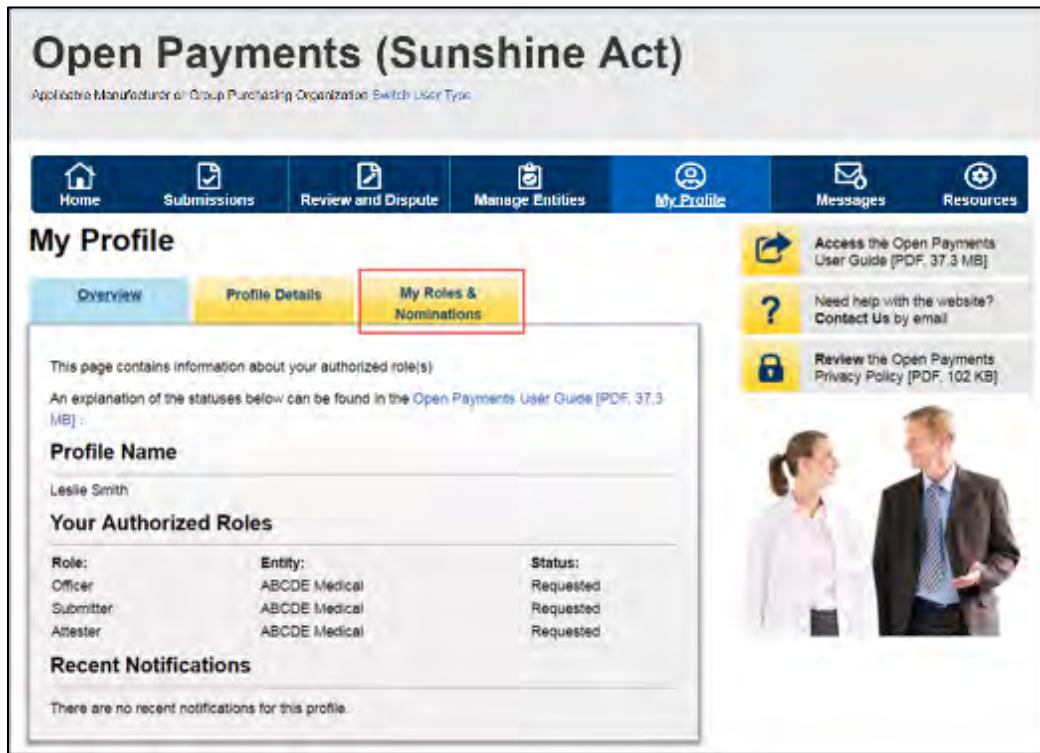
Step 3: From the "My Roles and Nominations" tab, select "Request a Role."

Figure 108: My Roles and Nominations tab
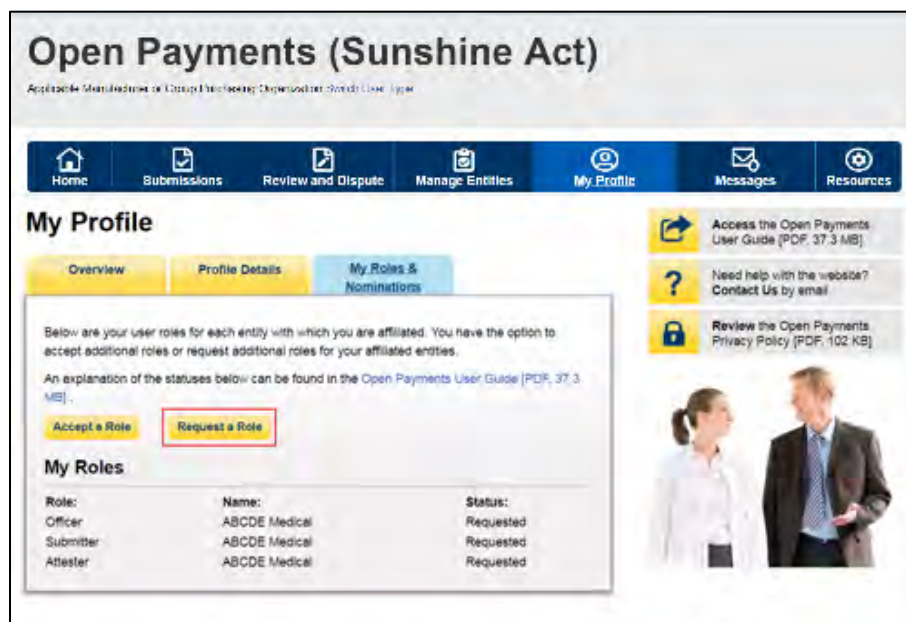
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<u>Step 4:</u> Enter the Taxpayer Identification Number/Employer Identification Number (TIN/EIN) of the reporting entity that you want to associate yourself with. The TIN must be nine digits, with a dash after the second digit. Select "Find."

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

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

Figure 109: Find an Entity page

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

Figure 110: Confirm Entity page

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

Figure 111: Your Role page

Open Payments (Sunshine Act)

Applicable Manufacturer or Group Purchasing Organization Switch User Type

Home	Submissions	Review and Dispute	Manage Entities	My Profile	Messages	Resources

Your Role

A field with an asterisk (*) is required.

To associate yourself with a reporting entity in the Open Payments system, you must nominate yourself for one or more user roles. The user roles are as follows:

Officer:

- Updates the applicable manufacturer or applicable GPO profile information and can approve and modify nominations for user roles.
- Can deactivate other users from the entity.
- Can review and download compliance messages on behalf of the applicable manufacturer or applicable GPO.

Submitter:

- Submits and edits payment information on behalf of the applicable manufacturer or applicable GPO.
- The submitter role can be held by individuals from third-party entities who submit records on behalf of the applicable manufacturer or applicable GPO.

Attester:

- Attests to the accuracy, completeness, and timeliness of the data submitted for the applicable manufacturer or applicable GPO.
- Can submit assumptions made in the reporting of payments, other transfers of value, or ownership or investment interests.

Compliance

- Can review and download compliance messages on behalf of the applicable manufacturer or applicable GPO.

Create Profile

- ✓ Select Profile Type
- ② Register Entity
  - ✓ Entity Information
  - Your Roles
- ③ Personal Information
- ④ Review and Submit Profile

Access the Open Payments User Guide [PDF]

Need help with the website? Contact Us by email

Review the Open Payments Privacy Policy [PDF]

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*First Name:
Leslie

Middle Name:

*Last Name:
Smith

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

*Business Email Address:
openpayments@yopmail.com

*Business Telephone Number:
999-999-9999 or Maximum 20 digits
555-555-5555

Indicate your role(s) in the Open Payments system. Only an officer may manage the access levels of attesters, submitters, compliance users, and other officers. Your role(s) is/are not confirmed until an officer with the reporting entity has approved your self-nomination. You will be notified via email if your nomination is approved.

Highest Level of Role
- ☑ Officer

Reporting-related Roles
- ☑ Submitter
- ☑ Attester

Compliance-related Roles
- ☑ Compliance

| Cancel | | Back | Continue |

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

Figure 112: Review and Submit Profile page

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

Figure 113: Success Confirmed page

3.6f: Approving or Modifying Nominations (Officers Only)

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

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

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

Figure 114: Open Payments system landing page for returning system users

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

Figure 115: Manage Entities Page

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

Figure 116: Entity details page

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

Figure 117: Manage Roles tab

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

Figure 118: Red box circles confirmation message

To modify the nomination, select "Modify."

Figure 119: Manage Roles tab

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

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

Figure 120: Manage Roles tab

You will receive an onscreen confirmation of the information submission.

Figure 121: Manage Roles tab

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

3.6g: Deactivating Users (Officers Only)

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

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

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

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

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

Figure 122: Open Payments system landing page for returning system users

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

Figure 123: Manage Entities Page

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

Figure 124: Manage Roles Tab

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

Figure 125: Deactivate User on Manage Roles Tab

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

Figure 126: Manage Roles tab. A pop up message is displayed to "Deactivate User"

Figure 127: Confirmation Message on Mage Roles Tab

Section 3.7: Vetting

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

3.7a: Entity Vetting

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

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

If a reporting entity fails vetting, its name in the home page's "Entity Status" section will contain a hyperlink. This link will take you to the reporting entity's profile for editing and resubmission. You can resubmit an entity for automated vetting three times. If your entity is unable to be successfully vetted automatically, you will need to contact the Open Payments Help Desk to receive a "Conditionally Active" status to gain access to the Open Payments system. "Conditionally Active" status is given on a discretionary basis by the Open Payments Help Desk. This status will allow the authorized official and additional users to perform tasks within the system to remain compliant with the program, though it will be noted that the entity could not be successfully vetted.

If you believe all of the information provided in the entity profile is correct and the entity should have been successfully vetted, contact the Open Payments Help Desk at any time during the vetting process for assistance at openpayments@cms.hhs.gov or 1-855-326-8366. **For the TTY line, call 1-844-649-2766.**

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

3.7b: Vetting Timeframe

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

Data Submission and Attestation

Chapter 4: Data Submission and Attestation

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

This chapter is divided into the following sections:

- **Data Submission** contains information on data submission for the Open Payments system.

- **Preparing Your Data** contains information on how to prepare data files, payment types, and location of data submission resources.

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

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

- **Record Validation and Matching** contains information about how submitted records are verified in the Open Payments system for accuracy.

- **Correcting Validation and Matching Errors** contains information about how to understand error reporting and how to correct errors in submitted records.

- **Deleting Records** contains information about how to delete individual records and entire CSV files.

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

- **Delay in Publication** contains information about the requirements and rules for requesting delays in publication for certain types of records.

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

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

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

Section 4.1: Overview of Data Submission and Attestation

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

Figure 128 provides an overview of the data submission and attestation process.

Figure 128: The Four Steps of Data Submission and Attestation

Notes:

- Applicable manufacturers and applicable GPOs must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the reporting entity's compliance for five years from the date of publication.

- Data reporting is complete <u>only</u> after electronic attestation is received for the program year.

- To assist with the preparation of data for submission, CMS has made resources available to help reporting entities confirm physician and teaching hospital identifying information. Physician identifying information can be found in the Validated Physician List (VPL). The documents can be downloaded from the "Submissions" page of the Open Payments system. Teaching hospital identifying information can be found in the Teaching Hospital list, which can be downloaded from the Resources page of the Open Payments website at https://www.cms.gov/openpayments/About/Resources.html.

- If the physician license information is not active in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

Section 4.2: Data Submission

The data submission process requires reporting entities to submit detailed information regarding payments or other transfers of value made to physicians and teaching hospitals, and then attest to the accuracy of the data. Reporting entities will submit data either through bulk file upload or manual data entry. Both submission options are covered later in this chapter.

Only individuals holding the role of submitter may submit the data in the Open Payments system, and only individuals holding the role of attester may attest to the data. To perform data submission, users in the role of submitter should:

- Submit data files to validate the file structure;

- Use the error report generated by the Open Payments system to fix any data errors in submitted files; and finally

- Perform final data submission.

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

Section 4.3: Preparing Your Data

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

4.3a: Covered Recipient Demographic Resources

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

- The Validated Physicians List (VPL) contains two separate files, one listing physicians who have an NPI and have been reported on in the Open Payments system, and the second listing physicians without an NPI and have been reported on in the Open Payments system. The VPL is **not** an exhaustive list of all physicians who should be included in Open Payments reporting. It can only be accessed within the Open Payments system, on the "Submissions" page.
- The Teaching Hospital Lists include all teaching hospitals that should be included in Open Payments reporting. They can be accessed via the Resources page on the Open Payments website (https://www.cms.gov/openpayments/About/Resources.html).

o For Program Years 2014 and later, use the hospital's "Doing Business As" name as the hospital name in the submitted record. The "Doing Business As" name is found in the Teaching Hospital List under the heading of "Hospital Name."

o For Program Year 2013 records, use the hospital's legal business name as the hospital name in the submitted record.

o For the address for the hospital in the submitted record, use the "NPPES Business Address" in the Teaching Hospital List.

Another key resource is the "Submission Data Mapping Document," which maps each data element in Open Payments records to the appropriate CSV field names. (Note that there are different versions of this document for PY 2013-2015 data, and PY 2016-2020 data.) The "Data Element Name", Column B in the "Submission Data Mapping Document," can be mapped to the "CSV Element Name" column of the sample file (template). You may also use this document as a guide when entering payments manually. Submission Data Mapping Documents can be found on the Resources page on the Open Payments website (https://www.cms.gov/openpayments/About/Resources.html).

4.3b: Validation Utility for Physicians

If you hold a submitter role for a reporting entity, you can access the physician validation tool to validate information on physician profiles, prior to reporting that physician on the payment record. . You must use the specific physician validation template provided on the Open payments "Validate Physician" page to upload physician profile information for validation. Once the validation process is concluded, you are able to download the results file for any physicians that were not successfully matched. Note: When you upload the physician information to the system, the information is matched using the same CMS resources that are used to perform matching the covered recipient physician on the payment record

Character-separated value (CSV) is the only file format accepted by the Open Payments system to validate physicians. Submitted bulk files may not exceed 50MB in size. If the data in your file exceeds that limit, you can split the data into more than one file. To validate physician information:

• Select the "Validate Physician" button located on the bottom of the "Submissions" Page.

• Submit physician information using the upload functionality on the Physician Validation page.

4.3b (1): Validating Physician Instructions

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

Figure 129: Submissions Tab

Step 2: You will be brought to the "Submissions" page. Select the "Validate Physician" button to begin the physician validation process.

Figure 130: Validate Physicians Button

Step 3: Download and use the "Physician Validation Template" available on the right pane of the "Physician Validation" page to validate physician information using this tool. An example of the "Physician Validation Template" data fields table is shown in figure 131.

Figure 131: Physician Validation Data Fields Table

Element	Description	Format
APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_ID	Enter the Applicable Manufacturer's/Applicable GPO's Registration ID in this data field	System generated field
PHYSICIAN_FIRST_NAME	Enter the textual first name of the physician (covered recipient) receiving the payment or other transfer of value.	Free form text
PHYSICIAN_LAST_NAME	Enter the textual last name of the physician (covered recipient) receiving the payment or other transfer of value	Free form text
PHYSICIAN_NPI	Physician (not the NPI of any group the physician belongs to)	Numeric digits only
PHYSICIAN_PRIMARY_TYPE	Enter Primary type of medicine practiced by the covered recipient physician.	The following codes are in this field: "1" = Medical Doctor; "2" = Doctor of Osteopathy; "3" = Doctor of Dentistry; "4" = Doctor of Podiatric Medicine; "5" = Doctor of Optometry; "6" = Chiropractor
PHYSICIAN_LICENSE_STATE_AND_LICENSE_NUMBER_1	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999

Element	Description	Format
PHYSICIAN_LICENSE_STATE_AND_LICENSE_NUMBER_2	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999
PHYSICIAN_LICENSE_STATE_AND_LICENSE_NUMBER_3	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999
PHYSICIAN_LICENSE_STATE_AND_LICENSE_NUMBER_4	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999
PHYSICIAN_LICENSE_STATE_AND_LICENSE_NUMBER_5	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999

Figure 132: Physician Validation Page

The delimiter for CSV files for Open Payments submission files is a pipe (|). When creating CSV files for Open Payments using Excel on a Windows-based computer, you must first update the computer's regional settings to display "pipe" as the field delimiter instead of "comma." You can find the regional settings in your computer's Control Panel under *Region and Language -> Additional Settings -> List Separator*. Once this is complete, you can create the pipe by holding down the shift key and selecting backslash (i.e., "\").

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

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

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

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

- Ensure that rows of data are not contained within quotation marks

Step 4: Select the "Choose File" button to choose a file to be uploaded. Select the "Upload File Button" to upload the chosen file to the Open Payments system. Select the "Refresh Status" button to refresh the "Physician Validation" page

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Figure 133: Choose file Pop-Up Window
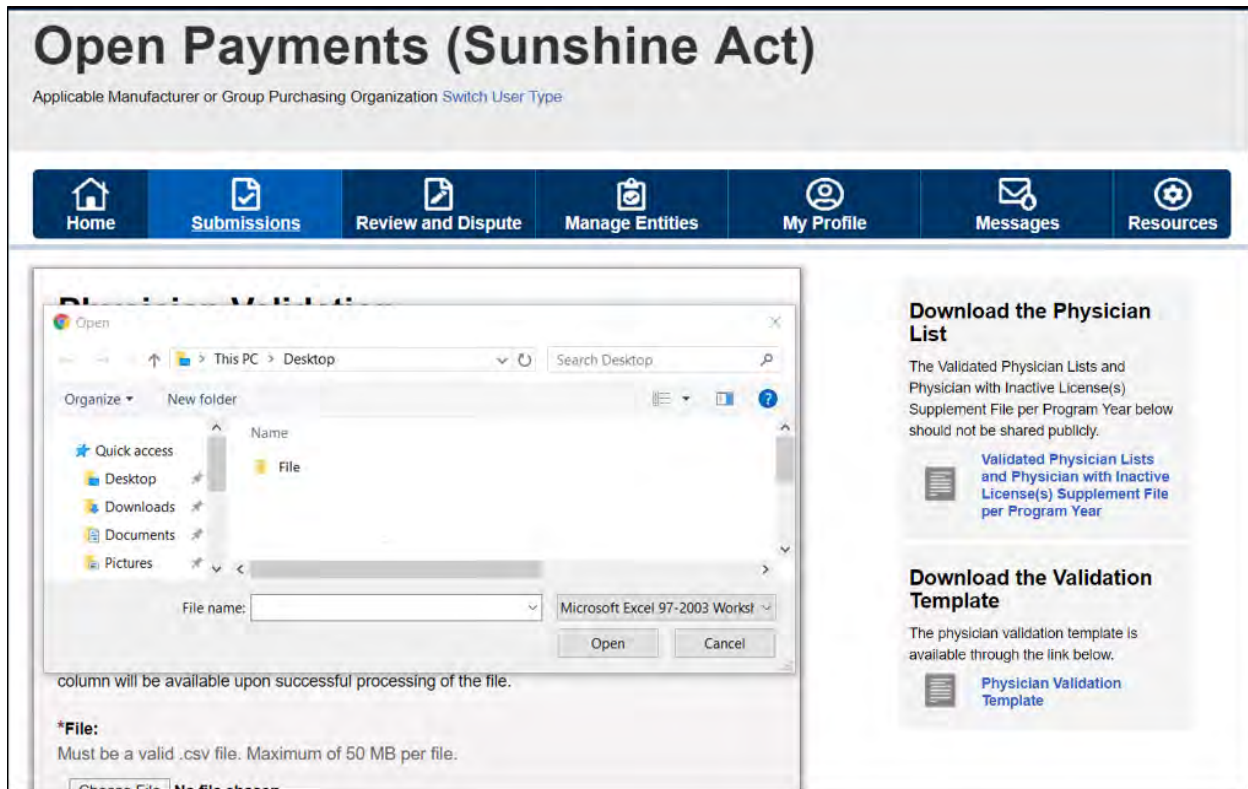
You will receive a confirmation message stating "You have successfully refreshed the page" and you will be able to download a results file. **Note: Selecting the "Cancel" button will cause you to lose all data entered.**

Step 5: Click the "Download" button to download the results file. The result file will include only physician profiles with errors. If the system found a successful match on the entered physician profile then the results file will not include that physician profile. The system will display the results file for 90 days after the upload within the Open Payments system.

Figure 134: Physician Validation with Download Option

Section 4.4: Bulk File Upload

The Open Payments system allows applicable manufacturers and applicable GPOs to submit payments or other transfers of value, and ownership or investment interest information via bulk file uploads. Files can be submitted as an individual entity submitting a single report or as a consolidated report on behalf of multiple entities (see Section 4.12 for information on Consolidated Reporting).

Bulk files may be used to perform four actions:

- Add new records to the Open Payments system (refer to Section 4.4b and 4.4c);

- Change existing records in the Open Payments system (refer to Section 4.8a);

- Delete existing records (refer to Section 4.9); and

- Update the delay in publication status of existing records (refer to Section 4.11).

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

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

Submitted bulk files may not exceed 250MB in size. If the data in your file exceeds that limit, you can split the data into more than one file or compress the CSV file into a ZIP file. A ZIP file containing compressed CSV files must be under 250MB after compression.

While there are no system limitations to the number of data lines or rows that can be included in a file as long as the file size remains below 250MB, it is recommended that bulk files contain no more than 400,000 records, as this is the limit that can be downloaded in the system at any one time.

Note: Applicable GPOs are required to report Ownership/Investment Interest records only if there is a corresponding General/Research Payment record reported for that physician for that program year.

4.4a: Delay Limit Reached
Per the Final Rule, records can only be delayed from publication for 4 years from the year of payment (i.e., the record's program year). As such, records attributed to Program Years 2013, 2014, and 2015, are no longer eligible for a delay in publication, and will be included in the June 2020 publication.

Records that have reached the delay-in-publication limit will have one of two "Delay in Publication" statuses in the Open Payments system. The particular status depends on the rationale given for the delay when it was first requested, either "research and development" or "clinical investigation." Delay in publication status displayed as:

- No Delay - R & D on New Product - Limit Reached

- No Delay - C.I. on New Product - Limit Reached

For program years that have reached the delay limit, users will be prevented from requesting a delay in publication on new or updated records.

Records submitted via bulk file that have a Resubmission File Indicator value of "N" or "Y" (i.e., new records or resubmitted records, respectively) and that request a delay in publication but are not eligible for a delay based on their program year will fail record validation.

When attempting to submit a bulk file, if a user selects the "Renew Delay in Publication" option from the "Resubmission File Indicator" drop-down on the "Upload Payments" page (i.e., indicating all records in the file have a Resubmission File Indicator value of "R"), the system will display an on-screen error message and prevent the file from being uploaded.

4.4b: Creating CSV Files

Bulk upload files for Open Payments data must be CSV (character-separated value) files and built upon sample files/reporting templates provided by Open Payments. A bulk upload file can contain records of only one payment type (General, Research or Ownership and Investment Interest) and must be built using the template for its payment type.

The sample files for all three payment types are available on the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html). The CSV sample files include sample data and show the exact format to be used by reporting entities to upload data in the Open Payments system.

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Figure 135: CMS Open Payments website "Resources" page
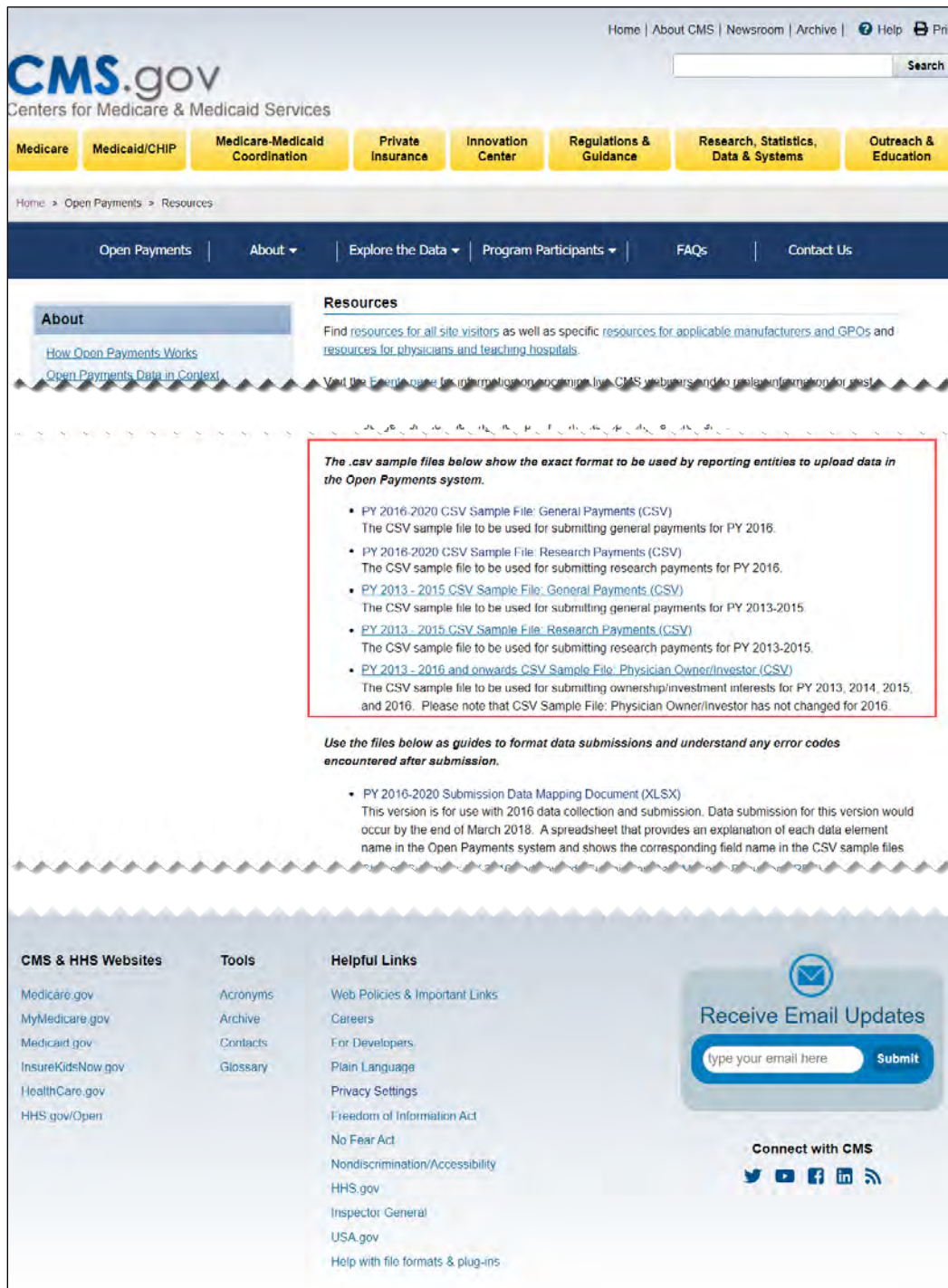
Reporting templates are available within the Open Payments system and can be accessed on the "Resources" tab by users who hold the submitter role. The templates define the exact format and layout of the files accepted in the Open Payments system.

Figure 136: Open Payments system "Resources" tab for submitters displaying available reporting templates

The correct template files must be used for the corresponding reporting category (i.e., general payment records must be in general payments template file format, etc.) and program year. Data entered for the records must conform to the restrictions for the data fields given in the "Submission Data Mapping Documents." The "Submission Data Mapping Documents" are available on the Resources page of the Open Payments website.

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

- **To prepare general payment and research payment records for Program Years 2016-2020**, refer to the guidance in the "PY 2016-2020 Submission Data Mapping Document." The names of the sample files and templates vary depending upon where you locate them:

    o On the "Resources" page of the Open Payments website, the sample files are named "PY 2016-2020 CSV Sample File: General Payments" and "PY 2016-2020 CSV Sample File: Research Payments."

    o On the "Resources" tab within the Open Payments system, the templates are named "PY 2016-2020 CSV Template File: General Payments" and "PY 2016-2020 CSV Template File: Research Payments."

- **To prepare physician owner/investor records for Program Years 2016-2020**, refer to the guidance in the "PY 2016-2020 Submission Data Mapping Document." The names of the sample files and templates vary depending upon where you locate them:

    o On the "Resources" page of the Open Payments website, the sample files are named "PY 2013 - Onwards CSV Sample File: Physician Owner/Investor."

    o On the "Resources" tab within the Open Payments system, the template is named "PY 2016-2020 CSV Template File: Physician Owner/Investor."

- **To prepare payment records of any type from program years before 2016**, refer to the guidance in the "PY 2013-2015 Submission Data Mapping Document." The names of the sample files and templates vary depending upon where you locate them:

    o On the "Resources" page of the Open Payments website, the templates are named "PY 2013-2015 CSV Sample File: General Payments," "PY 2013-2015 CSV Sample File: Research Payments," and "PY 2013 and Onwards CSV Sample File: Physician Owner/Investor."

    o On the "Resources" tab within the Open Payments system, the templates are named "PY 2013 - 2015 CSV Template File: General Payments," "PY 2013 - 2015 CSV Template File: Research Payments," and "PY 2013 and Onwards CSV Template File: Physician Owner/Investor."

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

To create a CSV using Excel on a Windows-based computer, load an applicable CSV sample file downloaded from the Open Payments website. Next, enter required data within the columns, "auto-fit"

the columns to make all data visible to ensure the data is entered correctly, and save the file. Be sure to save the file in the file format of "CSV" (Excel default is either ".XLS" or ".XLSX").

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

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

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

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

4.4c: Bulk File Upload Instructions

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

Figure 137: Open Payments system landing page for returning system users

Step 2: You will be brought to the "Submissions" page. Select the "Bulk File Upload" button to begin the bulk file upload process.

Figure 138: Submission Landing page

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

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

Note: You may only submit one data file at a time. If you have multiple files to upload, repeat the bulk upload process for each file. To upload the file, select the "Submit File to Open Payments" button.

Figure 139: Upload Payments page

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

Figure 140: Confirmation Message on Uploads Payments Page

You will receive an email notification if records did not pass validation or matching, and can subsequently review the errors in the error log. Records that failed validation and/or matching cannot proceed to final submission. You must correct them and resubmit the records. Records that passed validation and matching may trigger warnings relating to expired physician licenses or late submissions. Such records should be reviewed for accuracy, but can proceed to final submission without correction. NOTE: If the physician license information is inactive in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

See Section 4.8 for details on record correction and resubmission.

4.4d: Review File Status page

AM/GPO users with a submitter role may check the status of their file upload from the "Review File Status" page. This page provides a centralized dashboard that allows users to view the status and submission information of files that have been submitted to the system for their associated entities since 01/01/2019. To access the "Review File Status" page, follow the steps below:

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

Figure 141: Open Payments system landing page for returning system users
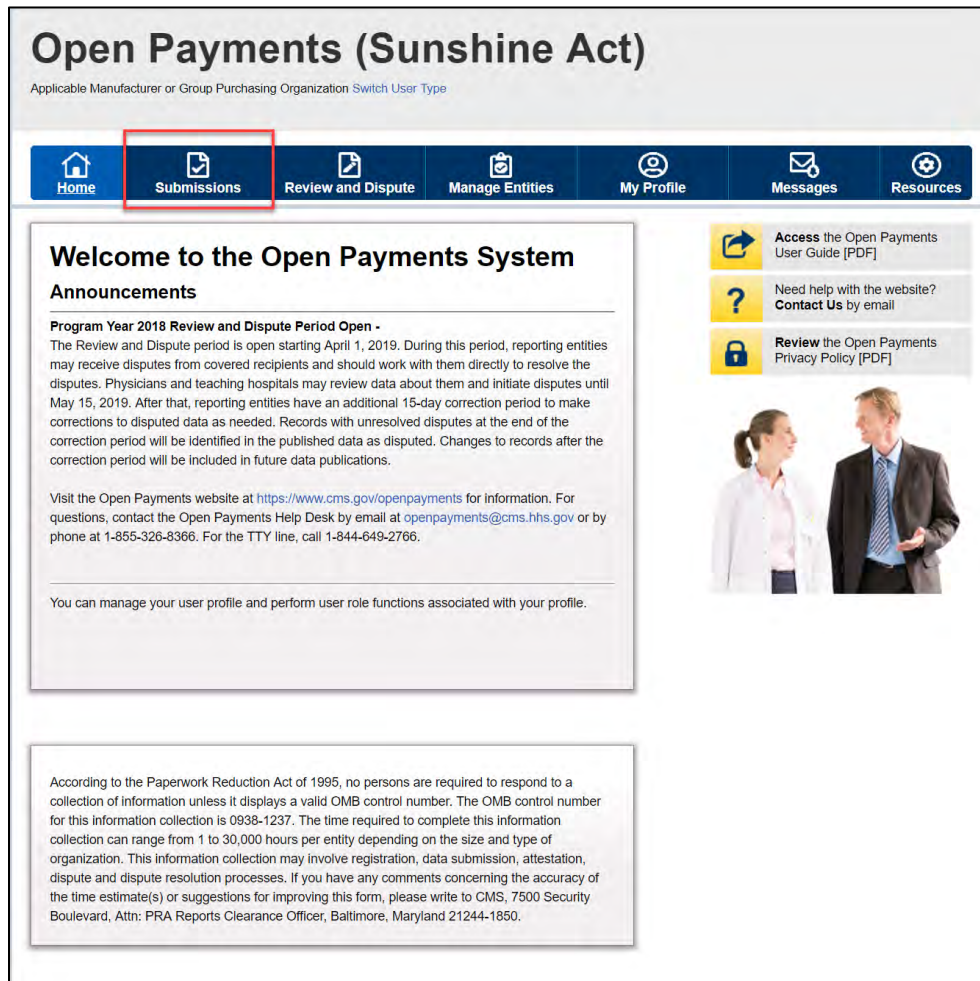
Step 2: You will be brought to the "Submissions" page. Select the "Review File Status" button under the Review Submitted Files(s) Status section. Note: This section is only available for users with a submitter role.

Figure 142: Review File Status Button

On the "Review File Status" page, you may search for files by choosing the file-level search criteria and selecting "Search." The search results will be displayed in the file table on the bottom of the page, and the following information is provided for each file.

- File ID

- File Name

- File Status

- Submitted Date

- Submitted By (i.e. User First Name and Last Name Corresponding to EIDM ID)

- Payment Category

- Program Year

- Submission Type

- Entity

- Deleted Date

- Deleted By (i.e. User First Name and Last Name Corresponding to EIDM ID)

The displayed files may have the following file statuses:

a. **In Process** - The file is being processed by the system.
b. **Rejected** - The file is rejected by the system and user is notified via email. No records were uploaded.
c. **Submitted Successfully** - The file is uploaded successfully.
d. **Submitted with Errors** - The file is uploaded successfully but one or more records in the file are in "Failed Validation" or "Failed Matching" status.
e. **Processed with Warning** - The file contains records with late submission and/or expired license warning. No action is required for records with late submission warnings. Submitters should review the records that triggered an expired license warning. If the information is valid, no action is required and the record can continue through final submission without further updates. If the information is not valid, correct or delete the records.
f. **System Failure Occurred** - There is a hardware failure or an infrastructure issue. The file will not be processed and may have to be re-uploaded once the system is recovered.
g. **Rejected - File Infected** - The virus scan has resulted in an infected file. Re-upload a virus free file.
h. **Deleted -** File was deleted successfully from the system after the user had selected the "Delete File" button.

Figure 143: Review File Status page

Note: To access the Error Log for files "Submitted Successfully", "Submitted with Errors" or "Submitted with Warnings", select the "File ID" link in the File ID column to the left of the payment file you wish to access. The "File ID" link will display the "File ID" page which contains the Error Log. Select the link to the error log on the bottom of the page. You can delete a file using the "Delete File" button.

Figure 144: File ID Home Page

Note: Another way to access the Error Log for files "Submitted Successfully", "Submitted with Errors" or "Submitted with Warnings", is to select the "Back to Submissions" button to return to the "Submissions" page. Under the "Review Submitted Payment Records" select the Entity and Program Year from the drop-downs and select the "Review Records" button. Once on the "Review Records" page select the "View All" under the desired payment category. On the "Payment Category" page, search the "File ID". The "File ID" link will display the "File ID" page that contains the Error Log.

4.4e: Review Records

You may check the status of records that were successfully uploaded at any time via the "Review Records" page.

1. Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/.

2. Select the "Submissions" tab on the menu bar. Under the "Review Submitted Records" section of the page, select the reporting entity and program year of the records to be reviewed, then select the "Review Records" button.

3. The "Review Records" page displays the total number of records in each record status for the program year, sorted by payment category. Record must be in "Ready for Submission" status to undergo Final Submission. Any records that are in "Failed Validation" or "Failed Matching" status must be corrected before they are eligible for "Final Submission".
   Records in the submission process will be in one of the following statuses:
   a. **System Processing** - Records which the Open Payments system is still processing and validating.
   b. **Failed Validation** - Records that did not pass field validation checks.
   c. **Failed Matching** - Records that were not successfully matched to a valid covered recipient.
   d. **Ready for Submission** - Records which are successfully validated and matched, and are ready for final submission.

4. Select the "Refresh Status" button to update the counts for all payment categories. Once the "Refresh Status" button is selected, all other buttons on the "Review Records" page will be disabled until the page has been refreshed and a confirmation message will display when the refresh action is completed.

5. Select the "View All" button next to a payment category to go to the "Payment Category" page and view the individual records for that category.

6. Select the "Record ID" link for an individual record on the "Payment Category" page to view the record details. The "Record ID" page displays the record's error messages including those related to matching, and the expired license warning. In the case of expired license related warnings, a warning icon is also displayed next to the "Record ID" on the Payment Category page.

7. Select the "File ID" link to view details about the submitted file. File Upload Statuses are displayed on the File ID page and on the File Modal:
   a. **Submitted Successfully** - File uploaded successfully.
   b. **Submitted with Errors** - The file is uploaded successfully but one or more records in the file are in "Failed Validation" or "Failed Matching" status.
   c. **Processed With Warning** - File contains records with late submission and/or expired license warnings. Users should review the warnings that are issued. No action is required for late submission warnings, however the user should determine if corrections or deletions are required for records with an expired license warning. If it is confirmed that the information is valid, the record can continue through final submission without further updates. Associated Error Log file displays specific warning message(s).
      NOTE: If the physician license information is inactive in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

Take note that once the data has been uploaded to the system and undergone these checks, it still must undergo the final submission process in the Open Payments system. Performing bulk file upload only **uploads** the file and checks each record to ensure that it adheres to a valid data format and matching requirements. **You must complete the final submission and attestation process for the data to be considered reported.** See Section 4.10 for details on final submission and Section 4.14 for details on attestation.

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

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

The Open Payments system provides the ability to enter information regarding individual payments or other transfers of value through an online interface.

The "Submission Data Mapping Documents," available on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html, provide guidance and descriptions on each of the fields that will be entered during the manual data entry process. There are two versions of the Submission Data Mapping document, one for Program Years 2013-2015, and one for Program Years 2016-2020. Both are available on the Resources page. Have the appropriate version of this document available during manual entry for reference.

Note: The Open Payments program requires group purchasing organizations (GPOs) to report physician Ownership/Investment Interest if there is a General/Research payment reported for that physician and program year

GPO users can access a report that identifies physicians on General/Research Payment records that are missing attested Ownership/Investment Interest record for the same program year. See section 4.7c for more details on the report.

You can manually enter one record at a time. The manual entry process will differ slightly depending on the type of payment you are reporting. The process for all three payment types is outlined below. Repeat the steps below for each payment that must be reported. Note that an "Add" button is available in several places during the Manual Data Entry process. You must select the "Add" button to save entered information in those places. If you proceed without selecting "Add," the information you entered will not be saved and the system will not allow you to continue the data entry process.

Note: Manual data entry does not complete the submission process. Once a record is manually entered, it will be subject to the matching process for validation of the covered recipient information. Once this process is successful, the record(s) must then undergo final submission and attestation (Section 4.10) for the submission to be complete.

Note that the steps provided below assume that a user is entering the data in a consecutive manner, however, users are able to utilize the "Payment Navigation Bar", located on top of the record, to go directly to a specific page, assuming there are no errors on the page they are currently on.

4.5a: Manual Entry of General Payments Data

To enter general payments data manually, follow these steps:

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

Figure 145: Open Payments system landing page for returning system users

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

Figure 146: Manual Data Entry Button

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Step 3: On the "Add payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year for the record to be entered.

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

Select the "Continue" button to proceed to the "Covered Recipient Demographic Information" page.

Figure 147: Add Payment Page

Step 4: On the "Covered Recipient Demographic Information" page, select the Covered Recipient Type: Physician or Teaching Hospital.

The next steps will differ depending on the Covered Recipient Type selected.

Step 4a: **For Teaching Hospitals**: Enter information as requested on the page. Required fields are marked with asterisks.

For complete and accurate identifying information for a teaching hospital, refer to the CMS Teaching Hospital Lists. These lists, vetted and compiled by CMS, contain identifying information for teaching hospitals and are updated annually. Refer to the Teaching Hospital List of the same year as the program year of the record.

Teaching Hospital Lists can be accessed from the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html.

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

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

When you have entered all of your information, select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to "Associated Related Products" page.

Figure 148: Covered Recipient Demographic Information page

Step 4b: **For Physician**: Enter information as requested on the page below. Required fields are marked with asterisks. Consult the Validated Physician List (VPL), downloadable from the "Submissions" tab, to confirm the identifying information for the physician.

To fill in the taxonomy code value, refer to the taxonomy code list 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 cannot be entered. If the physician's taxonomy code is not available, select the code that most closely represents the physician's specialty.

To add the physician's license information, select the state in which the license is held and enter the license number. The license number field may contain up to 25 characters, including special characters such as hyphens (-). When done, select the "Add" button. If you input data into the license fields and select the "Continue" button before selecting the "Add" button, the system will throw an error message. To proceed, either select the "Add" button or clear the information from the license field. If the physician has licenses in more than one state, enter in one state and license number and then select the "Add" button. This will add the information to the record and open up another set of license fields. Repeat until all of the physician's state licenses have been added. You can enter up to five licenses. NOTE: If the physician license information is inactive in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

When you have entered all of your information, select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to "Associated Related Products" page.

Figure 149: Covered Recipient Demographic Information page

Step 5: On the "Associated Related Products" page, enter the associated drugs, biologicals, devices, or medical supplies, if applicable, to the record.

This process varies depending upon the program year of the record.

For Program Years 2016-2020:

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

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

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

Figure 150: Associated Related Products page for Program Years 2016-2020

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

Figure 151: Associated Related Products page for Program Years 2016-2020

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

- "Covered" is to be used when reporting only payments or other transfers of value related to covered drugs, biologicals, devices, or medical supplies.

- "Non-Covered" is to be used when reporting payments or other transfers of value related to only non-covered drugs, biologicals, devices, or medical supplies.

In the "Indicate Drug, Device, Biological, or Medical Supply" drop-down, select the appropriate value. Enter the appropriate information in the "Product Category or Therapeutic Area" and the "Marketed Name of Drug, Device, Biological, or Medical Supply" text fields.

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

- 9999-9999-99

- 99999-999-99

- 99999-9999-9

NDCs entered that do not match one of these three formats or contain all zeroes will not be accepted. NDCs can be found on the U.S. Food and Drug Administration's website at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm.The Drug Name and National Drug Code (NDC) reference file and PDF Instructions document are zipped together and are available within the Open Payments system Resources tab.

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

Figure 152: Add Button on the Add General Payment Page

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

Figure 153: Add Button on the Associated Related Products page for Program Years 2016-2020

Open Payments (Sunshine Act)

Applicable Manufacturer or Group Purchasing Organization Switch User Type

| Home | Submissions | Review and Dispute | Manage Entities | My Profile | Messages | Resources |

Add General Payment

User Guide

| Overview | Covered Recipient Demographics | Products | Payments | General Information | Review & Save |

Associated Related Products

A field with an asterisk (*) is required.

Select "Yes" or "No" from the Related Product Indicator drop-down list. If "Yes" is selected, enter the applicable information for the associated covered drugs, devices, biologicals, or medical supplies. Select "Add" after completing each entry. At least one product must be added if the Related Product Indicator value is set to "Yes". You may enter up to five drugs, biologicals, devices, or medical supplies for each record.

To download the list of Drug Name & National Drug Codes (NDC) and instruction document, see the Resources tab.

*Related Product Indicator:

Yes ▼

Associated Drug, Device, Biological, or Medical Supply Information

Covered or Non-Covered Product Indicator:	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic Area:	Marketed Name of Drug, Device, Biological, or Medical Supply:	Associated Drug or Biological NDC:	Actions:	
Covered	Drug	Therapeutic	Biological 1		Edit	Delete

Add

Cancel   Back   Continue

Contact Us   Privacy Policy

Figure 154: Enter Additional Associated Related Product Information

If you need to correct or delete the product information after adding it, select the "Edit" or "Delete" buttons in the table of saved products. Once you have saved all products (maximum five) into the record, select the "Continue" button or the "Payments" icon on the "Payment Navigation Bar" to proceed to the "General Payment or Other Transfer of Value Information" page, the system will generate the warning message if the reported drug or biological data does not match with the CMS approved Drug Name and NDC data set.

The following validations are performed and the submitter receives a warning accordingly:

- The Drug or Biological Name entered by the user is valid against the CMS approved data set.

- The Drug or Biological Name and NDC combination is valid (if NDC provided) against the CMS approved dataset.

Select "Yes" to proceed without correcting the warning or "No" to go back and correct the warning. You can continue with record submission without fixing the warning.

Figure 155: Drug Information Validation Warning Message
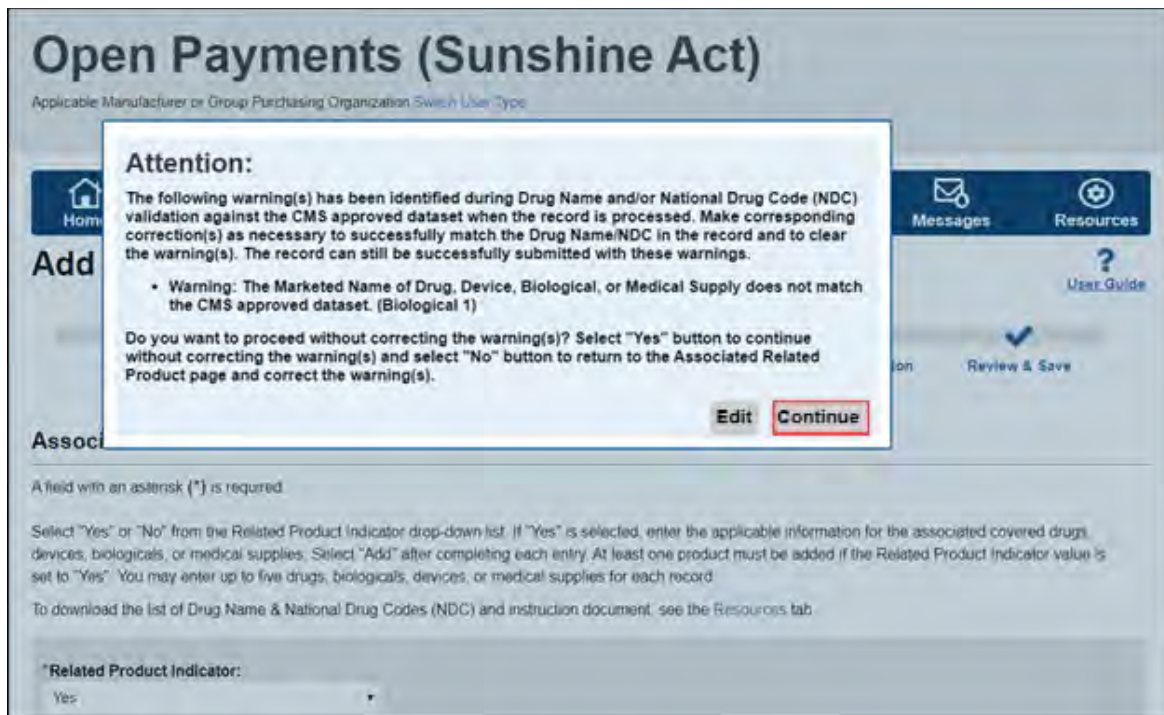
If there are no warnings upon selecting the "Continue" button or the "Payments" icon, or if you select "Continue" in the warning message to continue without correcting the warning generated, you can proceed to the "General Payment or Other Transfer of Value Information" page.

Figure 156: Edit and Delete Button for Associated Related Product Information

Open Payments (Sunshine Act)

Applicable Manufacturer or Group Purchasing Organization Switch User Type

Home	Submissions	Review and Dispute	Manage Entities	My Profile	Messages	Resources

Add General Payment

? User Guide

Overview	Covered Recipient Demographics	Products	Payments	General Information	Review & Save

Associated Related Products

A field with an asterisk (*) is required.

Select "Yes" or "No" from the Related Product Indicator drop-down list. If "Yes" is selected, enter the applicable information for the associated covered drugs, devices, biologicals, or medical supplies. Select "Add" after completing each entry. At least one product must be added if the Related Product Indicator value is set to "Yes". You may enter up to five drugs, biologicals, devices, or medical supplies for each record.

To download the list of Drug Name & National Drug Codes (NDC) and instruction document, see the Resources tab.

*Related Product Indicator:
Yes ▼

Associated Drug, Device, Biological, or Medical Supply Information

Covered or Non-Covered Product Indicator:	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic Area:	Marketed Name of Drug, Device, Biological, or Medical Supply:	Associated Drug or Biological NDC:	Actions:
Covered	Drug	Therapeutic	Biological 1		Edit Delete

Associated Drug, Device, Biological, or Medical Supply Information

*Covered or Non-Covered Product Indicator:
Covered ▼

*Indicate Drug, Device, Biological, or Medical Supply:
Device ▼

*Product Category or Therapeutic Area:
Cardiology

Marketed Name of Drug, Device, Biological, or Medical Supply:
Pacemaker

Associated Drug or Biological NDC:
9999-9999-99 **OR** 99999-999-99 **OR** 99999-9999-9 ❓

Cancel Product   Add

Cancel   Back   Continue

Contact Us   Privacy Policy

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For Program Years 2013-2015:

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

1. "Covered" is to be used when reporting only payments or other transfers of value related to covered drugs, biologicals, devices, or medical supplies.
2. "Non-Covered" is to be used when reporting payments or other transfers of value related to only non-covered drugs, biologicals, devices, or medical supplies.
3. "None" is to be used when the reported payment was not made in relation to a drug, biological, device, or medical supply.
4. "Combination" is to be used when reporting payments or other transfers of value related to a combination of both covered and non-covered drugs, biologicals, devices, or medical supplies.

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

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

- 9999-9999-99

- 99999-999-99

- 99999-9999-9

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

Select the "Continue" button or the "Payments" icon on the "Payment Navigation Bar" to proceed to the "General Payment or Other Transfer of Value Information" page. The system will generate the warning message if the reported drug or biological data does not match with the CMS approved Drug Name and NDC data set.

The following validations are performed and the submitter receives a warning accordingly:

- The Drug or Biological Name entered by the user is valid against the CMS approved data set.

- The Drug or Biological Name and NDC combination is valid (if NDC provided) against the CMS approved dataset.

Select "Yes" to proceed without correcting the warning or "No" to go back and correct the warning. You can continue with record submission without fixing the warning.

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Figure 157: Drug Information Validation Warning Message
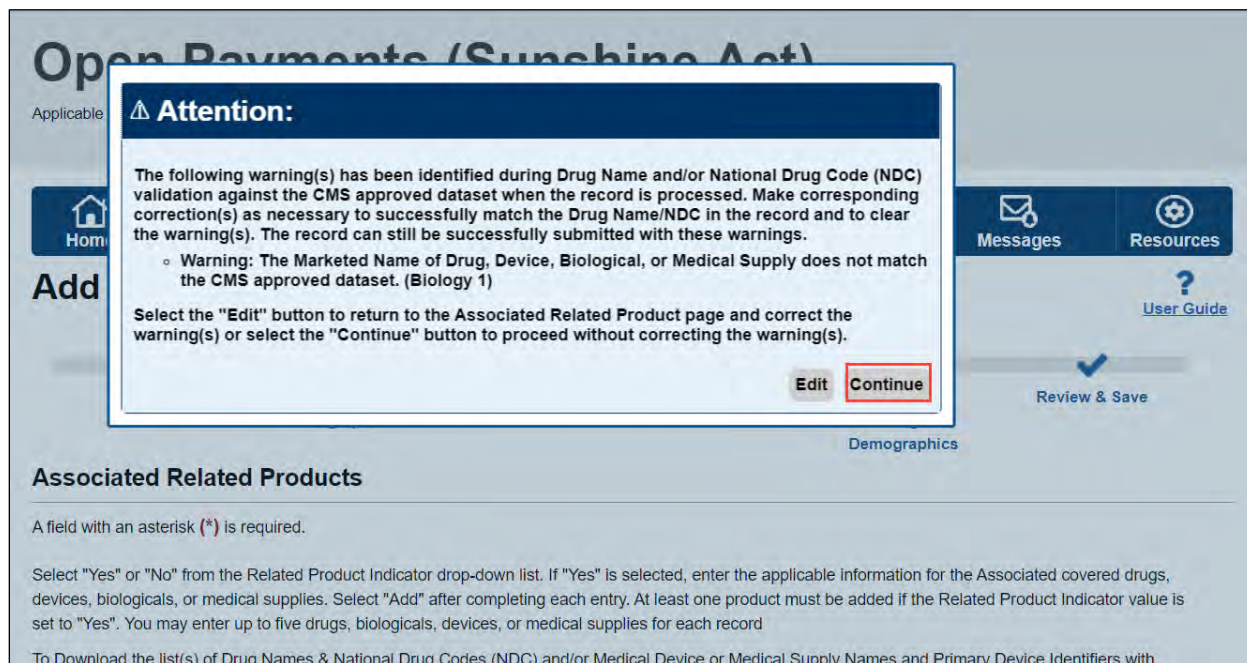
If there are no warnings upon selecting "Continue" button or the "Payments" icon or if you select "Continue" in the warning message to continue without correcting the warning generated then you can proceed to the "General Payment or Other Transfer of Value Information" page.

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

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

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

Once all information is entered, select the "Continue" button or the "Payments" icon on the "Payment Navigation Bar" to proceed to the "General Payment or Other Transfer of Value Information" page.

Figure 158: Product Indicator Drop-Down Field

Select the "Continue" button or the "Payments" icon on the "Payment Navigation Bar" to proceed to the "General Payment or Other Transfer of Value Information" page. The system will generate the warning message if the reported drug or biological data does not match with the CMS approved Drug Name and NDC data set.

The following validations are performed and the submitter receives a warning accordingly:

- The Drug or Biological Name entered by the user is valid against the CMS approved data set.

- The Drug or Biological Name and NDC combination is valid (if NDC provided) against the CMS approved dataset.

Select "Yes" to proceed without correcting the warning or "No" to go back and correct the warning. You can continue with record submission without fixing the warning.

Figure 159: Drug Information Validation Warning Message
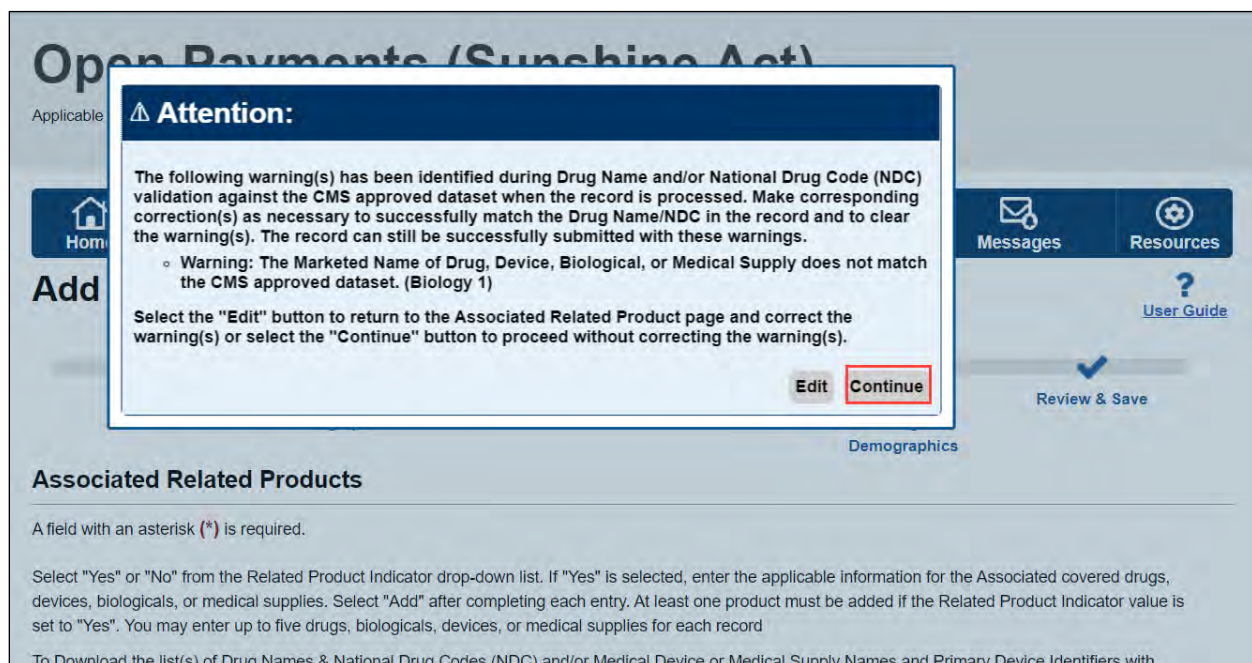
If there are no warnings upon selecting the "Continue" button or the "Payments" icon, or if you select "Continue" in the warning message to continue without correcting the warning generated, you can proceed to the "General Payment or Other Transfer of Value Information" page.

Step 6: Enter payment information in the required fields on the General Payment or Other Transfer of Value Information page: Total Amount of Payment, Date of Payment, Number of Payments Included in Total Amount, Form of Payment or Transfer of Value, and Nature of Payment or Transfer of Value. If "Travel and Lodging" is selected for Nature of Payment or Transfer of Value, select a Country of Travel and enter a City of Travel.

Note that only positive dollar values are allowed when reporting payment amounts; negative dollar values and zeroes are not permitted.

Once all information is entered, select the "Continue" button or the "General Information" icon on the "Payment Navigation Bar" to proceed to the "General Record Information" page.

Figure 160: General Payment or Other Transfer of Value Information Page

Step 7: Enter all required information on the "General Record Information" page.

If the "Delay in Publication of Research Payment Indicator" field is set to request a delay in publication, the "Contextual Information" text box must include the name of the relevant research study. The "Contextual Information" text box is a free-form text field where you can enter any information you deem helpful or appropriate regarding the payment or other transfers of value. The text field has a limit of 500 characters. All special characters found on a standard U.S. keyboard can be used in the text box, not including ALT+NUMPAD ASCII Key characters.

- Users may request a delay in publication, if the payment meets certain conditions.

- Note: Per the Final Rule, records can only be delayed from publication for up to 4 years from the year of payment (i.e., the record's program year); records attributed to the Program Year 2013, 2014, and 2015, are no longer eligible for a delay in publication in calendar year 2020.

- If a delay is requested for an ineligible record, the system will not accept the record and will display an error message.

Select the "Continue to Review" button or the "Review & Save" icon on the "Payment Navigation Bar" to proceed to the "Review and Save" page to proceed.

Figure 161: Continue to Review Button on General Records Information Page

Step 8: Review the payment information entered in the previous pages on the Review and Save page. If necessary, select the "Back" button at the bottom of the page to go back and edit information. Users can also select an icon from Payment Navigation Bar, located on top of the page, to go directly to the desired page. Once the record is accurate, select the "Save Record" button to continue.

Figure 162: Review and Save page

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

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Figure 163: Record Saved Successfully page

Take note that once the data has been uploaded to the system and undergone all checks including matching validations, it still must go through the Final Submission process in the Open Payments system. Manual data entry only uploads the record and checks it to ensure that it adheres to a valid data format and matching requirements. **You must complete the final submission and attestation process for the data to be considered reported.** See Section 4.10 for details on final submission and Section 4.14 for details on attestation.

4.5b: Manual Entry of Research Payments

To enter research payment data manually, follow these steps:

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

Figure 164: Open Payments system landing page for returning system users

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

Figure 165: Manual Data Entry Button on Submissions Landing Page

Step 3: On the "Add Payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year. You may enter the Home System Payment ID (if applicable) of the record you will submit. The Home System Payment ID is the identifier associated with the payment transaction in your home system.

Select the "Continue" button to proceed.

Figure 166: Add Payment Page

Step 4: On the "Recipient Demographic Information" page, select the Recipient Type: Covered Recipient Physician, Covered Recipient Teaching Hospital, Non-Covered Recipient Entity, or Non-Covered Recipient Individual. The next steps will differ depending on the Recipient Type selected.

Step 4a: **For Covered Recipient Teaching Hospital**: Enter information as requested on the page. Required fields are marked with asterisks.

For complete and accurate identifying information for a teaching hospital, refer to the CMS Teaching Hospital Lists. These lists, vetted and compiled by CMS, contain identifying information for teaching hospitals and are updated annually. Refer to the Teaching Hospital List of the same year as the program year of the record.

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

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

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

When you have entered all of your information, select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to the "Associated Related Products" page.

Figure 167: Recipient Type Drop-Down for Teaching Hospital

Step 4b: **For Covered Recipient Physician**: Enter information as requested on the page below. Required fields are marked with asterisks. Consult the Validated Physician List (VPL), downloadable from the "Submissions" tab, to confirm the identifying information for the physician.

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

To add the physician's license information, select the state in which the license is held and enter the license number. The license number field may contain up to 25 characters, including special characters such as hyphens (-). When done, select the "Add" button. If you input data into the license fields and select the "Continue" button before selecting the "Add" button, the system will throw an error message. To proceed, either select the "Add" button or clear the information from the license field. If the physician has licenses in more than one state, enter in one state and license number and then select the "Add" button. This will add the information to the record and open up another set of license fields. Repeat until all of the physician's state licenses have been added. You can enter up to five licenses. NOTE: If the physician license information is inactive in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching. When you have entered all of your information, select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to the "Associated Related Products" page.

Figure 168: Recipient Type Drop-Down for Physician

Step 4c: For **Non-Covered Recipient Entity**: Enter information as requested on the page below. Required fields are marked with asterisks. Select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to the "Associated Related Products" page.

Figure 169: Recipient Type Drop-Down for Entity

Step 4d: For **Non-Covered Recipient Individual**: Make the appropriate selection from the drop-down on the "Recipient Demographic Information" page and select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to the "Associated Related Products" page.

Figure 170: Product page for Recipient Type

Step 5: On the "Associated Related Products" page, enter the associated drugs, biologicals, devices, or medical supplies, if applicable, to the record.

This process varies depending upon the program year of the record.

For Program Years 2016-2020:

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

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

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

Figure 171: Related Product Indicator Drop-Down

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

Figure 172: Input Fields for Related Product Indicator

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

- "Covered" is to be used when reporting only payments or other transfers of value related to covered drugs, biologicals, devices, or medical supplies.

- "Non-Covered" is to be used when reporting payments or other transfers of value related to only non-covered drugs, biologicals, devices, or medical supplies.

In the "Indicate Drug, Device, Biological, or Medical Supply" drop-down, select the appropriate value. Enter the appropriate information in the "Product Category or Therapeutic Area" and the "Marketed Name of Drug, Device, Biological, or Medical Supply" text fields.

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

- 9999-9999-99

- 99999-999-99

- 99999-9999-9

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

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

The system will generate the warning message if the reported drug or biological data does not match with the CMS approved Drug Name and NDC data set.

The following validations are performed and the submitter receives a warning accordingly:

- The Drug or Biological Name entered by the user is valid against the CMS approved data set.

- The Drug or Biological Name and NDC combination is valid (if NDC provided) against the CMS approved dataset.

Select "Yes" to proceed without correcting the warning or "No" to go back and correct the warning. You can continue with record submission without fixing the warning.

Figure 173: Drug Information Validation Warning Message

If there are no warnings upon selecting the "Continue" button or the "Payments" icon or if you select "Continue" in the warning message to continue without correcting the warning generated then you can proceed to the "General Payment or Other Transfer of Value Information" page.

Figure 174: Add Button for Associated Related Products Page

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

Figure 175: Add Button for Additional Associated Product

Figure 176: Input Fields for Additional Associated Related Product

The Open Payments System will verify the submitted drug data against an FDA reference dataset to ensure that valid national drug codes (NDCs) and names are provided for related drugs and that the reported combination of drug name and NDC is valid. In the case where the marketed name of the drug, biological, or medical, supply does not match the CMS approved data sheet, a warning message will appear stating the warning message. The system is enhanced to validate the Drug or Biological information against the CMS approved Drug and National Drug Code (NDC) dataset and provide a warning message when the submitter submits invalid data for a related product information on a general and/or research payment record that is submitted.

The following validations are performed and the submitter receives a warning accordingly:

- The Drug or Biological Name entered by the user is valid against the CMS approved data set.

- The Drug or Biological Name and NDC combination is valid (if NDC provided) against the CMS approved dataset.

For Program Years 2016-2020, the warning message is generated after the user is done with adding multiple drugs and then selects continue.

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

Once you have saved all products (maximum five) into the record, select the "Continue" button or the "Payments" icon on the "Payment Navigation Bar" to proceed to the "Research Payment or Other Transfer of Value Information" page.

Figure 177: Edit and Delete Button for Associated Related Product Page

Open Payments (Sunshine Act)

Applicable Manufacturer or Group Purchasing Organization Switch User Type

Home	Submissions	Review and Dispute	Manage Entities	My Profile	Messages	Resources

Add Research Payment

? User Guide

Overview	Recipient Demographics	Products	Payments	Principal Investigator Demographics	Review & Save

Associated Related Products

A field with an asterisk (*) is required.

Select "Yes" or "No" from the Related Product Indicator drop-down list. If "Yes" is selected, enter the applicable information for the associated covered drugs, devices, biologicals, or medical supplies. Select "Add" after completing each entry. At least one product must be added if the Related Product Indicator value is set to "Yes". You may enter up to five drugs, biologicals, devices, or medical supplies for each record.

To download the list of Drug Name & National Drug Codes (NDC) and instruction document, see the Resources tab.

*Related Product Indicator:

Yes ▼

Associated Drug, Device, Biological, or Medical Supply Information

Covered or Non-Covered Product Indicator:	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic Area:	Marketed Name of Drug, Device, Biological, or Medical Supply:	Associated Drug or Biological NDC:	Actions:
Covered	Device	Therapeutic Area 1	Biological 1		Edit Delete

Associated Drug, Device, Biological, or Medical Supply Information

*Covered or Non-Covered Product Indicator:

Please Select ▼

Indicate Drug, Device, Biological, or Medical Supply:

Please Select ▼

Product Category or Therapeutic Area:

Marketed Name of Drug, Device, Biological, or Medical Supply:

Associated Drug or Biological NDC:
9999-9999-99 OR 99999-999-99 OR 99999-9999-9

Cancel Product

Add

Cancel

Back   Continue

Contact Us   Privacy Policy

For Program Years 2013-2015:

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

- "Covered" is to be used when reporting only payments or other transfers of value related to covered drugs, biologicals, devices, or medical supplies.

- "Non-Covered" is to be used when reporting payments or other transfers of value related to only non-covered drugs, biologicals, devices, or medical supplies.

- "None" is to be used when the reported payment was not made in relation to a drug, biological, device, or medical supply.

- "Combination" is to be used when reporting payments or other transfers of value related to a combination of both covered and non-covered drugs, biologicals, devices, or medical supplies.

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

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

- 9999-9999-99

- 99999-999-99

- 99999-9999-9

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

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

The Open Payments System will verify submitted drug data against an FDA reference dataset to ensure that valid national drug codes (NDCs) and names are provided for related drugs and that the reported combination of drug name and NDC is valid. In the case where the marketed name of the drug, biological, or medical, supply does not match the CMS approved data sheet, a warning message will appear stating the warning message. The system is enhanced to validate the Drug or Biological information against the CMS approved Drug and National Drug Code (NDC) dataset and provide a warning message when the submitter submits invalid data for a related product information on a general and/or research payment record that is submitted.

The following validations are performed and the submitter receives a warning accordingly:

- The Drug or Biological Name entered by the user is valid against the CMS approved data set.

- The Drug or Biological Name and NDC combination is valid (if NDC provided) against the CMS approved dataset.

For Program Years 2016-2020, the warning message is generated after user is done with adding multiple drugs and then selects continue.

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

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

Once all information is entered, select the "Continue" button or the "Payments" icon on the "Payment Navigation Bar" to proceed to the "Research Payment or Other Transfer of Value Information" page.

Figure 178: Continue Button for Associated Related Product Page

In the case where the marketed name of the drug, biological, or medical, supply does not match the CMS approved data sheet, a warning message will appear stating the warning message. The system is enhanced to validate the Drug or Biological information against the CMS approved Drug and National Drug Code (NDC) dataset and provide a warning message when the submitter submits invalid data for a related product information on a general and/or research payment record is submitted.

The following validations are performed and the submitter receives a warning accordingly:

- The Drug or Biological Name entered by the user is valid against the CMS approved data set.

- The Drug or Biological Name and NDC combination is valid (if NDC provided) against the CMS approved dataset.

Select "Continue" in the warning message to proceed without correcting the warning or "Edit" in the warning message to go back and correct the warning. You can continue with the record submission without fixing the warning.

Figure 179: Drug Information Validation Warning Message
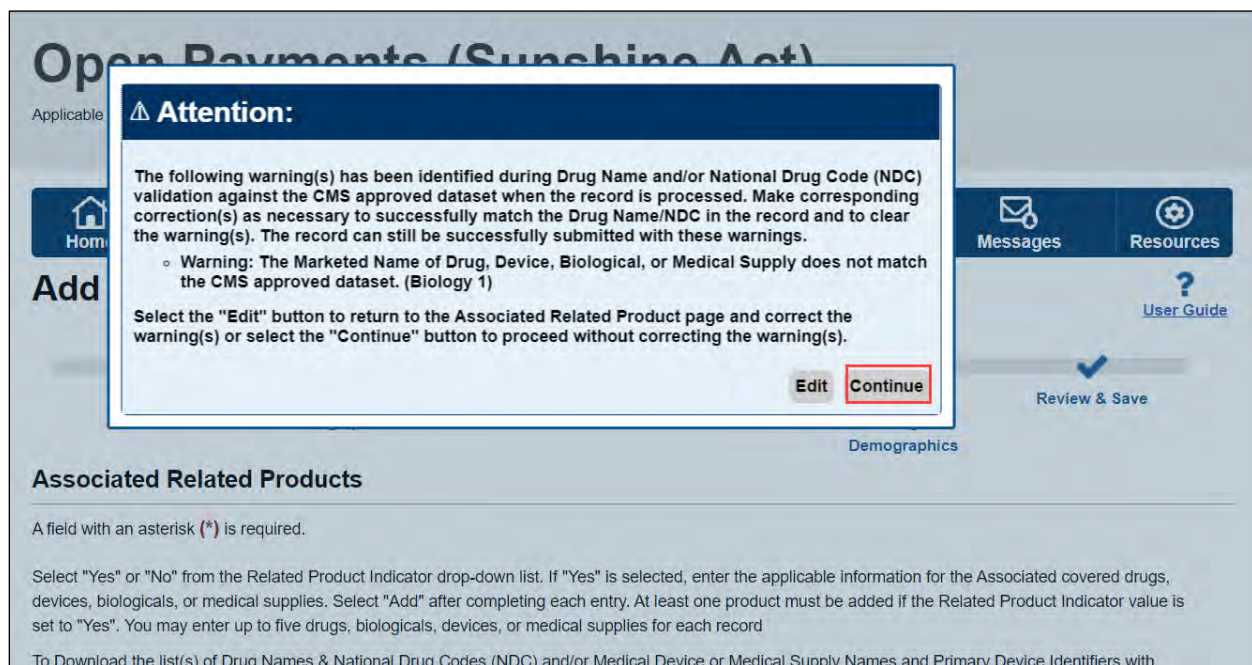
Step 6: Enter all required information on the "Research Payment or Other Transfer of Value Information" page. Note that only positive dollar values are allowed when reporting payment amounts. Negative dollar values or zeroes are not permitted.

If users wish to request a delay in public reporting of that payment, they can request a delay in the "Delay in Publication of Research Payment Indicator" by selecting one of the following from the drop-down values:

- R&D on New Product

- Clinical Investigation on New Product

Note: Per the Final Rule, records can only be delayed from publication for up to 4 years from the year of payment (i.e., the record's program year); records attributed to the Program Year 2013, 2014, and 2015, are no longer eligible for a delay in publication in calendar year 2020.

If a delay is requested for an ineligible record, the system will not accept the record and will display an error message.

Select the "Continue" button or the "Principal Investigator Demographics" icon on the "Payment Navigation Bar" to proceed to "Principal Investigator Demographic" page.

Figure 180: Add Research Payment Page

Step 7: If the record has one or more physician principal investigators associated with it, select "Yes" from the "Principal Investigator Covered Recipient Physician Indicator" drop-down box on the "Principal Investigator Demographic" page. The screen will expand to provide fields for entering identifying information for one principal investigator. Provide the required information for one covered recipient, then select "Add Principal Investigator" to add that individual to the record. If the "Continue to Review" button or the "Review & Save" icon on the "Payments Navigation Bar" is selected before selecting the "Add Principal Investigator" button, the system will throw an error message. Up to five principal investigator covered recipients can be added.

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

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

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

The rules for principal investigator input varies based upon the type of recipient on the record (Covered Recipient Physician, Covered Recipient Teaching Hospital, Non-Covered Recipient Entity, or Non-Covered Recipient Individual):

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

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

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

Once all information is entered, select the "Continue to Review" button or the "Review & Save" icon on the "Payment Navigation Bar" to proceed to the "Review and Save" page.

Figure 181: Principal Investigator Demographic Page

Step 8: Review the payment information entered in the previous pages on the "Review and Save" page. If necessary select the "Back" button at the bottom of the page to go back and edit information. Users can also select an icon from the "Payment Navigation Bar", located on top of the page, to go directly to the desired page. Once the record is accurate, select the "Save Record" button to continue.

Figure 182: Review and Save Page

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

Figure 183: Record Saved Successfully Page
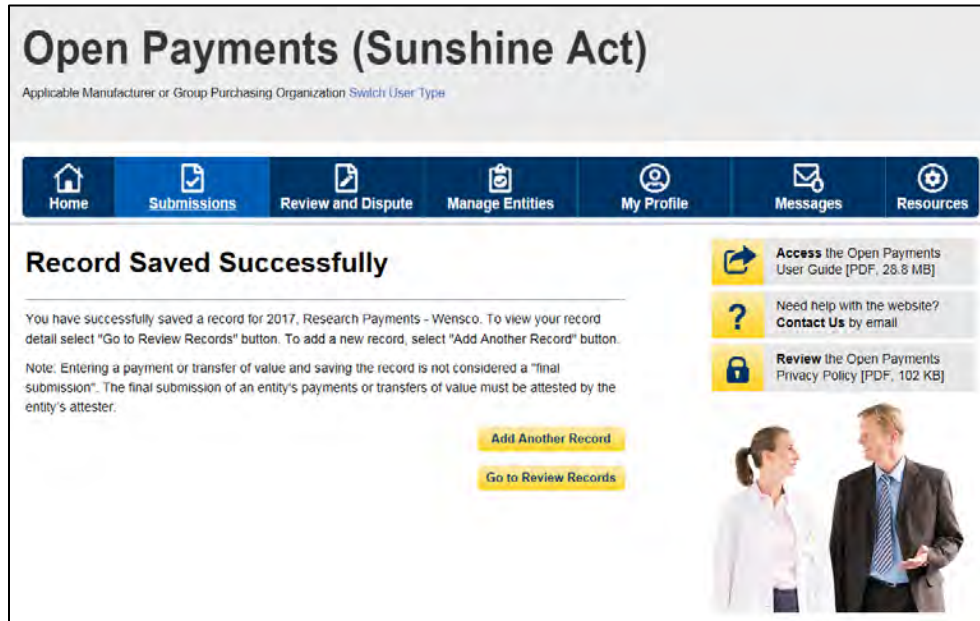
Take note that once the data has been uploaded to the system and undergone all checks including matching validations, it still must go through the Final Submission process in the Open Payments system. Manual data entry only uploads the record and checks it to ensure that it adheres to a valid data format and matching requirements. **You must complete the final submission and attestation process for the data to be considered reported.** See Section 4.10 for details on final submission and Section 4.14 for details on attestation.

4.5c: Manual Entry of Ownership/Investment Interests Payments

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

Note: Group Purchasing Organizations (GPOs) must report Ownership/Investment Interest Payments only if there is a corresponding General/Research Payment reported for that physician in that program year.

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

Figure 184: Submissions Tab for Open Payments system landing page for returning system users
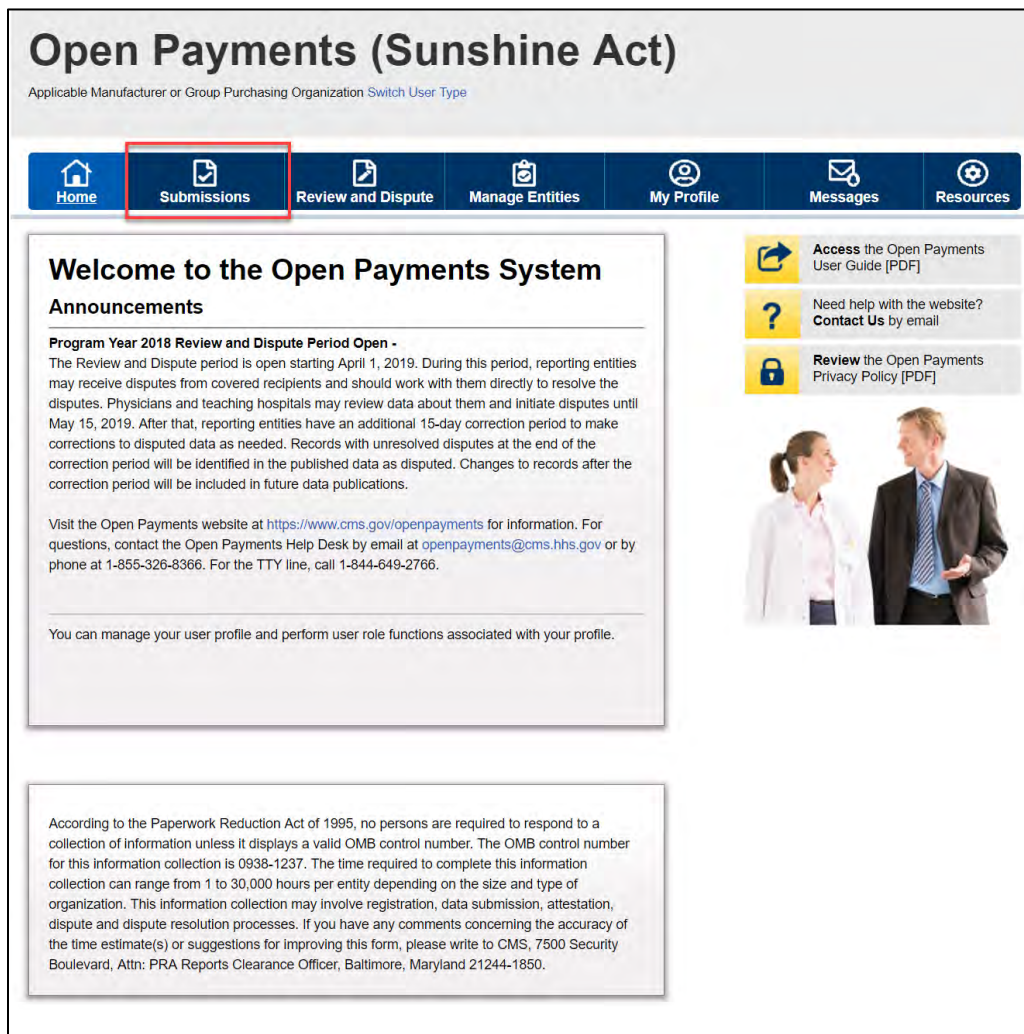
Step 2: Select the "Manual Data Entry" button from the "Submissions" page.

Figure 185: Manual Data Entry Button

Step 3: On the "Add Payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year. You may enter the Home System Payment ID (if applicable) of the record you will submit. The Home System Payment ID is the identifier associated with the payment transaction in your home system.

Select the "Continue" button to proceed.

Figure 186: Add Payment page displaying Payment Category

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

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

To add the physician's license information, select "Add License" and enter the state in which the license is held and the license number. The license number field may contain up to 25 characters, including special characters such as hyphens (-). When done, select "Add License." If you input data into the field and select "Continue" before selecting "Add License," the system will throw an error message. To proceed, either select "Add License" or clear the information from the license field. If the physician has licenses in more than one state, enter in one state and license number and then select "Add License." This will add the information to the record and open up another set of license fields. Repeat until all of the physician's state licenses have been added. You can enter up to five licenses. NOTE: If the physician license information is inactive in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

Select the "Continue" button or the "Ownership or Investment Information" icon on the "Payment Navigation Bar" to proceed to the "Ownership or Investment Information" page.

Figure 187: Physician Demographic Information page

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

Figure 188: Continue Button for Physician Demographic Information page

 Step 5: Enter the ownership or investment interest information. Required fields are marked with asterisks.

Note that the total sum of the payment must exceed zero dollars. Correspondingly, either the "Dollar Amount Invested" or "Value of Interest" fields must have an amount greater than 0.00. The "Terms of Interest" field must contain a description of any applicable terms of the ownership or investment interests. When reporting the terms of any ownership or investment interests, provide the type of ownership or investment interests, including but not limited to stock, stock options, partnership shares, loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion of that property or revenue. The field is a free-form text field, with a 500-character maximum. All special characters found on a standard U.S. keyboard can be used in the text box, not including ALT+NUMPAD ASCII Key characters.

Once all information is entered, select the "Continue to Review" button or the "Review & Save" icon on the "Payment Navigation Bar" to proceed to the "Review and Save" page.

Figure 189: Continue to Review Button for Physician Demographic Information page

Step 6: Review the ownership or investment interest information entered in the previous pages on the "Review and Save" page. If necessary, select the "Back" button at the bottom of the page to go back and edit information. Users can also select an icon from the Payment Navigation Bar, located on top of the page, to go directly to the desired page. Once the record is accurate, select the "Save Record" button to continue.

Figure 190: Save Record Button for Physician Demographic Information page

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

Figure 191: Record Saved Successfully page
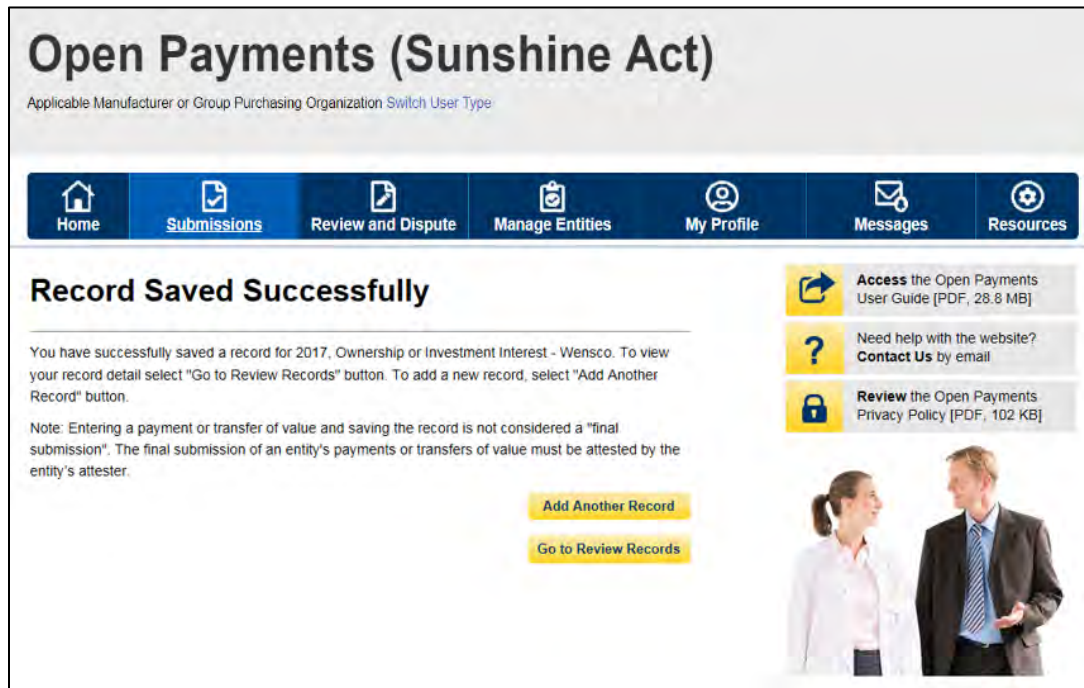
Take note that once the data has been uploaded to the system and undergone all checks including matching validations, it still must go through the Final Submission process in the Open Payments system. Manual data entry only uploads the record and checks it to ensure that it adheres to a valid data format and matching requirements. **You must complete the final submission and attestation process for the data to be considered reported.** See Section 4.10 for details on final submission and Section 4.14 for details on attestation.

Section 4.6: Record Validation and Matching

Records submitted to the Open Payments system must pass several validation steps in order to become eligible for final submission and attestation. The steps are shown in Figure 192, below.

Figure 192: Validation Steps

Details on these types of validation are given below.

4.6a: Validation Step 1: File-Level Validation

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

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

- The submitted file size is larger than 250 MB.

- The file is not in CSV or ZIP format.

- The file header row is not present.

- Columns are missing in the data file.

- The sample file used to create the submitted file and payment category of the file selected at upload do not match.

- The Applicable Manufacturer ID or Applicable GPO Registration ID included in the file's records does not match the Applicable Manufacturer or Applicable GPO Registration ID in the reporting entity's profile.

- The payment category selected in the dropdown menu on the Upload Payments page of the Open Payments system does not match the payment category of the submitted file.

- A value other than "Y" or "N" was entered for the Consolidated Report Indicator.

- The Consolidated Report Indicator value is not the same for all of the records in the file.

- The Applicable Manufacturer or Applicable GPO Making Payment Registration ID did not match the Applicable Manufacturer or Applicable GPO Registration ID and the Consolidated Report Indicator value was set to "N".

- The submitting user did not hold the submitter role with the reporting entity corresponding to the Applicable Manufacturer or Applicable GPO Making Payment Registration ID or Applicable Manufacturer Applicable GPO Registration ID in the record.

- The Applicable Manufacturer or Applicable GPO Making Payment Registration ID provided in the record does not exist in the Open Payments system.

- The Resubmission File Indicator in the uploaded file does not match the value selected for the Resubmission File Indicator drop-down menu on the Upload Payments page of the Open Payments system.

- The payment date in a record does not correspond to the Program Year selected on the Upload Payments page of the Open Payments system.

- The submitted template does not match the Program Year selected on the Upload Payments page of the Open Payments system.

- The Applicable Manufacturer or Applicable GPO Making Payment Registration ID is not included; this value is required for General Payment and Research Payment records.

- The Applicable Manufacturer or Applicable GPO Reporting Ownership Registration ID is not included; this value is required for Ownership/Investment records.

- The Resubmitted Payment Record ID has an invalid format or length.

- An invalid value was provided for the Delay in Publication of Research Payment Indicator.

- The required fields for update of delay in publication are not populated for all records in the file.

- The required fields for deletion are not populated for all records in the file.

- The required fields for new submission are not populated for all records in the file.

- The required fields for resubmission are not populated for all records in the file.

- A service within the Open Payments system was down and the file could not be processed.

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

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

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

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

- All required fields are populated;

- The information in each field meets the formatting and data input requirements of that field;

- If the record is submitted to change an existing record (i.e., the record is a resubmission or is intended to delete or renew the delay in publication of an existing record), an original version of the record exists within the Open Payments system.

Record field requirements are detailed in the Submission Data Mapping Documents, which are available on the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html). Refer to the Submission Data Mapping Document that corresponds to the record's program year.

4.6c: Validation Step 4: Record Matching

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

Records containing physician licenses that were valid after August 1, 2013 (start date of data collection for the Open Payments program) but were expired during the entirety of the program year of the record will **not** fail matching due to the expired licenses but will trigger warnings to the user. Refer to Section 4.7, "Identifying Errors," for details.

Section 4.7 Identifying Errors

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

4.7a: Identifying Errors - Bulk File Upload

Errors in files or records submitted via the bulk file upload process are communicated to submitters via notification emails. Users can also review the submitted file(s) statuses on the Review File Status page, refer to Section 4.4d for more details.

4.7a (1) Determining the Step Where the Error Occurred

Users can determine at what step the file or records failed based upon the format of the notification email, or by reviewing the file upload status on the "Review File Status" page.

- **File Validation failure (Step 1)**: The email describes a file validation failure, the reason for the failure, and, if applicable, the line number of the submitted data file where the failure occurred. Files that fail at this step will have a status of "Rejected" on the "Review Files Status" page. Step 1 validations stop upon finding an error.

- **Pre-Upload Record Validation failure (Step 2):** The email lists the reasons for record rejections, the number of records in the file that failed for each reason, and identifies up to a set number of records for each rejection reason. Files with records that meet this criteria will have a status of "Submitted with Errors" on the "Review File Status" page.

- **Record Validation failure (Step 3):** The email explains that the file has been processed, and one or more records were found to contain validation errors. The email also provides instructions for locating the Error Log that lists the errors found in the records. Files with records that meet this criteria will have a status of "Submitted with Errors" on the "Review File Status" page.

- **Matching Validation failure (Step 4):** The email explains that records were submitted successfully, but they may contain records in Failed Matching status or records with Warnings. Files with records that meet this criteria will have a status of "Submitted Successfully" or "Processed with Warnings" on the "Review File Status" page.

Warning messages, such as those issued for late submission or records with expired licenses, do not themselves trigger notification emails. However, the warnings will be included in the error log associated with the bulk file. Records with expired license related warnings are also identified with a warning icon next to the Record ID on the Payment Category page. A warning message will appear if a marketed name of the drug or biological does not match the CMS approved data sheet and if the Drug or Biological Name and NDC combination does not match the CMS approved data sheet.

Note that if a bulk file submission makes it past Step 1, all of the records within the file are checked individually for Steps 2-4. A bulk file that passes Step 1 might include records that fail at Step 2, records that fail at Step 3, records that fail at Step 4 and records that upload successfully. In that scenario, the submitter would receive multiple notification emails.

4.7a (2) If Errors Occur During File Validation (Step 1):

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

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

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

4.7a (3) If Errors Occur During Record Validation - Pre-Upload (Step 2)

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

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

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

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

4.7a (4) If Errors Occur During Record Validation - Post-Upload (Step 3) or Matching Validation (Step 4)

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

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

Another method for identifying records that failed Steps 3 and 4 is by searching within the Open Payments system. To do so, follow the steps below:

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

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

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

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

- "Failed Validation" means that the data in at least one field in the record does not match the required formatting and data reference validations for that field.

- "Failed Matching" means that the covered recipient information in the record, including principal investigator information, cannot be matched to a valid covered recipient physician or teaching hospital.

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

Follow the steps below to **view a file's upload status** on the File ID page and to **download an Error Log** for records that failed Steps 3 or 4 and interpret the error codes it contains:

Step 1: Go to the table at the bottom of the Payment Category page, which will be filtered for failed records per the process above. Select the hyperlink in the "File ID" column of a record to be examined, which opens the "File ID" page.

Step 2: Check the file's upload status on the "File ID" page. One of three statuses will be given:

- **Submitted with Errors** - The file is uploaded successfully but one or more of the records in the file are in "Failed Validation" or "Failed Matching" status. An error log will be generated for a file that contains records that generated errors for failed validation or matching.

- **Processed With Warning** - The file contains records with late submission and/or expired license warning. Users do not need to take any action for late submission warning, however, they can correct or delete records with expired license warning. If it is confirmed that the information is valid, the record can continue through final submission without further updates.

- **Submitted Successfully** - The file uploaded successfully. An error log will be generated for a file that contains records that generated warnings.

Step 3: On the "File ID" page, select the "Error Log" hyperlink at the bottom of the page to download the error log.

Step 4: Find the error code displayed in the "Error Message ID" column of the error log. A sample Error Log is shown below. The codes listed in the "Error Message ID" column are error codes. For data elements that have multiple fields and may contain multiple values (e.g., physician license), the error log file column "Data Element Value" displays the specific value that produced the error.

Figure 193: Sample Error report in Excel showing error message ID's and Data Element Values

Step 5: Once you have determined the error codes for each record, consult the Error Code Key, which is available on the Resources page of the Open Payments website at https://www.cms.gov/openpayments/About/Resources.html or within the Open Payments system by selecting the "Resources" tab. The Error Code Key lists error IDs along with a description regarding the relevant data element name, an error description, and steps to avoid and correct the error.

4.7a (5) To see errors on individual records in the Open Payments System

If a record fails validation or matching, details of the failure in the individual record can be seen within the Open Payments system.

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

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

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

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

In certain scenarios, such as if a physician's license was found to be expired during the program year, or if the record is considered to be a late payment, a warning message will be listed in the downloadable error log. These records should be reviewed to confirm their accuracy. If necessary, update or delete the record associated with the warning message. If the information is believed to be valid, the records can be processed through final submission and attestation without further updates.

If the physician license information is inactive in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

4.7b: Identifying Manual Entry Errors

Records entered manually do not undergo Step 1 or Step 2 validations. Step 3 validations are applied during the manual data entry process, and any failures of Step 3 will trigger on-screen error messages. Error messages for data elements with multi-entry values, are displayed in bracket(s) on-screen.

Manual entry of a record cannot be completed until all Step 3 errors are resolved.

Once a manually entered record has been uploaded, it undergoes Step 4 (matching) validations. Records that fail Step 4 validations will not trigger a notification email. To determine if a manually entered record failed Step 4 validations, search in the Open Payments system for records that failed matching validation. To search the Open Payments system to find which records failed Step 4, follow the steps below:

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

- On the "Review Submitted Records" section, select the entity and program year for the records you wish to review, then select the "Review Records" button

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

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

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

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

1. Go to the table at the bottom of the Payment Category page, which will now be filtered for failed records per the process above. Select the hyperlink in the "Record ID" column for a record or select the "View" hyperlink under the "Actions" column. This will take you to the record's "Record ID" page.
2. On the "Record ID" page, error messages related to this record will be visible. The onscreen error messages for multiple-value fields will also identify the specific value that produced the error.

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

Note: Records that trigger the physician expired license warning message can be identified by a warning icon ⚠ on the Payment Category page, and on the individual record's "Record ID" page. For records submitted by bulk file, the error log for the bulk file will also provide expired license warnings for each record with an expired license and specify the expired license(s). Records that have warnings but passed validation and matching are processed successfully but should be reviewed for accuracy. If the data is determined to be accurate, no further action on the records is required before proceeding to final submission.

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4.7c: GPO Users Only - Identifying Recipients Missing Attested Ownership Record

This section is for applicable group purchasing organizations (GPOs) users only.

The Open Payments program requires group purchasing organizations (GPOs) to report physician Ownership/Investment Interest if there is a General/Research payment reported for that physician and program year. To confirm compliance with this rule, GPO users can access a report that identifies physicians on General/Research Payment records that are missing attested Ownership/Investment Interest record for the same Program Year by following the steps below:

1. Log into the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/ and select the "Submissions" tab on the toolbar.
2. GPO users have access to the "Download Recipients Missing Ownership Record" section. Under the section, select the entity that you wish to review, then select the "Download Report" button.

Figure 194: Submissions page for Group Purchasing Organization users

3. In the downloaded Zip file, save or open the Excel file to review the recipients specified on general/research records that are missing an attested ownership/investment interest record in the same program year as the general/research record. The report shows the following information:

   a. GPO Making Payment Name
   b. GPO Making Payment Registration ID
   c. Program Year
   d. Covered Recipient First Name
   e. Covered Recipient Last Name
   f. General Payment - Sample Record ID(s) that the covered recipient is included on (separated by semicolon): This field includes up to 25 latest general payment record IDs that are associated with the physician. Only those in Ready for Submission, Returned to Submitter, Ready for Attestation, Attested, and Attested as Marked for Deletion statuses are included.
   g. Research Payment - Sample Record ID(s) that the covered recipient is included on (separated by semicolon): This field includes up to 25 latest research payment record IDs that are associated with the physician. The listed physician can be a covered recipient or a principal investigator of a research record. Only those in Ready for Submission, Returned to Submitter, Ready for Attestation, Attested, and Attested as Marked for Deletion statuses are included.
   h. Is there at least one associated Ownership/Investment Interest record in Ready for Attestation status: This field will be populated as "Yes" if the physician will meet the compliance requirements upon attestation.

Review your submissions to confirm that an ownership/investment interest record for the associated physician on the general or research record is entered for that Program Year. Enter a new ownership/investment interest record or attest to the existing ownership/investment interest records if required. No further action is required if there are no records shown in the report.

Section 4.8: Correcting Records

Records that contain validation or matching errors must be corrected and re-submitted until the records are free from errors. Records that have warnings but not validation or matching errors do not need to be corrected before proceeding, but should be reviewed for accuracy.

Once free from errors, you can complete the submission process for these records. Records can be corrected via bulk file upload or manual editing in the Open Payments system.

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

after the submission deadline. Refer to section 4.14 for details about the assumptions statement. The relevant fields that identify the record's covered recipient or principal investigators are as follows:

- For physicians (including principal investigators): First Name, Last Name, NPI, License State, and License Number.

- For teaching hospitals: Teaching Hospital Name, the hospital address fields, and Taxpayer Identification Number.

Changing a record may affect the publication of that record, depending on when the changes are made. 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.

Note: if a record containing multiple physician state licenses failed matching due to one of those licenses, and the license information is as accurate as can be determined, it is permissible to remove that license from the record before resubmission, as only one license is required.

4.8a: Correcting Records via Bulk File Upload

To correct records via bulk file upload:

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

- If the file failed in steps 1 or 2, the Resubmission File Indicator for the records does not need to be changed from the original submission.

- If the record(s) in the file failed in steps 3 or 4, the record(s) must undergo resubmission or deletion and new records submitted in their place.

  - For resubmissions, each corrected record must have its "Resubmission File Indicator" value set to "Y" and the original record's Record ID provided in the updated record's "Resubmitted Payment Record ID" field.

  - If the failed record must be deleted and replaced due to changes in identifying information (per the boldfaced text in the "Correcting Records" section above), consult the Deleting Records section 4.9. Replacement records will be new submissions and should have a "Resubmission File Indicator" value of "N".

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

4.8b: Correcting Records Manually

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

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

2. Locate the desired record in the data table at the bottom of the "Payment Category" page. You can use the filtering tools on the page to help find a relevant record. Once you have found the record, select the "Edit" hyperlink in the "Actions" column for that record.

3. Update the record information. Users can select an item from the "Payment Navigation Bar" located on top of the page to go directly to their desired page or go through the pages sequentially to fix the error(s). Once all the validations and errors have been fixed the user can navigate to the "Review & Save" page and select the "Save Record" button.
NOTE: The system will provide matching errors and/or warnings on the Overview page when the submitter edits payment records with matching errors/warnings.

4. The edited records must undergo final submission and attestation. Instructions are available in Section 4.14, Final Submission and Attestation.

Section 4.9: Copy/Duplicate Records

Records submitted to the Open Payments system by submitters may be copied and duplicated in the User Interface to reduce the effort of entering the same data repeatedly during the validation, matching, or the review and dispute process.

You are able to copy/duplicate payment records within the Open Payments system and allow the editing of those records without going through the entire data entry process.

All payment record related fields will be copied to a new payment record except the system generated fields, such as - Record ID, Submission Date, Submitted by etc.

Validation of fields are performed when you select continue on each page or save the new record and not at the time of copy action. NOTE: Payment Category field is read only on copied record.

The "Copy" button is provided in two places:

1. The payment category page, record view grid for every record under the Action column regardless of the record status.

2. The view Record ID Page at the top and bottom of the page.

The steps to copy a record are detailed in the section below.

4.9a: Copying a Record

The process outlined below will allow you to copy any existing payment.

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

Figure 195: Submissions Tab for Open Payments system landing page for returning system users
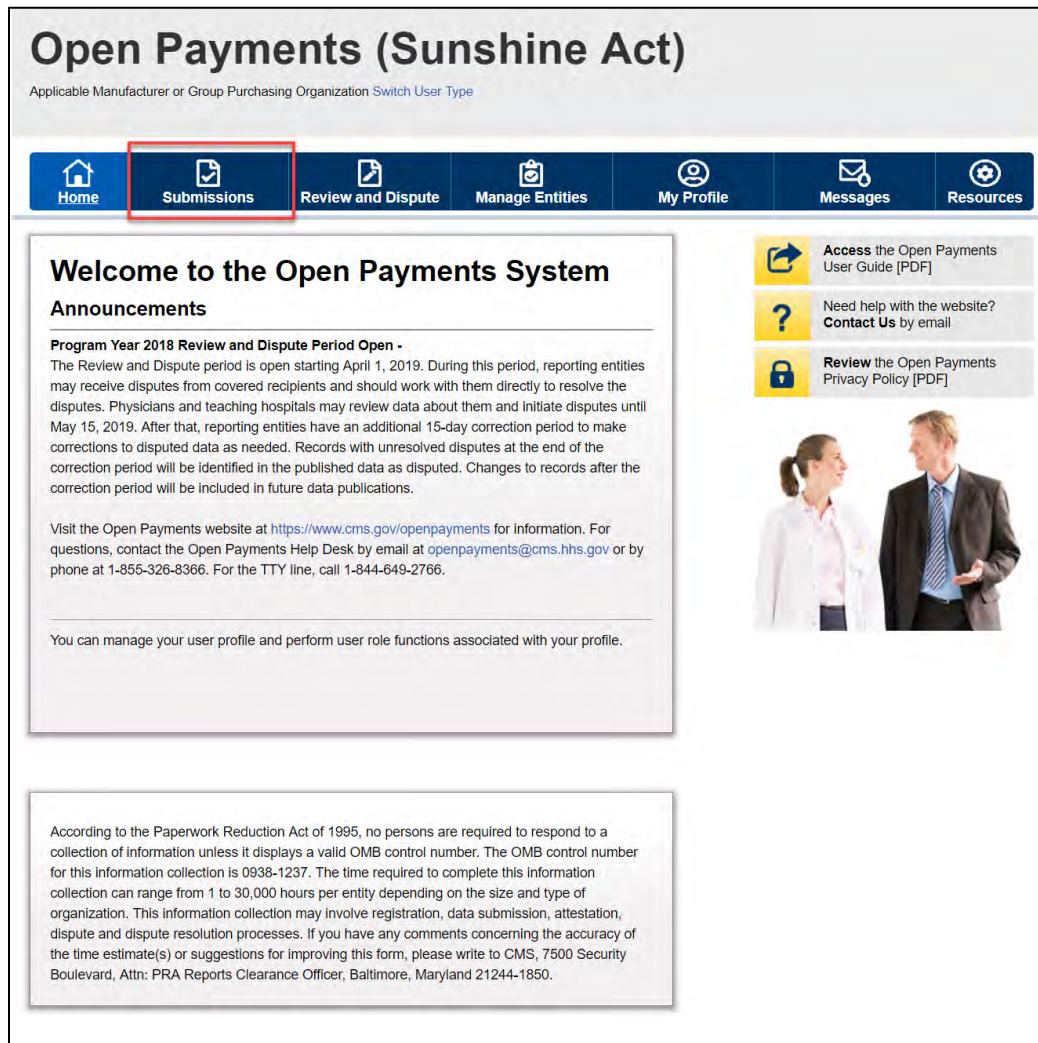
Step 2: Under the "Review Submitted Payment Records" heading, select the reporting entity whose records you want to delete and the program year for those records. Select the "Review Records" button.

Figure 196: Submissions Landing page

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

Figure 197: Review Records page with View All button for Research, General and Ownership or Investment Interest payments

Step 4a: At the bottom of the "Payment Category" page is a data table. Find one record from the file you wish to copy. Select the "Copy" hyperlink in that record's "Actions" column.

Figure 198: "Copy" Hyperlink from Reporting Entity General Payments Payment Category Page

Alternatively, according to the second method to copy an existing payment the steps are as follows:

Step 4b-1: At the bottom of the "Payment Category" page is a data table. Find one record from the file you wish to copy. Select the "View" hyperlink in that record's "Actions" column.

Figure 199: "View" Hyperlink from Reporting Entity General Payments Payment Category Page

Step 4b-2: Select the "Copy" Button from either the top of the bottom of the page.

Figure 200: Copy Button on Record ID Page
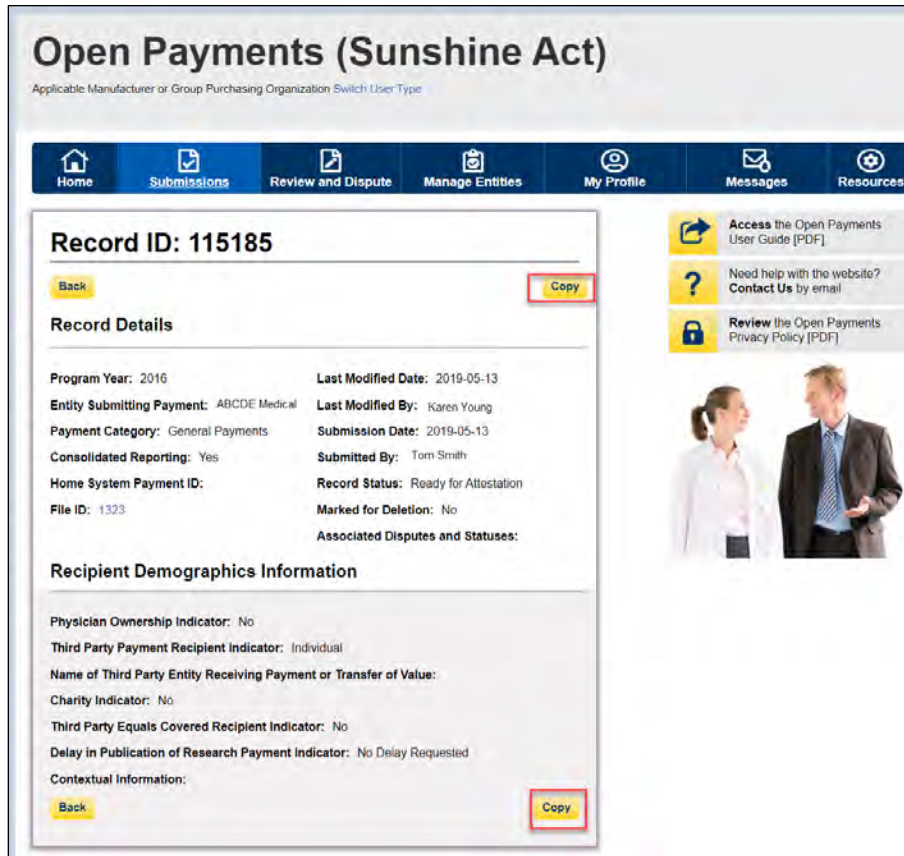
Step 5: A confirmation pop-up box appear. Select the "Yes" button.

Figure 201: Confirmation pop-up window

Upon selecting the "Yes" button, you will be redirected to the "Add General Payment" page. A confirmation message will be present on the "Add General Payment" page confirming the payment has been copied. You will be able to add data to the payment record that has been copied. You may update the record data as needed and the copied record will be successfully created only upon the "Review and Save" action.

Figure 202: Confirmation message on Add General Payment Page.

Section 4.10: Deleting Records

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

The record deletion process varies depending upon the status of the records to be deleted. Records that had not yet been attested to will be immediately removed from the Open Payments system. Records that had been previously attested to will be placed in a "Marked for Deletion" status rather than immediately deleted.

To complete the deletion of records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year, which includes attesting to the deletion of previously attested records. Until they are attested, and therefore removed from the system, records in "Marked for Deletion" status remain visible to covered recipients and are eligible for publication.

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

4.10a: Deleting a Bulk File

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

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

Figure 203: Submissions Tab for Open Payments system landing page for returning system users

Step 2: Under the "Review Submitted Payment Records" heading, select the reporting entity whose records you want to delete and the program year for those records. Select the "Review Records" button.

Figure 204: Submissions Landing page

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

Figure 205: Review Records page with View All button for Research, General and Ownership or Investment Interest payments

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

Figure 206: Reporting Entity General Payments Payment Category page

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

Figure 207: Delete File Button on File ID Page

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

Figure 208: Delete File confirmation message
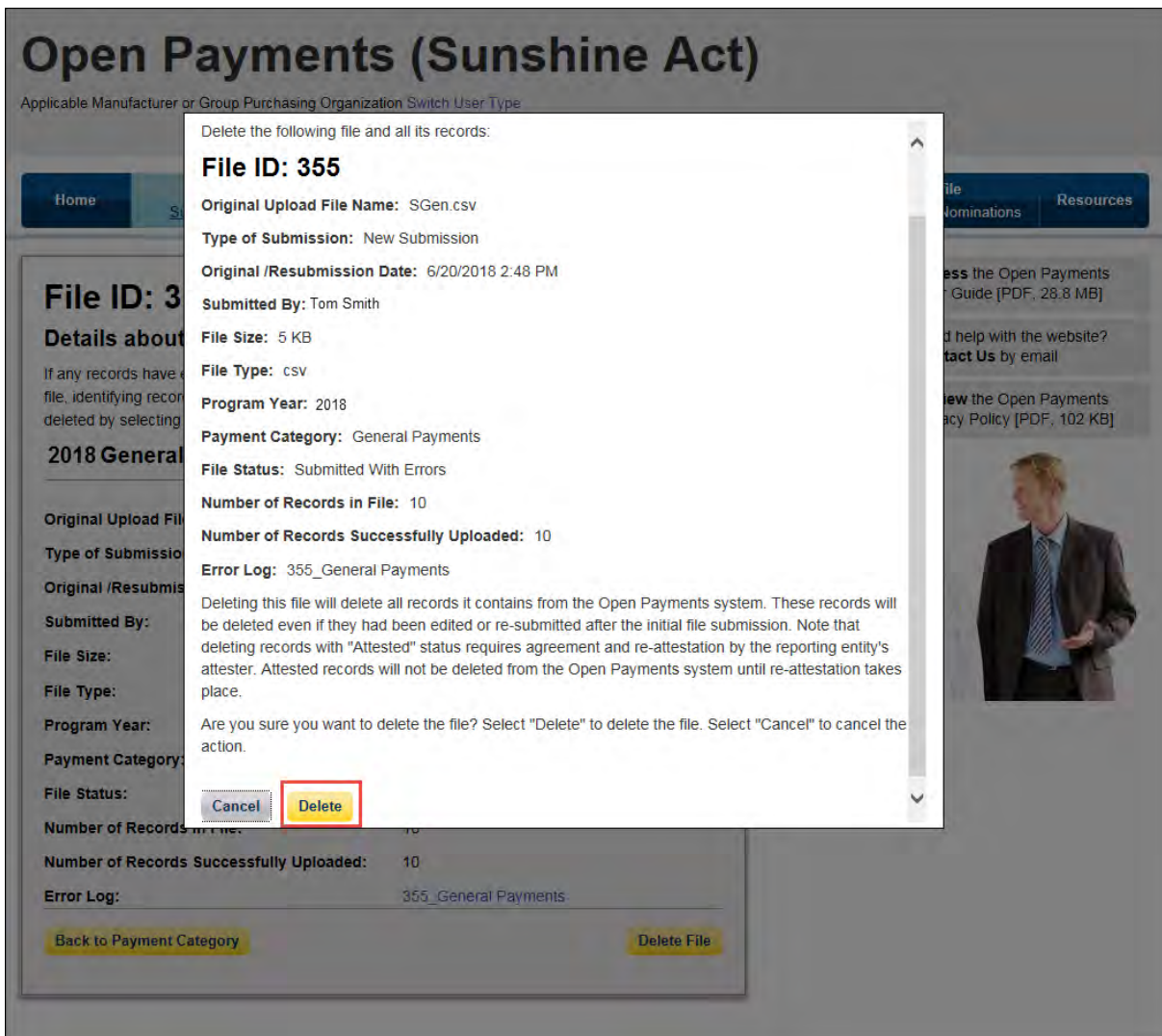
If any records from this bulk file had been previously attested to, the previously attested records will not be immediately deleted but marked for deletion. To delete records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year.

4.10b: Deleting Records via Bulk File Upload

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

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

- Applicable Manufacturer or Applicable GPO Registration ID;

- Consolidated Report Indicator;

- Resubmission File Indicator (must be "D" to delete records);

- Applicable Manufacturer or Applicable GPO Making Payment Registration ID;

- Resubmitted Payment Record ID; and

- Date of Payment (General and Research payment records only).

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

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

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

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

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

4.10c: Deleting a Record Manually

4.10c (1) Deleting a Record from the "Submissions" tab

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

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

Figure 209: Open Payments system landing page for returning system users
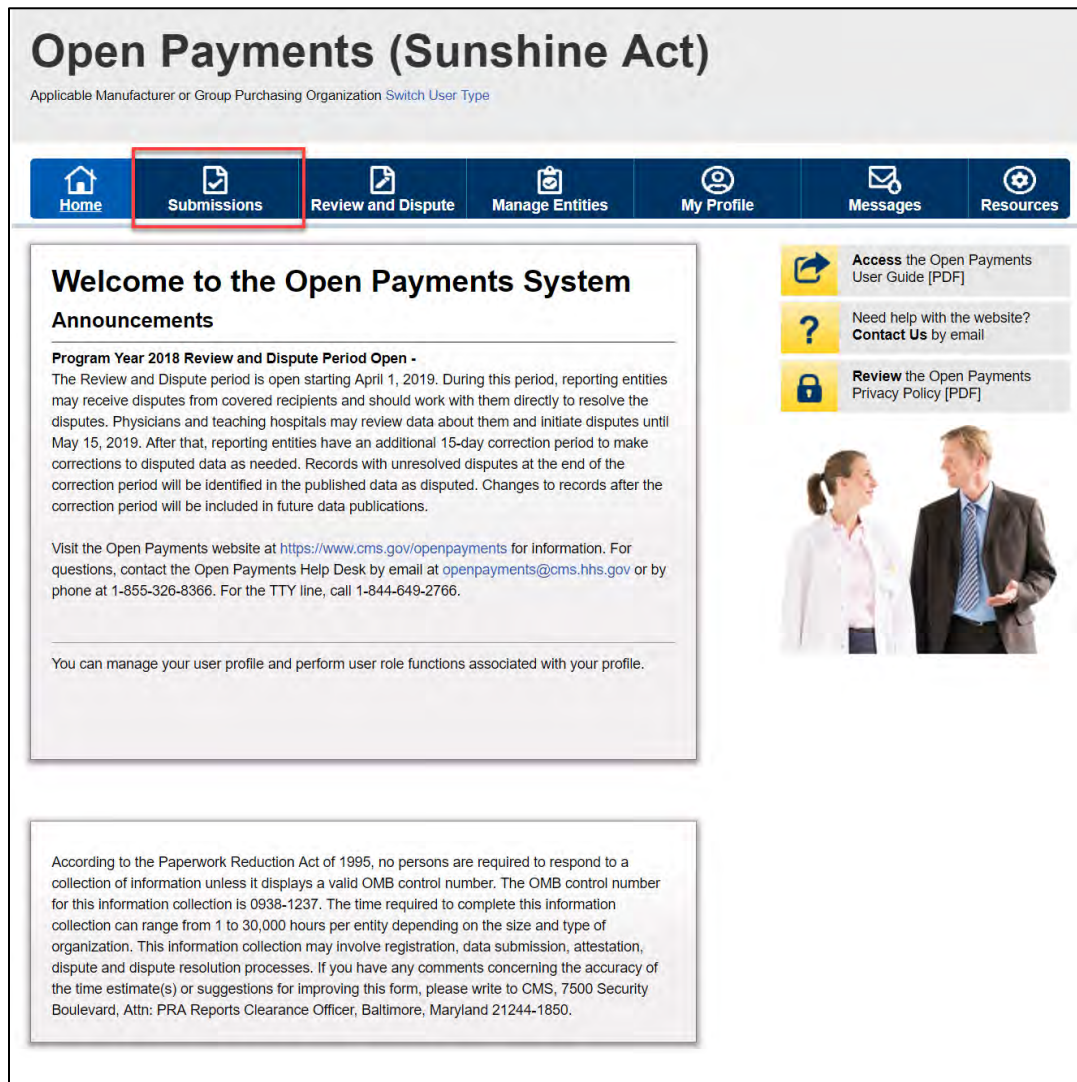
Step 2: Under the "Review Submitted Payment Records" heading, select the reporting entity whose record you want to delete and the program year for those records. Select the "Review Records" button.

Figure 210: Submissions Landing page

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

Figure 211: View All Button for Review record landing page

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

Figure 212: Delete Selected Button for Payment Category page for General Payments

Step 5: An on-screen message will appear to confirm you want to delete the selected record (s). To proceed with deletion, select the "Yes" button. To cancel, select "No."

Figure 213: Confirm Deletion Notification

You will receive an onscreen notification of the deletion.

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Figure 214: Sample General Payments Page With Deletion Confirmation Message

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

4.10c (2) Deleting a Record from the "Review and Dispute" tab

Submitters can also delete record(s) from the "Review and Dispute" tab. The process below will delete an individual unattested record and mark for deletion an individual attested record.

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

Figure 215: Review and Dispute Tab

Step 2: Select a reporting entity and appropriate program year from the "Show Disputes for" and "Program Year" drop-down fields. Select the "Show Disputes" button.

Figure 216: Show Disputes Button

Step 3: At the bottom of the "Review and Dispute" page, there is a data table. To delete a record, select that record in the data table by selecting the corresponding checkbox and select the "Delete Selected" button. A confirmation message will be displayed prompting the user to confirm if they would like to delete the record or not.

Figure 217: Review and Dispute Record

Step 4: An on-screen message will appear to confirm the user wants to delete the selected record. Select "Yes" to delete the selected record. Select "No" to cancel.

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Figure 218: Confirm Deletion Notification

Step 5: An on-screen message displays to confirm the deletion of the selected record.

Figure 219: Deletion Confirmation Message for General Payments

If the record had been previously attested to, it will not be immediately deleted but marked for deletion. To delete records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year. If the record is in "Attested" status, the record is "Marked for Deletion" until the record is re-attested to. If the record is in the process of being updated and has not been re-attested to, the record will be deleted without having to be re-attested to. The system will notify the covered recipient when a disputed record is deleted as part of a Review and Dispute action.

4.10c (3) Deleting a Record from the "Review File Status" Page

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

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

Figure 220: Open Payments system landing page for returning system users

Step 2: Under the "Review File Status" heading, select the "Review File Status" button.

Figure 221: Review File Status Button on Submissions Home Page

Step 3: Select the File ID link for the file you wish to delete.

Figure 222: File ID link on Review File Status Page

Step 4: Select the Delete button from the File ID Page.

Figure 223: Delete Button on File ID Page
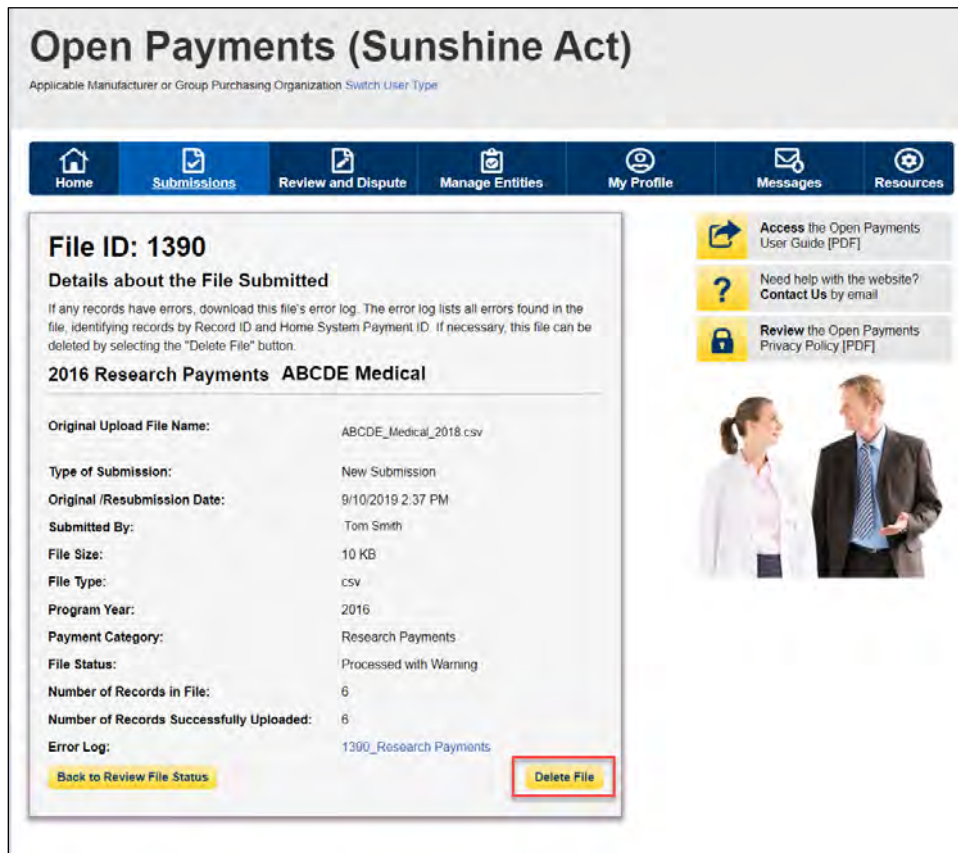
Step 5: From the pop-up window, select the Delete button to delete the file.

Figure 224: Delete button on File ID pop-window
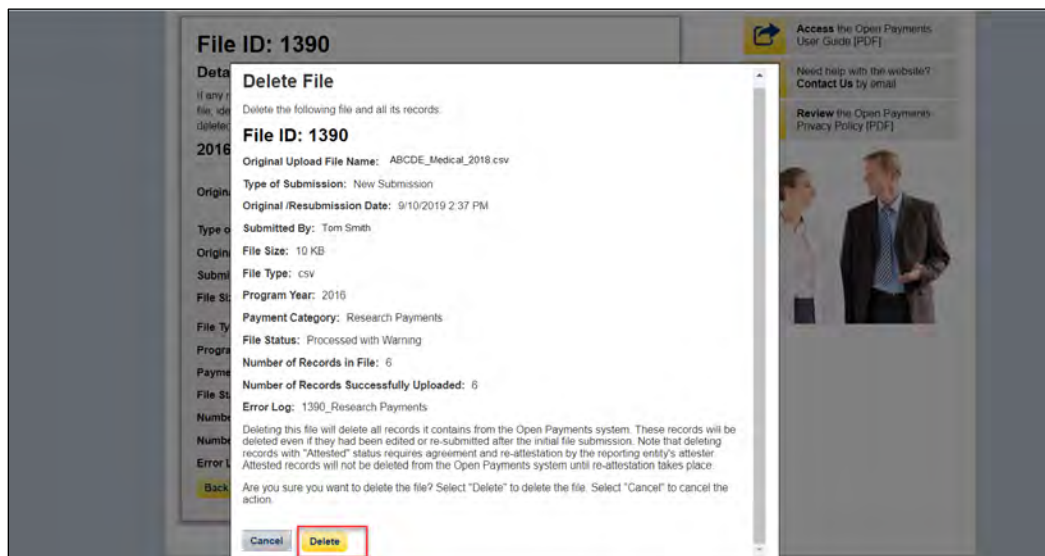
You will be redirected to the File ID home page and a confirmation message will be present, confirming the payment file has been deleted.

**Figure 225: Confirmation Message on File ID page**

4.10d: Viewing Records Marked for Deletion

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

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

Figure 226: Submissions Tab on Open Payments system landing page for returning system users.
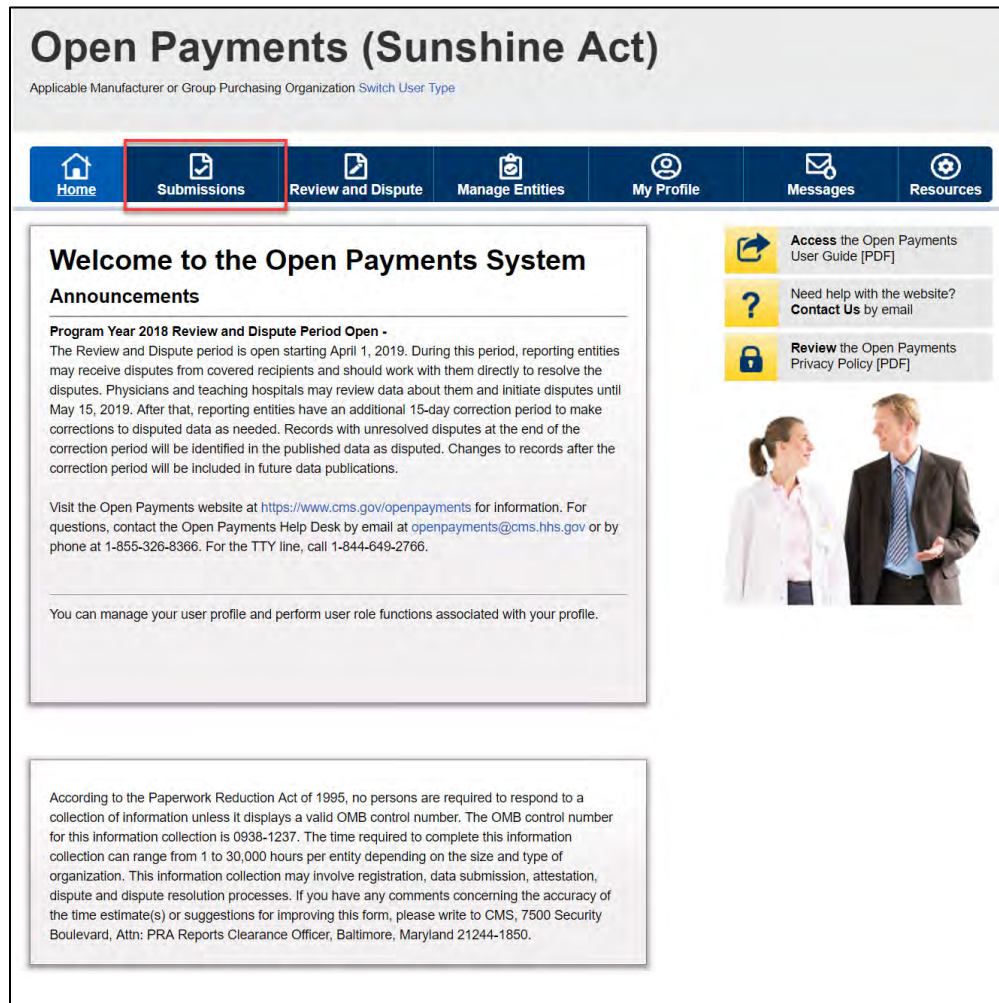
Step 2: From the "Submissions" tab, use the drop-down lists under the "Review Submitted Payment Records" heading to select the reporting entity and program year then select the "Review Records" button.

Figure 227: Review Records Button on Submissions Landing Page

Step 3: Select "View All" next to the payment category for the records you wish to review. If records are still processing select the "Refresh Status" button to refresh the status of the records as they are processed. Note that once the "Refresh Status" button is selected, all other buttons on the "Review Records" page will be disabled until the page has been refreshed. A confirmation message is displayed when the refresh action is completed as described above and displayed in the figure below.

Figure 228: Refresh Status Button for Reporting Entity Review Records page.

Step 4: On the following page, in the Record Status filter box, check the box for "Yes" under the heading "Marked for Deletion." Select the Search" button. This will display all the records "Marked for Deletion."

Figure 229: Marked For Deletion Button on Reporting Entity General Payments page

Section 4.11: Final Submission of Data

Final submission of data occurs after data has been uploaded, at least one record is in "Ready for Submission" status, and no records are in "System Processing" status. To perform final data submission, follow these steps.

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

Figure 230: Submissions Tab for Open Payments System Landing Page

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

Figure 231: Review Records for Open Payments System Landing Page

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

- **System Processing:** Records being processed by the system for field validation checks.

- **Failed Validation:** Records which did not pass field validation checks.

- **Failed Matching:** Records which did not pass data matching checks. See Section 4.6 for information on data matching.

- **Ready for Submission:** Records which have passed field validation and data matching and are ready for final submission.

- **Ready for Attestation:** Records which have been successfully submitted and are ready for attestation.

- **Returned to Submitter:** Records returned to the submitter by the attester because the records contain errors and require correction.

- **Attested:** Records which have been attested to as accurate by the attester.

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

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

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

Figure 232: View All Button for Open Payments system landing page

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

The "Final Submission" button will only be visible once at least one record is in "Ready for Submission" status and no record for the same payment category is in "System Processing" status. If this button is not visible, review the record's status in the "Record Status" column and make sure that at least one record is in "Ready for Submission" status.

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

Users can download the record information returned by searches on this page to a CSV file by selecting the "Download Zip File" link on the page. The download file will contain all of the columns of data displayed on the Payment Category page. Filters applied on the page will be applied to the download. Downloaded data files cannot exceed the acceptable limit of 400,000 records. If your record volume exceeds the record limit, apply filtering criteria to create smaller subsets of records and download them in multiple files.

Note: The filter for Teaching Hospital CCN should not be used for downloading failed records, as it only returns records that have been successfully validated and matched. It will not return records with a status of "Failed Validation" or "Failed Matching."

Figure 233: Final Submissions Button for sample Research Payments page

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

Figure 234: Confirm Final Submission page

Note that the Final Submission process can take several hours to complete, especially during peak submission times.

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

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

Figure 235: Reporting Entity Review Records Page

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

Section 4.12: Delay in Publication

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

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

A delay in publication can only be requested up to a period of four years from date of payment (i.e., the record's program year). After four years have elapsed, the delayed records will be published.

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

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

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

4.12a: Eligibility for Delay in Publication

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

- Research or development of a new drug, device, biological, or medical supply.

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

- Clinical investigations regarding a new drug, device, biological, or medical supply.

After four (4) years from the year of payment (i.e., the record's program year) have elapsed, records are no longer eligible for delay, and will be eligible for publication in the next publication cycle.

Records that have reached the delay-in-publication limit will have one of two "Delay in Publication" statuses in the Open Payments system. The particular status depends on the rationale given for the delay when it was first requested, either "research and development" or "clinical investigation."

- No Delay - R & D on New Product - Limit Reached

- No Delay - C.I. on New Product - Limit Reached

For program years that have reached the delay limit, users will be prevented from requesting a delay in publication on new or updated records.

4.12b: Initially Requesting a Delay in Publication

When submitting a new record, users can request a delay in its publication as part of the record creation process if it is eligible.

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

- For general payment records, the delay in publication indicator is found on the "General Record Information" page.

- For research payment records, the delay in publication indicator is found on the "Research Payment or Other Transfer of Value Information" page.

- Ownership/investment records cannot be delayed.

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

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

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

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

4.12c: Updating a Delay in Publication

Users may request that payment records have their publication delayed for up to four years after the date of payment. The request for a delay must be renewed each year.

If this request is not renewed each year by the end of the data submission period, the record will be automatically flagged for publication in the next publication cycle.

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

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

For program years that have reached the delay limit, users will be prevented from requesting a delay in publication on new or updated records. These records will automatically be made available for publication.

Delayed records that are no longer eligible for a delay but are in "Returned to Submitter" status will not be updated to a "Limit Reached" delay status. These records must be edited and the Delay in Publication Indicator changed to "No Delay Requested" as they are no longer eligible.

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

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

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

4.12c (1): Finding Records Eligible for a Renewal in Delay in Publication
To find which records previously delayed for publication are eligible for delay in publication renewal, follow the steps below.

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

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

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

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

Figure 236: Reporting Entity General Payments Page

4.12c (2): Updating a Delay in Publication Indicator via Bulk File Upload

Users can update the Delay in Publication Indicator of existing eligible records(s) via bulk file upload through two methods: by setting the "Resubmission File Indicator" field to Resubmission ("Y") or Renew Delay in Publication ("R"). If a record is not eligible, an error will be issued.

Note: Before preparing the bulk file to update delays in publication, refer to the "Resubmission File Indicator" area of the Submission Data Mapping Documents for details on required fields.

- To update the delay in publication field only, you can set the "Resubmission File Indicator" field to "R". Records renewed via this process will not be revalidated nor sent through the matching process again. Note there are fewer fields required for files submitted via this process.

  o This process can only be performed on records in "Ready for Submission", "Ready for Attestation," or "Attested" record status.

  o This process cannot be used to change the delay in publication indicator value from "3= No Delay Requested" to "1= R&D on New Product" or "2= Clinical Investigation on New Product." To change the delay in publication indicator value from 3 to 1 or 2, you must perform a full resubmission ("Resubmission File Indicator" is set to "Y").

  o If a record is for a program year that is not eligible for delay, the user will receive an on-screen error message when they attempt to submit the file and the file will not be uploaded into the Open Payments system. The record must be edited to change the Delay in Publication Indicator to "No Delay Requested."

- The process where the "Resubmission File Indicator" field in each record set to "Y" is a full resubmission. The record must include all required fields. Records renewed via this process will undergo revalidation and the matching process. This process can be performed on records in any record status.

  o Ineligible records that are submitted with the Resubmission File Indicator set to "Y" (Resubmission) and a request for delay in publication will fail validation checks. The submitters will receive an email notification of the records' failure and an error log file will be created for the file. The failed records must be edited to change the Delay in Publication Indicator to "No Delay Requested" and resubmitted again.

4.12c (2)a: Update Delay in Publication Indicator via Resubmission File Indicator Set to "R"

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

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

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

- Applicable Manufacturer or Applicable GPO Registration ID;

- Consolidated Report Indicator;

- Resubmission File Indicator (must be "R" for this process);

- Applicable Manufacturer or Applicable GPO Making Payment Registration ID;

- Resubmitted Payment Record ID (the "Record ID" assigned to the original record by the Open Payments system);

- Date of Payment; and

- Delay in Publication of Research Payment Indicator.

  o <u>To renew a delay in publication:</u> Set the indicator to '1' if you are requesting a delay because the record relates to research and development on a new product, or '2' if you are requesting a delay because the record relates to clinical investigation on a new product.

  o <u>To indicate a delay is no longer requested:</u> Set the indicator to '3,' which indicates no delay is requested.

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

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

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

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

4.12c (2)b: Update Delay in Publication Indicator via Resubmission File Indicator Set to "Y"
The process below can be performed to update most data elements on the record, including the Delay in Publication indicator. Records updated via this process will go through the entire matching and validation process upon resubmission, and are not restricted to records in certain record statuses.

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

- The "Resubmission File Indicator" for all records must be set to "Y."

- The Resubmitted Payment Record ID must be the "Record ID" assigned to the original record by the Open Payments system.

- Provide a value for the "Delay in Publication of Research Payment Indicator" field.

  - To Renew a Delay in Publication: Set the value to '1' if you are requesting a delay because the record relates to research and development on a new product, or '2' if you are requesting a delay because the record relates to clinical investigation on a new product.

  - To Indicate a Delay is No Longer Requested: Set the value to '3,' which indicates no delay is requested.

- For a general payment record, if you are selecting a value of '1' or '2', ensure that the name of the research study is displayed in the "Contextual Information" field, as well as any additional information you deem helpful regarding the payment or other transfer of value. "Contextual Information" is not required if you select a value of '3.'

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

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

You will receive email notifications regarding your file and record processing statuses. If the file fails file-level validations or records in the file fail record-level validations, including a validation that records are eligible to be delayed, you will receive an email identifying the issue. Review the email to determine the issues, correct the records, and resubmit accordingly.

For more details on record correction, refer to Sections 4.6 and 4.7. If the records uploaded successfully, proceed to step 4.

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

4.12c (3): Updating the Delay in Publication Indicator via Manual Data Entry

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

- Using the edit functionality; and

- Using the Delay in Publication Update button.

Both methods are explained below.

4.12c (3)a: Updating the Delay in Publication Indicator via Manual Data Entry - Using Edit Functionality

To manually update the delay in publication status of a general or research payment record using the edit functionality, follow the steps below. Users will receive an on-screen error message if they select to delay the publication of a record that is not eligible for a delay. The record's Delay in Publication Indicator must be changed to "No Delay Requested."

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

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

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

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

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

To Renew a Delay in Publication: From the "Delay in Publication of Research Payment Indicator" drop-down, select either "R&D on New Product" or "Clinical Investigation on New Product." For a general payment record, ensure that the name of the research study is displayed in the "Contextual Information" field, as well as any additional information you deem helpful or appropriate regarding the payment or other transfer of value.

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

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

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

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

4.12c (3)b: Updating the Delay in Publication Indicator via Manual Data Entry - Using Delay in Publication Update Functionality

You can update the delay of publication of eligible general and research payment record(s) from the Payment Category page using the "Update Delay Indicator" button.

Records updated through this process do not undergo re-validation and re-matching.

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

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

This functionality is not available for records that are not eligible for a delay in publication.

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

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

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

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

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

- R&D on New Product;

- Clinical Investigation on New Product; or

- No Delay Requested.

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

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

4.12d: Delay in Publication - Publication Impact

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

- Records with a Delay in Publication status of "Delay Requested" will not be published in the next publication cycle.

- Records with a Delay in Publication status of "No Delay Requested," "No Delay - R&D on New Product - Limit Reached," or "No Delay - C.I. on New Product - Limit Reached" will be published in the next publication cycle.

- If no action is taken on records with a Delay in Publication status of "Pending Renewal" by the end of the submission period, the records will be eligible for publication. These records will be published in the next publication cycle.

Section 4.13: Consolidated Reporting

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

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

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

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

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

4.13a: Performing Consolidated Reporting

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

- Set the "Consolidated Indicator" field in each record within the file to "Y."

- Provide the name and Open Payments registration ID for the entity <u>submitting</u> the consolidated report in the fields "Applicable Manufacturer or Applicable GPO Name" and "Applicable Manufacturer or Applicable GPO Registration ID."

- Provide the name and Open Payments registration ID for the entity that <u>made the individual payment or other transfer of value </u>in the fields "Applicable Manufacturer or Applicable GPO Making Payment Name" and "Applicable Manufacturer or Applicable GPO Making Payment Registration ID." This may be the same as the entity submitting the file.

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

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

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

Entity A made a consolidated report submission for itself, Entity B, and Entity C. Entities A, B, and C are all registered within the Open Payments system. Within the bulk data file, each record lists Entity A's information in the "Applicable Manufacturer or Applicable GPO Name" and "Applicable Manufacturer or Applicable GPO Registration ID" fields. The "Applicable Manufacturer or Applicable GPO Making Payment Name" and "Applicable Manufacturer or Applicable GPO Making Payment Registration ID" fields for each record contains the information for the entity that made that particular payment (Entity A, B, or C).

The submitter of the file must hold the role of submitter for all three entities, A, B, and C. Similarly, the attester must have the role of attester for all three entities, A, B, and C. to attest to records from all three entities.

Once the submission is accepted in the Open Payments system, the payment records for Entity B and Entity C would be listed under those individual entities, and will not be listed under Entity A. When the data is published, the records for Entity A, Entity B, and Entity C will be listed under their own names.

Section 4.14: Third Party Data Submitters

Applicable manufacturers and applicable GPOs may choose to have their data prepared and submitted by a third party organization. Third party organizations may format, prepare, and submit data on behalf of a reporting entity. The role of submitter is the only role third party companies can fulfill within the Open Payments system on behalf of a reporting entity. **A specific individual within the third party must be identified as the submitter, not the third party itself.**

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

Section 4.15: Attestation and Assumptions

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

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

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

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

The attester has the option of submitting an assumptions statement during the attestation process. Assumptions explain the reasonable assumptions made, methodologies used, and unusual circumstances that may have occurred when reporting payments, other transfers of value, or ownership or investment interests. Assumptions will be documented in a free-form text field during the attestation process. Users can choose to write free-form text or cut and paste text from another document. Assumptions cannot be longer than 8,000 characters (including spaces) and can be edited later.

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

4.15a: Attestation Statements in the Open Payments System

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

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

The text in the Open Payments system reads as follows:

1. I attest that I am a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer for the reporting applicable manufacturer or applicable GPO with the authority to attest to the information submitted in the Open Payments system.

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

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

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

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

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

   c. My entity has a separate operating division that does not manufacture any covered drugs, devices, biologicals, or medical supplies. Therefore, my entity is only required to report payments or other transfers of value to covered recipients related to the

activities of these separating operating divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply.

d.   The only covered drug, device, biological, or medical supply manufactured by my entity is pursuant to a written agreement to manufacture a covered drug, device, biological, or medical supply for another entity. My entity does not hold the Food and Drug Administration approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and is not involved in the sale, marketing, or distribution of the covered drug, device, biological, or medical supply. Therefore, my entity is only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

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

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

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

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

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

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

5.   I attest that my entity is submitting a consolidated report because it is under common ownership, as defined by 42 C.F.R. § 403.902, with a separate entity or entities that are also applicable manufacturers.

6.   I am attesting to the action that my entity has deleted one or more records, which have previously been attested, and I am re-attesting that my entity's information reported is accurate and complete to the best of my knowledge and belief.

Note: In the event of data submitted as a consolidated report, each individual entity within the consolidated report must attest to the accuracy of its own data. See Section 4.12 for more information on consolidated reporting.

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4.15b: Attesting to Data in the Open Payments System

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

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

Figure 237: Open Payments system landing page for returning system users

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

Figure 238: Review Records Button on Submissions Landing Page

Step 3: On the "Review Records" page, select the "Begin Attestation of All Records" button.

If the "Begin Attestation of All Records" button is not available, check that all records for the program year are in "Ready for Attestation" or "Attested" status. If they are not, contact a submitter for the

reporting entity and alert him or her that records need to be advanced to "Ready for Attestation" status (i.e., undergo final submission) before attestation can begin.

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

Figure 239: Ready for Attestation Button on Reporting Entity Review Records Page

Step 4: On the "Confirm Payments" page, review the detailed summary of records being attested to for the program year, displayed per payment category.

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

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

Figure 240: Next Button for Confirm Payments Page

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

Type or paste your assumptions into this field, which has an 8,000-character limit. The text field allows all special characters found on a standard U.S. keyboard, not including ALT+NUMPAD ASCII Key characters. This text field can be edited later.

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

Figure 241: No Radio Button on Add Assumptions page

Figure 242: Yes Radio Button on Add Assumptions page

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

Figure 243: Agree to Attestations Page

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

Figure 244: Review and Attest Page

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

Figure 245: Reporting Entity Review Records Page

Review and Dispute

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

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

This chapter is divided into the following sections:

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

- **Acknowledging Disputes and Resolving Disputes with No Change** provides information on how applicable manufacturers and applicable GPOs can acknowledge and resolve disputes initiated by physicians, teaching hospitals, and principal investigators. The "resolved, no change" action acknowledges that the applicable manufacturer or applicable GPO and the physician, teaching hospital, or principal investigator have resolved the dispute in accordance with the guidance in the Final Rule, and no changes to the data were needed.

- **Correction and Resolution of Disputed Data** provides information on how applicable manufacturers and applicable GPOs can make corrections to disputed data to resolve disputes.

Section 5.1: Review, Dispute, and Correction Overview

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

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

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

Dispute resolution takes place outside of the Open Payments system. Nevertheless, the status of the dispute resolution should be captured within the Open Payments system.

CMS will not mediate disputes between physicians, physician principal investigators, teaching hospitals, and reporting entities. Reporting entities should work with the disputing party directly to resolve disputes. Only users who hold the role of submitter with the applicable manufacturer or applicable GPO will be able to perform activities related to review, dispute, and correction of record(s).

The process is outlined in **Figure 246**, below.

Figure 246: Review, Dispute, and Correction Process

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

5.1a: Review, Dispute and Correction Period

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

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

If you cannot resolve a dispute with a physician, teaching hospital, or physician principal investigator within the 60-day review, dispute, and correction period for a program year, all parties should continue to seek a resolution until the dispute is resolved. Once the dispute is resolved and any necessary corrections are made, the data will be updated in a subsequent publication based on when the corrections were made in the Open Payments system.

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

5.1b: Review and Dispute Statuses

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

- Initiated: Indicates that a physician, teaching hospital, or physician principal investigator has initiated a dispute against a record submitted by an applicable manufacturer or applicable GPO.

- Acknowledged: Indicates that an applicable manufacturer or applicable GPO has received and acknowledged a dispute initiated against them by a physician, teaching hospital, or physician principal investigator.

- Resolved No Change: Indicates that the applicable manufacturer or applicable GPO and the physician, teaching hospital, or physician principal investigator have resolved the dispute in accordance with the guidance in the Final Rule and no changes were made to the disputed record.

- Withdrawn: Indicates that a physician, teaching hospital, or physician principal investigator has withdrawn a dispute they initiated against a record submitted by an applicable manufacturer or applicable GPO.

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

This chapter explains how applicable manufacturers and applicable GPOs acknowledge, resolve with no change, and resolve disputes with corrections in the Open Payments system.

Email notifications are sent to alert applicable manufacturers, applicable GPOs, physicians, teaching hospitals, and physician principal investigators of review and dispute activities in the Open Payments system. These emails contain information necessary to locate the record in the Open Payments system and may contain contact information in the dispute details. The Reporting Entity Contact Information for disputes, included in your entity's profile, is available on the "Record ID" page of each individual record.

5.1c: Exporting Disputed Data

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

Figure 247: Download Disputes Zip File Hyperlink

Section 5.2: Acknowledging Disputes and Resolving Disputes with No Change

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

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

When a record undergoes revision to address a dispute, that record will be visible to the physician, teaching hospital, or physician principal investigators identified in it, under the "Deleted and In Progress Records" tab until the record is re-attested. The record will return to the "Available for Review and Dispute" tab of the physician, teaching hospital, or physician principal investigators view, only after the record regains "attested" status.

The five steps of the process are given in **Figure 248** below.

Figure 248: Acknowledging Disputes and Resolving Disputes with No Change Process

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

5.2a: Acknowledging a Dispute

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

Figure 249: Review and Dispute Tab on Open Payments System Landing Page

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

Figure 250: Show Disputes for and Program Year Fields on Review and Dispute landing page
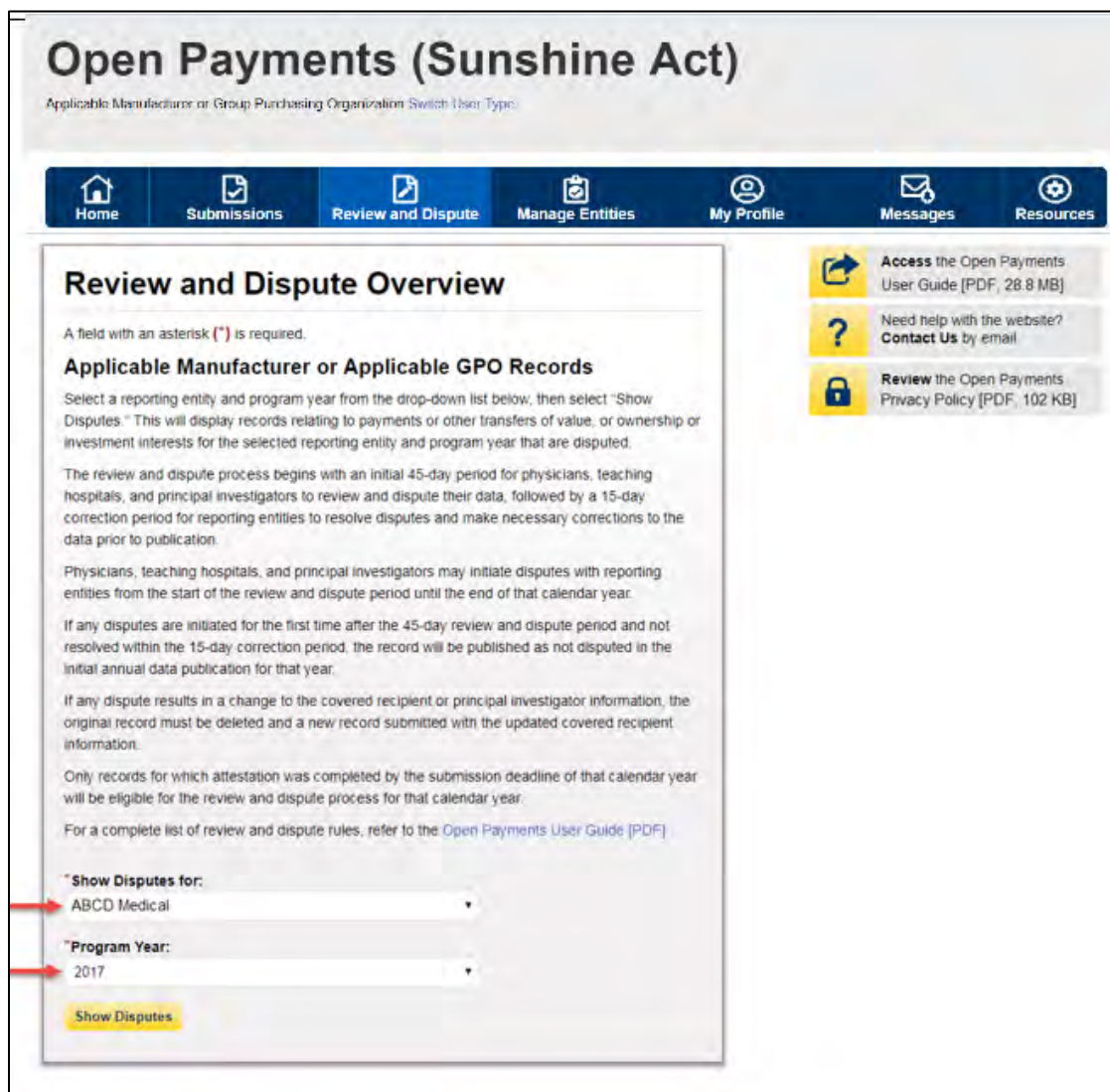
Step 3: On the "Review and Dispute" page, find the disputed record(s) to acknowledge. Users may filter the records using the search criteria options to help locate the correct record(s), such as filtering for records with a Review and Dispute status of "Initiated."

- View details about a disputed record by selecting the "View" hyperlink for the record under the "Action" column or by selecting the "Record ID" hyperlink under the "Record ID" column.

- View the detailed history for a record's disputes by selecting the "View" hyperlink for the record under the "History of Disputes" column.

For instructions on how to export this data, see Section 5.1c.

Figure 251: Search Button on Review and Dispute Reporting Entity Page

Step 4: Select the disputed record(s) to acknowledge, and then select "Acknowledge Dispute." Note: Record(s) must be in "Initiated" status to acknowledge dispute(s).

Figure 252: Acknowledge Dispute Button on Acknowledge Dispute" Button on Review and Dispute Reporting Entity Page

Step 5: Review the information displayed on the "Acknowledge Dispute" page. When finished, select the "Acknowledge" button.

Figure 253: Acknowledge Button on Acknowledge Disputes Page

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

Figure 254: Acknowledge Confirmation Message

5.2b: Resolved, No Change Disputes

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

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

Figure 255: Review and Dispute Tab on Open Payments System Landing Page

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

Figure 256: Review and Dispute Landing Page

Step 3: On the "Review and Dispute" page, find the disputed record(s) to resolve without changing. Users may filter the records by using the search criteria options to help locate the correct record(s), such as filtering for records with a Review and Dispute status of "Initiated" or "Acknowledged.

- View details about a disputed record by selecting the "View" hyperlink for the record under the "Action" column or by selecting the "Record ID" hyperlink under the "Record ID" column.

- View the detailed history for a record's dispute by selecting the "View" hyperlink for the record under the "History of Disputes" column.

Step 4: Select the disputed record(s) users wish to resolve with no changes, and then select the "Resolved No Change" button.

Note: Disputed Record(s) must be in "Initiated" or "Acknowledged" status to resolve dispute(s) with no changes.

Users may only resolve disputes with no changes if the reporting entity and the disputing physician, teaching hospital, or physician principal investigator have resolved the dispute in accordance with the guidance in the Final Rule.

For instructions on how to export this data, see Section 5.1c.

Figure 257: Resolved no Change on Review and Dispute Reporting Entity Page

<u>Step 5:</u> In the "Reason for dispute resolution with no change to the data" box, enter the reason the dispute has been resolved with no changes. When finished, select the "Resolved No Change" button.

The text box can contain up to 4,000 characters, including spaces. All special characters found on a standard U.S. keyboard can be used, not including ALT+NUMPAD ASCII Key characters.

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

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

Figure 258: Reason for Dispute Resolution With No Change to the Data Text Box

The following confirmation message will be displayed on the page.

Figure 259: resolved no change confirmation message

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

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

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

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

If the dispute is due to the Physician Demographic Information being incorrect, the record must be deleted and the updated record with the correct demographic information must be resubmitted. To delete a record from the "Review and Dispute" tab, see Section 4.9c.

After re-attestation to the corrected records is complete, the physician, teaching hospital, or physician principal investigator will receive an email notification that the record(s) has been edited and the dispute resolved. If to resolve the dispute the record needs to be deleted, the system will notify the covered recipient when a disputed record is deleted.

The five steps of the correction and resolution process are given in **Figure 230** below.

Figure 260: Correction and Resolution Process
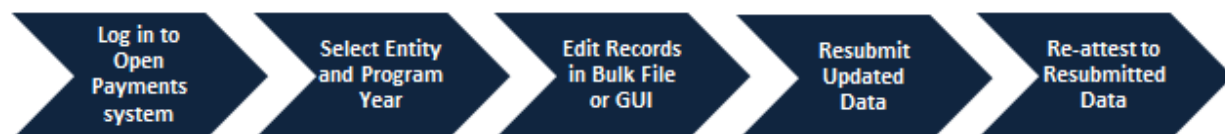
Note: If the dispute resolution changes any of the fields that identify the covered recipient, the original record must be <u>deleted</u> and <u>resubmitted as a new record</u>.

- For physicians (including principal investigators), these identifying fields are First Name, Last Name, NPI, License State, and License Number.

- For teaching hospitals, these identifying fields are Teaching Hospital Name, the hospital address fields, and Taxpayer Identification Number.

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

5.3a: Edit Information and Resubmit Record

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

Figure 261: Review and Dispute Tab

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

Figure 262: Show Dispute For and Program Year Drop-Down

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

To view details about a disputed record, select the "View" hyperlink under the "Actions" column. Users can also view the detailed history for a record's disputes by selecting the "View" link under the "History of Disputes" column. For dispute resolution, a useful filter would be to filter for records with a "Review and Dispute Status" of "Acknowledged" and/or "Initiated," as you can only update and/or correct record(s) with a review and dispute status of "Initiated" or "Acknowledged." For instructions on how to export this data, see Section 5.1c.

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

Figure 263: Edit Hyperlink

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

Note: Fields that identify the record's covered recipient including principal investigators cannot be changed once a record is in a "Ready for Attestation" or "Attested" status. If those fields need to be corrected, the original record must be deleted and then re-submitted as a new record. The relevant fields are as follows:

- For physicians (including principal investigators), these identifying fields are First Name, Last Name, National Provider Identifier (NPI), License State, and License Number.

- For teaching hospitals, these identifying fields are Teaching Hospital Name, the hospital address fields, and Taxpayer Identification Number.

If a reporting entity user edits or deletes a disputed record, an email notification is sent to the covered recipient who initiated the dispute. If the individual who initiated the dispute is a physician's authorized representative with dispute access, an email notification is sent to the physician listed on the record as well. Email notifications are also sent to principal investigators and teaching hospital authorized officials/representatives who disputed a record. All users that have an active dispute for that record will be notified only once per record.

Resubmission and deletion may affect the publication timing of the record. 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 data publication rules.

The dispute history of a record that has been updated will show versions of the record prior to the re-submission as having a status of "Inactive."

Once the record has been changed, it must be re-attested to be made available to the covered recipient under the "Available for Review and Dispute" tab, and the dispute is considered resolved. Until then, the record will be available to the physician or teaching hospital under the "Deleted and In-progress Records" tab with an "In Progress" status. See Section 5.3b.

5.3b: Re-Submission and Re-Attestation
Entities submitting corrected data must both re-submit and re-attest to the corrected data for the updates to be included in the public posting. Once re-attestation is complete, the records will be automatically placed in a review and dispute status of "Resolved." No further action is needed from the reporting entity.

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

If a record is deleted and replaced after the submission closing date, the Open Payments system will treat the record as a newly arriving late record rather than a correction. The new records will not be included in the current publication cycle and will be identified as eligible for review and dispute for a future publication. Once a record is deleted, it will no longer be visible to the physicians, teaching hospitals, or physician principal investigators identified in it under the "Available for Review and Dispute" tab. The record will display under the "Deleted and In-progress Records" tab with status "Deleted". Any disputes associated to the deleted record will not be available once the record has been deleted. A record marked for deletion but not yet deleted is still visible to the physicians, teaching hospitals, or physician principal investigators identified in it "Available for Review and Dispute" tab.

The attester will need to re-attest to the accuracy of all re-submitted or deleted data. An attester can only attest to records that have been successfully submitted and validated. Additionally, the attester may decline to attest and request that some or all of the data submitted be returned to the submitter for corrections and review. The attester can select one or more records to return to the submitter and then select the "Return to Submitter" button. The submitter must perform the corrective actions requested by the attester or indicate that no action is required, then select the "Return to Attester" button to notify the attester that records are ready for attestation. For more detailed instructions on attestation of data, see Section 4.14.

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

Chapter 6: Messages and Compliance

This chapter provides detailed information on how applicable manufacturers and applicable GPOs are able to track system generated emails for all users and how to review and download electronic correspondence uploaded by the CMS compliance team using the Messages tab. **Note: Only the officer and/or compliance user can access compliance messages upon successful acceptance of the role.**

This chapter is divided into the following sections:

- **System Tab** contains information on system generated email notifications sent and how to search for and view emails sent by the Open Payments system in the past 12 months.

  - **Compliance Tab -** contains information on the compliance related communications sent by the CMS Compliance Team to applicable manufacturers and applicable GPOs on how to view compliance communication information and download associated communication PDF documents.

6.1: System Tab

Reporting entity users have the ability to view system generated messages sent in the past 12 months to any role within the reporting entity. 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 reporting entity registers on the CMS Open Payments system, an email is sent out to the reporting entity confirming registration. This is a system generated email that is able to be viewed on the "System" tab. NOTE: only the officer and the compliance role will be able to view both the system and compliance tab on the "Messages" home page.

The "System" tab is accessible from the "Messages" home page. The "Messages" home page is accessible by clicking the "Messages" tab from the CMS Open Payments home screen banner on the CMS Open Payments home page. Once you are redirected to the "Messages" page from the CMS Open Payments home page, click on the "System" tab to view the following searchable fields: (1) Entity Name, (2) File ID, (3) Record ID, (4) Message Category, and (5) Payment Category. All of these fields are optional to refine your search.

If you are not actively associated to any entity, onscreen text is displayed explaining that you are not currently actively associated with any organization. In this case, the search criteria and table is not displayed.

If you are actively associated with at least one entity, on landing, you are presented with only the search criteria. You are required to select values from the search criteria and select the "Search" button before system generated messages are displayed in the result data table. There are no default results on page landing.

6.1a: Instructions for searching messages

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

Figure 264: Messages Tab
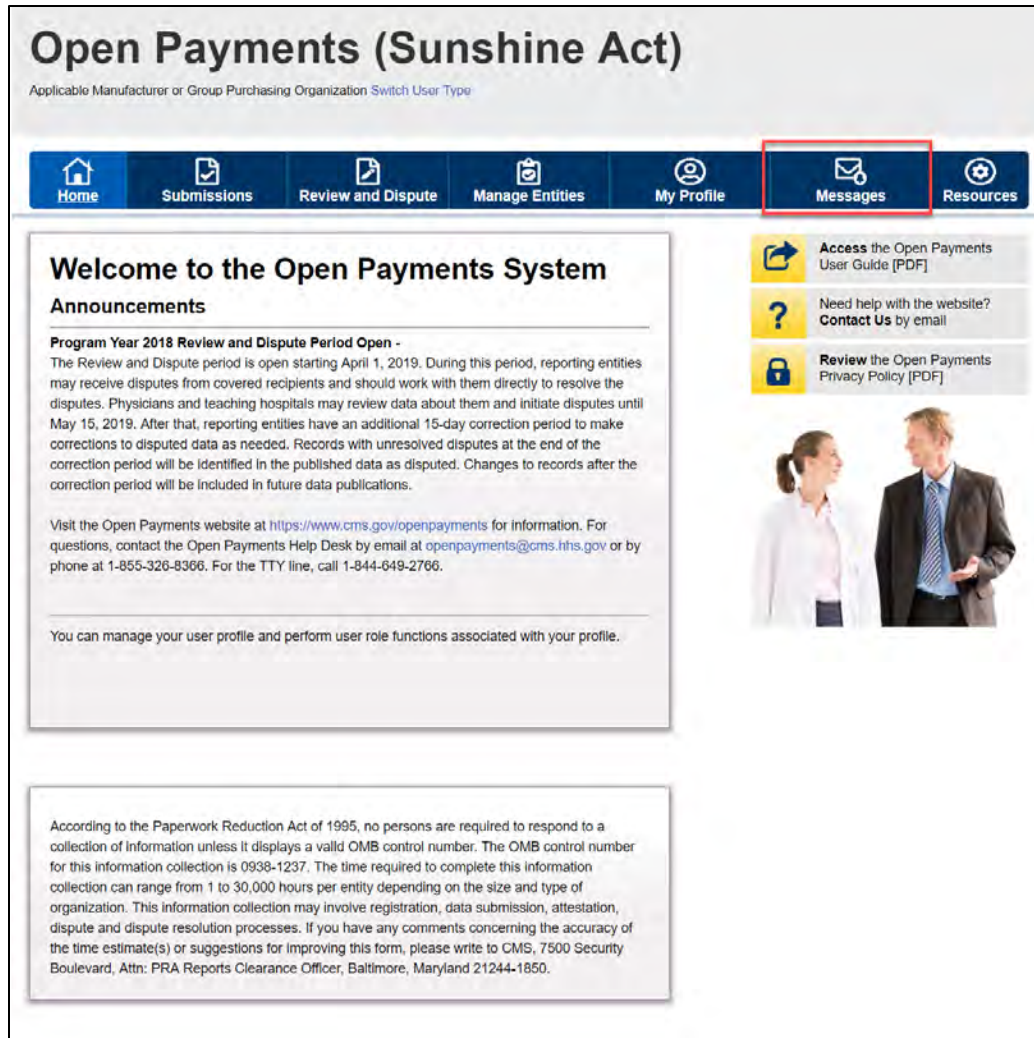
Step 2a: If you only hold the role of submitter and/or attester for your reporting entity, you will be brought directly to the "Messages" page.

Figure 265: Messages Page

Step 2b: If you hold the role of officer and/or compliance for your reporting entity, you will be brought to the "Messages" page containing the "System" sub-tab and the "Compliance" sub-tab. Select the "System" sub-tab.

Figure 266: System Tab in Messages Page

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

- Entity Name

- File ID (only applicable for Message Category of "File Processing")

- Record ID (only applicable for Message Category of "Review and Dispute")

- Message Category

- Payment Category (only applicable for Message Category of "Submissions", "Review and Dispute", "File processing")

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

Figure 267: Entity Name, File ID, Record ID, Message Category, and Payment Category Fields

Step 4: Select the "Search" button to initiate the search. After selecting the "Search" button, a data table with the list of all messages sent in the last 12 months will display. This list of messages is sorted by newest to oldest. You will see an expandable row section that displays more details about each of the messages.

Figure 268: Search Button for System Tab
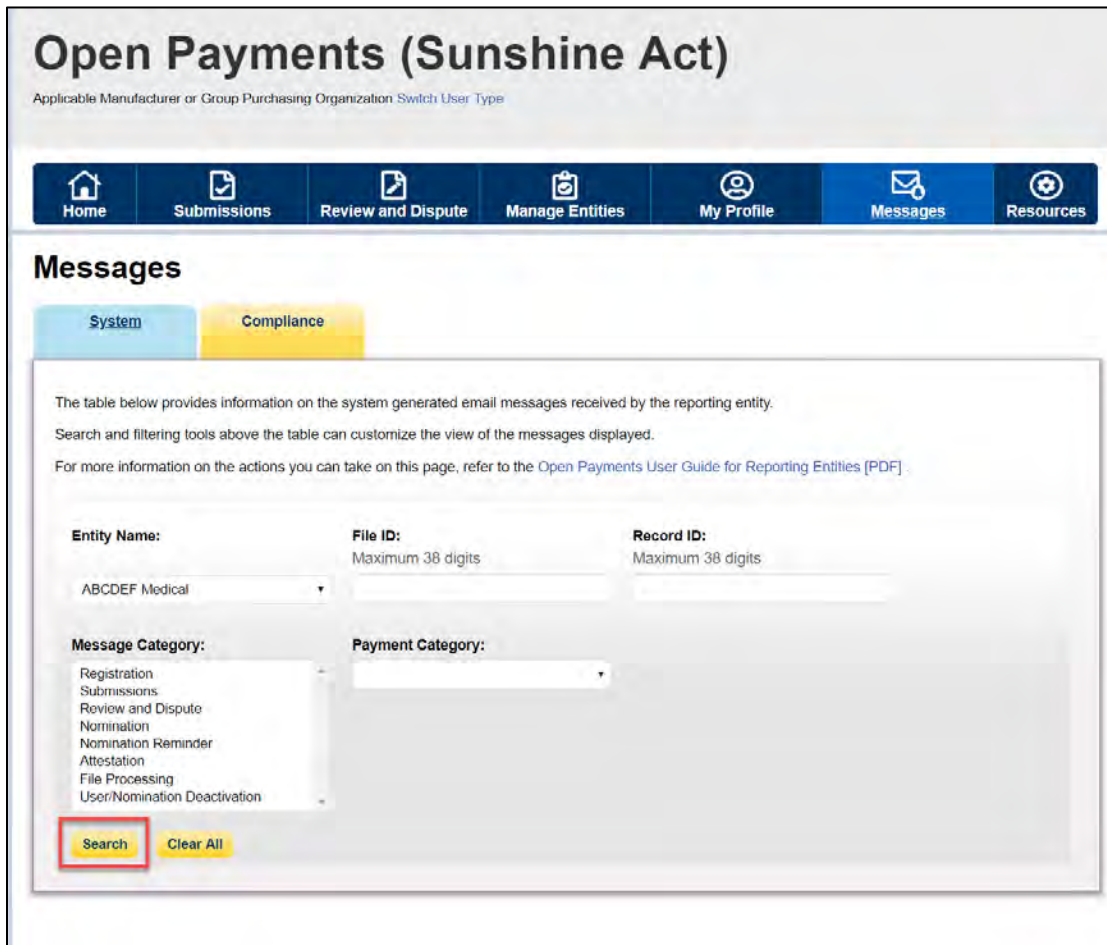
Step 5: Select the expandable arrow next to the message you wish to view. You will view the message details. You will also see a "View Full Message" button to view the full message.

Figure 269: Message Expandable Arrow

Step 6: Select the "View Full Message" to view the full message. The message will be displayed in a pop-up window.

Figure 270: View Full Message Button

6.2: Compliance Tab

Only reporting entity users, who have officer role or the compliance role, can access the compliance communications. See Section 3.3: Open Payments Users and User Roles for more information on how to assign a user a compliance role. When a compliance communication is uploaded by the CMS compliance team for your entity, an email notification is received by the reporting entity officers, compliance user(s) and primary point of contact

6.2a: Instructions for Searching Compliance Communications

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

Figure 271: Home Page Showing Messages Tab
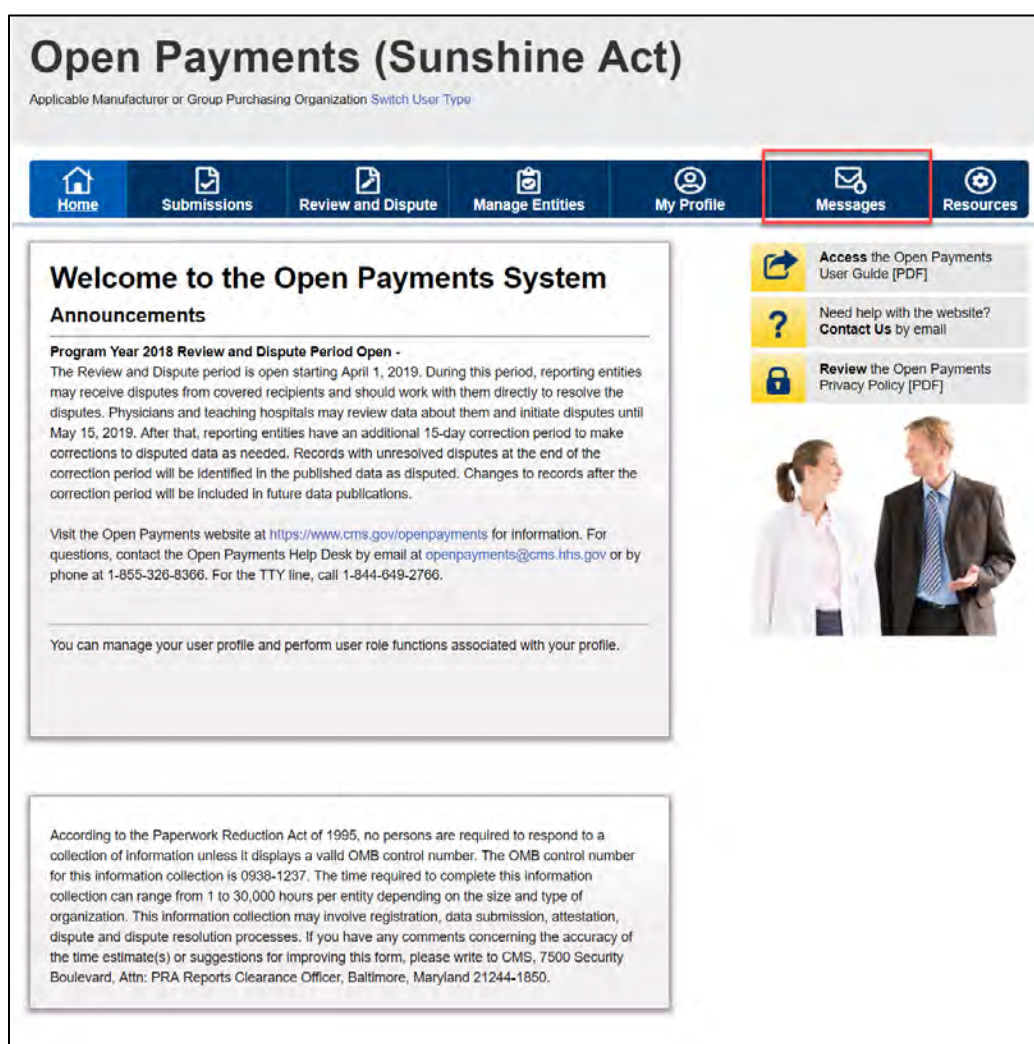
Step 2: You will be brought to the "Messages" page. Select the "Compliance" tab. **NOTE: This functionality is available only for the officer and/or Compliance role.**

Figure 272: Compliance Tab on Messages Home Page

Step 3: You will be able to view all Compliance communications. Select the expandable arrow next to the communication you wish to view. You will see an expandable view of the message text. You will also see a "Download PDF" button. Select the "Download PDF" button to download the compliance document related to each communication.

Figure 273: Download PDF Button

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 *Physicians* for an extensive explanation of how Open Payments defines this group) who are not employees of the applicable manufacturer that is reporting the payment; or teaching hospitals that receive payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. (See 42 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 274: Special Characters Allowed in Free-Text Fields

Special Character	Description
+	Plus sign
&	Ampersand
'	Apostrophe
*	Asterisk
@	At sign
\	Backslash
^	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
"	Quotation marks
)	Right parenthesis
}	Right curly brackets
]	Right square brackets
;	Semi-colon
|	Pipe
~	Tilde
+	Plus sign

Characters used in foreign languages that are not used in English must be converted to English characters to be acceptable to the Open Payments system. Refer to the conversion table below.

Figure 275: 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
Í	I
Î	I
Ï	I
Ò	O
Ó	O
Ô	O
Õ	O
Ö	O
Ø	O
Ù	U
Ú	U
Û	U
Ü	U

Teaching Hospital:

Teaching hospitals are hospitals that receive payment for Medicare direct graduate medical education (GME), IPPS indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. (See 42 C.F.R. § 403.902). The full list of affected teaching hospitals can be found on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html.

Appendix B: Submission Error Codes

Error codes generated by the Open Payments system for records with validation errors can be found in the Error Code Key, which is located on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html or within the Open Payments system by selecting the "Resources" tab.